Talking the walk

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Talking the walk: Applying data-driven patient profiles in the design of tailored services in orthopaedics

Dissertation

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by

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Voor Nienke, Mees en ...

Contents

Summary

For patients that undergo a total hip replacement (Total Hip Arthroplasty, THA), tailored communication through printed or digital information channels may improve the patient experience. Communication and information provision have been shown to be particularly important for these patients, because THA is an elective procedure and therefor a conscious and carefully planned choice. There are also differences between patients in e.g. their information needs or emotional state, especially after surgery. THA care paths with few post-surgery consultations may be sufficient on a clinical level, but a challenge remains to meet individual patients' varying perioperative information and support needs.

Tailored communication is originally described as "intended to reach one specific person, based on characteristics that are unique to that person, related to the outcome of interest, and derived from an individual assessment."[a] Computer tailoring has been conceptualized as a process of segmentation (dividing a generic target population into subgroups) and customization (making person-specific adaptations within each subgroup). The more communication is adapted in this way to recipient characteristics, the more it can be seen as tailored.

Computer-tailored interventions that promote habitual healthy behavior have been studied for several decades, but there are few describing tailored information provision strategies for THA patients. To fill this knowledge gap, the main research questions of this thesis was: *How can a segmentation of the Total Joint Arthroplasty (TJA, both knee and hip surgery) patient population be used to design tailored information tools for THA patients?* The segmentation was established in another PhD project, and consisted of three patient profiles: An 'Optimistic' profile, showing limited coping strategies, lower communication needs and good preoperative clinical status; A 'Managing' profile with a diverse set of coping strategies, strong communication needs, and poor preoperative clinical status; and a 'Modest' profile, consisting of older people with higher anxiety and lower self-efficacy in communicating about health.

[a] Kreuter MW, Strecher VJ, Glassman B. One size does not fit all: the case for tailoring print materials. *Ann Behav Med* 1999; 21: 276–283.

The secondary research questions (RQs) in this project were as follows:

1. Given a set (or segmentation) of three profiles of TJA patients based on clinical, psychological and communication characteristics, which individual differences in patients' preferences regarding communication and information provision throughout the patient journey are relevant to customize tailored information tools for TJA?
2. What is the effect of applying the TJA patient profiles as a segmentation strategy in the design of tailored information tools for THA on patients, medical professionals, and the design process?
3. Based on the patient profiles and design insights, what design guidelines can be formulated for the design tailored information tools for each profile?

This project resulted in a set of design guidelines that can be used by creative industry and healthcare providers to tailor products and services for THA patients. Based on the results, this thesis also provides general considerations and a critical reflection on the merits and risks of using patient profiles to design tailored health services.

Chapter 1 provides an overall introduction to the thesis, including the general background, definitions, and project goals. Chapter 2 provides an overview of the theoretical foundation and research approach of this project. It is explained that this PhD project uses a Research through Design (RtD) approach, generating insights both from the development and evaluation of prototypes in the early design stage. As an example of this approach, this chapter explains in detail the protocol for the design and evaluation of paper-based prototypes for patients of each profile. The results of this study are described in Chapter 5.

Chapter 3 describes a contextual inquiry that was conducted with Total Joint Arthroplasty (TJA, both hip and knee surgery) patients, in order to assess individual differences in preferences regarding communication and information provision. (RQ1; Hip and knee surgery patients were both included as overall information needs are generally similar.) These individual differences were expected to be useful to customize information and communication services for TJA patients. Patients participated in generative sessions in which they created objects describing their experience with surgery and their hopes for the future regarding the TJA patient experience. Participants indicated differences in information needs: Some wanted open and full information, while this was less valued by others. Participants also reported differences in their support needs throughout the care process, for instance at discharge from the hospital or during rehabilitation. Additionally, differences were found in participants' preference for a social connection with care providers. It was concluded that an individual patient's mind-set, and their social support needs, in combination with their physical condition and medical history, should guide the provision of tailored information and communication services.

Chapter 4 presents the results from a storyboard evaluation with patients, in order to define an initial set of profile-specific design guidelines (RQs2 and 3). Twelve THA patients participated in this study, with multiple patients from each profile. The preferences indicated by participants aligned with the results from the survey study that was used to create the profiles, but further validation in tangible prototypes was necessary to validate the preliminary findings.

Chapter 5 aimed to expand and validate the guidelines of Chapter 4 and to provide general recommendations and considerations for developing tailored information tools (RQs 2 and 3). It provides a detailed account of the development and evaluation of a set of paper prototypes, for and with patients from each profile. (The protocol for this study was described in Chapter 2.) In the design phase most input came from patients' previous feedback and summaries of the patient profiles, but the extent to which this could be translated into variations in the prototypes without additional feedback from patients was more limited than expected. In the evaluation phase, suggestions made by participants from each profile confirmed that there were differences in preferences between the profiles. These were mostly in line with the preliminary profile-specific guidelines from Chapter 4. The profile-specific guidelines presented in Chapter 5 provided further guidance for the next design iteration. In general, the use of low-fidelity prototypes and several early stage iterations was recommended for design processes like this one.

Chapter 6 presents the subsequent development and evaluation of a tailored digital THA patient information tool with the aim to improve post-surgery support (RQs 2 and 3). This chapter focused on the use and evaluation of the web application by patients (n = 20) and provides a final update on profile-specific guidelines. Participants recorded their daily step counts, and received tailored information based on this input and their assigned profile. Most notably, no patients in the optimistic profile were recruited. This indicates that the application was generally less relevant to this profile. Small differences in use were observed in this sample: For instance, patients in the modest profile accessed the application slightly less often than the managing profile. Participants from both profiles wanted more options for input, and complained about step counter accuracy. Chapter 6 confirmed that the profiles are an adequate starting point for designing tailored information tools in THA. However, to increase its relevance, the tailored information should align with an individual patient's course of recovery (e.g. complications). Resolving generic technical and usability issues is also essential.

Chapter 7 provides a general discussion of the thesis. The results of Chapters 5 and 6 indicate that the tailored features provided added value for at least part of the study populations in these studies. However, the profile assignment alone is not enough to determine whether a patient will experience a benefit from tailored information tools. It also remains uncertain what is the best way to measure the impact or contribution of tailored information tools for patients.

A majority of the patients (n = 13, 81%) in the final study (Chapter 6) indicated that they preferred the information variant that they had been using over variants for other profiles. This finding suggests that the right adaptations were made in the design based on these profiles (and that the right profiles were assigned to users based on their responses.)

The use of patient profiles made the design process in this project more complicated: careful consideration was needed to define and implement a relevant set of features, and profile-specific variations of these features had to be developed simultaneously. The scope of features in the final design was also limited due to time and budget constraints, as well as requirements for assessing the impact on patients within a scientific research context. The (intermediate) profile-specific guidelines that were fed back into the design process had their limitations, but they provided general guidance to develop a new design. However, based on the results of Chapter 6 in particular, different levels of support for each profile seem to be more appropriate.

This project resulted in a set of profile-specific design guidelines, but several adaptations were made to optimize these for non-scientific audiences. First, they were defined abstractly to that they could be used in projects other than the specific design cases in this PhD project. Second, illustrations and examples were made for each guideline. Third, a statement was added that the guidelines can inform both designers and care providers, but that they can only be used as a starting point for a design or for direct communication with patients. The guidelines are provided in Chapter 7 and available online including examples (www.medisigntudelft.nl/research/patientprofiles).

The thesis mainly contributes to the theory of patient profiles in the context of computer-tailoring. Several issues surrounding the use of patient profiles and the design of tailored e-Health were also surfaced or clarified through the act of designing and evaluating information tools. Second, this project provides insights on how to communicate RtD to audiences outside the design research community which can support future RtD projects in healthcare. Third, both design practitioners and care providers can use the profile-specific guidelines in this thesis to support tailored communication to patients. Finally, the design results in this thesis (and in particular the web application in Chapter 6) have the potential to support THA patients after surgery.

Other design research directions may further advance tailored care for THA patients: It could be considered to vary the intensity of guidance for patients in different profiles, and information tools could be developed that are adaptive to both patients' and healthcare providers' personal communication preferences. In all, there are many possibilities to use the patient profiles to improve THA care paths. The key to making tailored information tools successful in care practice lies in balancing the added value of a tool for patients with its feasibility for care providers. Even if the resulting design simply allows healthcare providers to be more compassionate to patients, the effort will be worthwhile.

Samenvatting

Voor mensen die een totale heupvervanging (Totale Heup Artroplastie, THA) krijgen zou de patiëntervaring kunnen worden verbeterd door communicatie op maat te ontwikkelen via geprinte of digitale kanalen. Het is namelijk aangetoond dat communicatie en informatievoorziening zeer belangrijk is voor deze patiëntgroep, aangezien er bewust voor een THA gekozen wordt en dit zorgvuldig kan worden gepland.. Er zijn ook verschillen tussen patiënten in dit opzicht, bijvoorbeeld in individuele informatiebehoeften of emotionele staat, vooral na de operatie. THA-zorgpaden met slechts enkele contactmomenten tussen patiënt en zorgverleners na de operatie zijn wellicht klinisch gezien afdoende, maar er blijft een uitdaging bestaan om de verscheidenheid aan informatie- en ondersteuningsbehoeften van verschillende patiënten na de operatie te bedienen.

Communicatie op maat werd oorspronkelijk omschreven als "bedoeld voor één specifiek persoon, gebaseerd op karakteristieken die uniek zijn voor die persoon, gerelateerd aan een uitkomst van interesse, en afgeleid uit individuele beoordeling."[a] Geautomatiseerde communicatie op maat wordt voorgesteld als een proces van segmentatie (het opdelen van een algemene populatie in subgroepen) en maatwerk (het maken van persoonsgebonden aanpassingen binnen elke subgroep). Hoe meer communicatie op deze manier wordt aangepast op karakteristieken van de ontvanger, hoe meer het kan worden gezien als communicatie op maat.

Interventies met geautomatiseerde communicatie op maat (d.w.z. door een algoritme gegenereerd) worden al meerdere decennia bestudeerd in de context van bijvoorbeeld gezonde gewoontes, maar er zijn heel weinig studies die geautomatiseerde communicatie op maat gebruiken voor THA-patiënten. Om de kennis hierover aan te vullen hanteerde dit PhD-project de volgende onderzoeksvraag: *Hoe kan een segmentatie van de populatie die Totale Gewricht Artroplastie ondergaat (heup- en knievervanging, Total Joint Arthroplasty, TJA) gebruikt worden om informatietools op maat te ontwikkelen voor THA-patiënten?* De segmentatie werd vastgesteld voor TJA in een ander PhD-project, en bestond uit drie patiëntprofielen: Een 'optimistisch' profiel, die weinig met stress hoefden

[a] Kreuter MW, Strecher VJ, Glassman B. One size does not fit all: the case for tailoring print materials. *Ann Behav Med* 1999; 21: 276–283.

om te gaan, geen hoge communicatiebehoeften hadden, en preoperatief een goede klinische status; een ‘beherend’ profiel, met mensen die diverse manieren hadden om met stress om te gaan, die sterke communicatiebehoeften hadden, en een slechtere preoperatieve klinische status; en een ‘bescheiden’ profiel, met oudere mensen die meer bezorgd waren en minder goed over hun gezondheid konden communiceren.

De secondaire onderzoeksvragen (OV) in dit project waren als volgt:

1. Gegeven een set (of segmentatie) van drie profielen van TJA-patiënten gebaseerd op klinische, psychologische, en communicatiekarakteristieken, welke individuele verschillen in de voorkeuren van patiënten met betrekking tot communicatie en informatievoorziening gedurende het gehele zorgproces zijn er verder belangrijk om maatwerk te realiseren in informatietools op maat voor TJA-patiënten?
2. Wat is het effect van het toepassen van de TJA patiëntprofielen als segmentatiestrategie in het ontwerpen van informatietools op maat voor THA op patiënten, zorgprofessionals, en het ontwerpproces?
3. Gegeven de patiëntprofielen en ontwerpinzichten die resulteren uit dit proces, welke richtlijnen kunnen worden geformuleerd voor elk profiel voor het ontwerpen van informatietools voor op maat?

Dit project resulteerde in een lijst van richtlijnen die gebruikt kunnen worden door ontwerpers, maar ook door zorgprofessionals, in het op maat maken van producten en diensten voor THA-patiënten. Op basis van de resultaten geeft deze thesis ook algemene overwegingen en een kritische reflectie op de voor- en nadelen van het gebruik van patiëntprofielen bij het ontwerpen van eHealth op maat.

Hoofdstuk 1 geeft een algemene introductie van de thesis, met een beschrijving van de achtergrond, definities, en projectdoelen. Hoofdstuk 2 beschrijft de theoretische onderbouwing en methodologie in meer detail. Er wordt uitgelegd dat dit project gebruik maakt van een ontwerpende methodologie (Research through Design, RtD). In deze aanpak worden inzichten gegenereerd door zowel de ontwikkeling als evaluatie van prototypes, in de eerste delen van het ontwerpproces in dit geval. Als voorbeeld van deze aanpak wordt ingezoomd op het protocol voor een studie met een papieren prototype. Er wordt uitgelegd hoe dit prototype wordt ontworpen en geëvalueerd. De resultaten van deze studie worden beschreven in Hoofdstuk 5.

Hoofdstuk 3 beschrijft een contextueel onderzoek (contextual inquiry) dat werd uitgevoerd met TJA-patiënten (zowel heup- als knievervanging), om zicht te krijgen op individuele verschillen in voorkeuren rondom communicatie en informatievoorziening (OV 1; heup- en knievervanging werden samengenomen omdat de behoeften van patiënten over het algemeen heel vergelijkbaar zijn.) Deze individuele verschillen werden geacht relevant te zijn voor het realiseren van maatwerk in informatiediensten voor TJA patiënten. Patiënten die werden gerekruteerd namen deel aan generatieve sessies, waarin zij objecten creëerden die hun ervaring met de operatie en wensen voor de toekomst van de TJA patiëntervaring beschreven. Deelnemers gaven verschillen aan in informatiebehoeften: Sommigen wilden open en volledige informatie, terwijl dit door anderen minder belangrijk werd gevonden. Deelnemers rapporteerden ook verschillen in hun behoefte aan ondersteuning tijdens het gehele zorgproces, bijvoorbeeld bij ontslag uit het ziekenhuis of tijdens de revalidatie. Verder werden verschillen gevonden in de voorkeuren van deelnemers voor een sociale verstandhouding met zorgverleners. Er werd geconcludeerd dat de mind-set en behoefte aan sociale support van patiënten, in combinatie met hun fysieke conditie en medische voorgeschiedenis, leidend moet zijn in het realiseren van informatie en communicatie op maat.

Hoofdstuk 4 presenteert de resultaten van een evaluatie van storyboards (gevisualiseerde ontwerpscenario's) met patiënten, met de bedoeling om een eerste set van profiel-specifieke richtlijnen vast te stellen (OV 2 en OV 3). Twaalf THA-patiënten namen deel aan dit onderzoek, met meerdere patiënten van elk profiel. Deze resultaten lagen in lijn met de studie waarin de profielen werden vastgelegd, maar verdere validatie in bruikbare prototypes werd noodzakelijk geacht om deze bevindingen te valideren.

Hoofdstuk 5 had daarom als doel om de richtlijnen uit hoofdstuk 4 te valideren en uit te breiden, alsmede om algemene aanbevelingen en overwegingen te geven voor het ontwikkelen van eHealth op maat (OV 2 en OV 3). Het is een gedetailleerd verslag van de ontwikkeling en evaluatie van een set papieren prototypes, voor en met patiënten uit elk profiel. (Het protocol voor deze studie werd in detail omschreven in Hoofdstuk 2.) In de ontwerpfase kwam de meeste input voor de ontwerpvarianten uit de eerste richtlijnen en uit samenvattende beschrijvingen van de patiëntprofielen, maar de mate waarin deze inzichten konden worden vertaald in variaties in de prototypes was beperkter dan van tevoren werd verwacht. In de evaluatiefase werd door de suggesties en commentaren van patiënten bevestigd dat er verschillen in voorkeuren waren tussen de drie profielen. Deze verschillen waren grotendeels in lijn met de richtlijnen uit Hoofdstuk 4. De profiel-specifieke richtlijnen die uiteindelijk in Hoofdstuk 5 worden gepresenteerd konden echter weer worden gebruikt in de volgende ontwerpslag. In het algemeen onderstreepte deze studie het belang van eenvoudige (bijv. papieren) prototypes en verschillende ontwerpslagen in de vroege stadia van dit soort ontwerpprocessen.

Hoofdstuk 6 presenteert vervolgens de ontwikkeling en evaluatie van een digitale informatietool op maat voor THA-patiënten, met als doel om de ondersteuning na de operatie voor patiënten te verbeteren (OV 2 en OV 3). Dit hoofdstuk richt zich vooral op het gebruik en de evaluatie van de webapplicatie door patiënten (n = 20) en biedt de basis voor een laatste herziening van de ontwerprichtlijnen. In de webapplicatie hielden patiënten hun dagelijkse stappenaantallen bij (door middel van een stappenteller), en op basis van deze input en hun profiel kregen ze hierover informatie op maat. Het viel vooral op dat er geen patiënten in het optimistische profiel werden gerekruteerd voor deze studie. Dit is een indicatie dat de webapplicatie in het algemeen minder relevant was voor dit profiel. Er werden kleine verschillen gevonden in hoe de deelnemers uit verschillende profielen de applicatie gebruikten: Patiënten in het bescheiden profiel bezochten de applicatie bijvoorbeeld iets minder vaak dan patiënten in het beherend profiel. Deelnemers in beide profielen wilden meer informatie kunnen doorgeven via de applicatie, en bij beide profielen waren er klachten over de accuraatheid van de stappenteller. Hoofdstuk 6 bevestigde dat de profielen een adequaat startpunt vormen voor het ontwerpen van informatietools op maat voor THA-patiënten. Maar om de relevantie van een applicatie als deze te vergroten, moet de informatie op maat ook rekening houden met het daadwerkelijke herstelproces van de individuele patiënt (bijv. de aanwezigheid van complicaties). Het oplossen van algemene technische en bruikbaarheidsproblemen is daarnaast essentieel.

Hoofdstuk 7 is een algemene discussie over het proefschrift. De resultaten van Hoofdstukken 5 en 6 laten zien dat de informatie op maat voor tenminste een deel van de studiepopulaties van toegevoegde waarde was. Echter, de toewijzing aan een profiel is niet voldoende om te bepalen of een patiënt voordeel zal ondervinden van informatietools op maat. Het blijft ook onzeker wat de beste manier is om de impact of bijdrage te meten van dit soort tools voor patiënten.

Een ruime meerderheid van patiënten (n = 13, 82%) gaf in de laatste studie (Hoofdstuk 6) de voorkeur aan de informatievariant die zij hadden gebruikt boven varianten voor de andere profielen. Deze bevinding suggereert dat de juiste aanpassingen zijn gemaakt in het ontwerp op basis van de profielen (en dat de juiste profielen aan de gebruikers zijn toegekend op basis van de vragenlijsten.)

Het gebruik van patiëntprofielen maakte het ontwerpproces in dit project ingewikkelder: Er moest met zorg worden bekeken welke functies in een informatietool voor THA-patiënten relevant zouden zijn, en tegelijkertijd moesten van deze functies varianten voor elk profiel worden ontwikkeld. De hoeveelheid functies in het uiteindelijke ontwerp werd ook gelimiteerd door beperkingen in tijd en onderzoeksbudget, alsmede vereisten voor het wetenschappelijk onderzoeken van de impact op patiënten. De (tussentijdse) ontwerprichtlijnen per profiel boden wel enige ondersteuning in dit proces, ook al hadden ze hun beperkingen. Op basis van de resultaten, die van Hoofdstuk 6 in het bijzonder, lijkt het er echter op dat verschillende niveaus van ondersteuning per profiel passender zijn.

Dit project resulteerde in een lijst van ontwerprichtlijnen per profiel, maar er moesten verschillende aanpassingen gedaan worden om deze te optimaliseren voor een niet-wetenschappelijk publiek. Ten eerste werden ze waar mogelijk geabstraheerd, zodat ze konden worden gebruikt in andere projecten dan de specifieke designcases in dit PhD project. Ten tweede werden illustraties en voorbeelden gemaakt voor elke richtlijn. Ten derde werd er een algemene uitleg en waarschuwing toegevoegd aan de richtlijnen: De richtlijnen kunnen zowel ontwerpers als zorgverleners informeren, maar zij kunnen de richtlijnen alleen als startpunt gebruiken voor een ontwerp of voor directe communicatie met patiënten. De richtlijnen worden opgesomd en zijn (inclusief voorbeelden) online te vinden (www.medisigntudelft.nl/research/patientprofiles).

Dit proefschrift levert vooral een bijdrage aan de theorie van patiëntprofielen in de context van geautomatiseerde informatie op maat. Verschillende vraagstukken rondom het gebruik van patiëntprofielen en het ontwerpen van eHealth op maat werden ook aan het licht gebracht of opgehelderd door middel van het ontwerpen en evalueren van informatietools. Daarnaast werd in het project kennis opgedaan over hoe RtD gecommuniceerd moet worden naar doelgroepen buiten de gemeenschap van ontwerponderzoekers. Deze kennis kan toekomstige RtD projecten in de zorg ondersteunen. Verder kunnen de richtlijnen die uit dit project resulteerden zowel door ontwerpers als zorgverleners worden gebruikt om communicatie op maat met patiënten te realiseren. Tot slot hebben de ontwerpresultaten in dit proefschrift (in het bijzonder de applicatie in Hoofdstuk 6) de potentie om THA-patiënten na de operatie te ondersteunen.

Andere ontwerprichtingen kunnen ook worden overwogen om zorg op maat voor THA-patiënten een stap verder te brengen: Er zou overwogen kunnen worden om de intensiteit van begeleiding te variëren voor patiënten uit de verschillende profielen, en er zouden ook informatietools kunnen worden ontwikkeld die zich kunnen aanpassen op de voorkeuren van zowel patiënten als zorgverleners. Al met al zijn er veel mogelijkheden om de patiëntprofielen te gebruiken om THA-zorgpaden te verbeteren. De sleutel tot het ontwikkelen van succesvolle informatietools voor de zorgpraktijk ligt daarbij in het balanceren van toegevoegde waarde voor patiënten, en de haalbaarheid voor zorgverleners. Zelfs als het resulterend ontwerp simpelweg zorgverleners in staat stelt om patiënten met meer compassie te benaderen, zal dit de moeite waard zijn.

Foreword

In 2012, the project HiPP (Highly individualized Patient Projects) was established as a partnership between Zimmer Biomet Inc (Warsaw, USA), Reinier de Graaf hospital (Delft, The Netherlands) and the faculty of Industrial Design Engineering (IDE) of Delft University of Technology. HiPP was aimed at optimizing the experience journey of people that opt for a total hip replacement surgery (Total Hip Arthroplasty, THA). The partnership was based on mutual interests and goals: Zimmer Biomet Inc, a leading medical device manufacturer, wanted to stimulate innovation in their products and services. Reinier de Graaf, a leading Dutch clinical teaching hospital, strived to improve patient care. And the faculty of Industrial Design Engineering was aimed to further extend its body of knowledge on healthcare design.

Over the course of the collaboration, over a hundred design cases were developed. Two of those formed a starting point for this thesis and PhD project. The first design is called BiConnect, which was developed by Rosèl van den Berg (2014).[1] BiConnect is an information application that supports the communication between patient and physician during consultations. It also aims to support the management of a patient's expectations of the period after surgery. The development of BiConnect was based on a set of four subgroups or profiles of patients, with different needs and capabilities. The second design is a rehabilitation device called BioCoach. This project was developed by students in several Master's courses at the IDE faculty (2012, 2013).[2] This product-service system supports outpatients by providing feedback on rehabilitation exercises at home. Exercise data generated by the BioCoach can also be used to support meetings with e.g. a physiotherapist. Both designs were developed on a generic embodied level (impression in figure 1).

Figure 1. Impression of BiConnect application (left),[1] BioCoach application and leg band (right).[2]

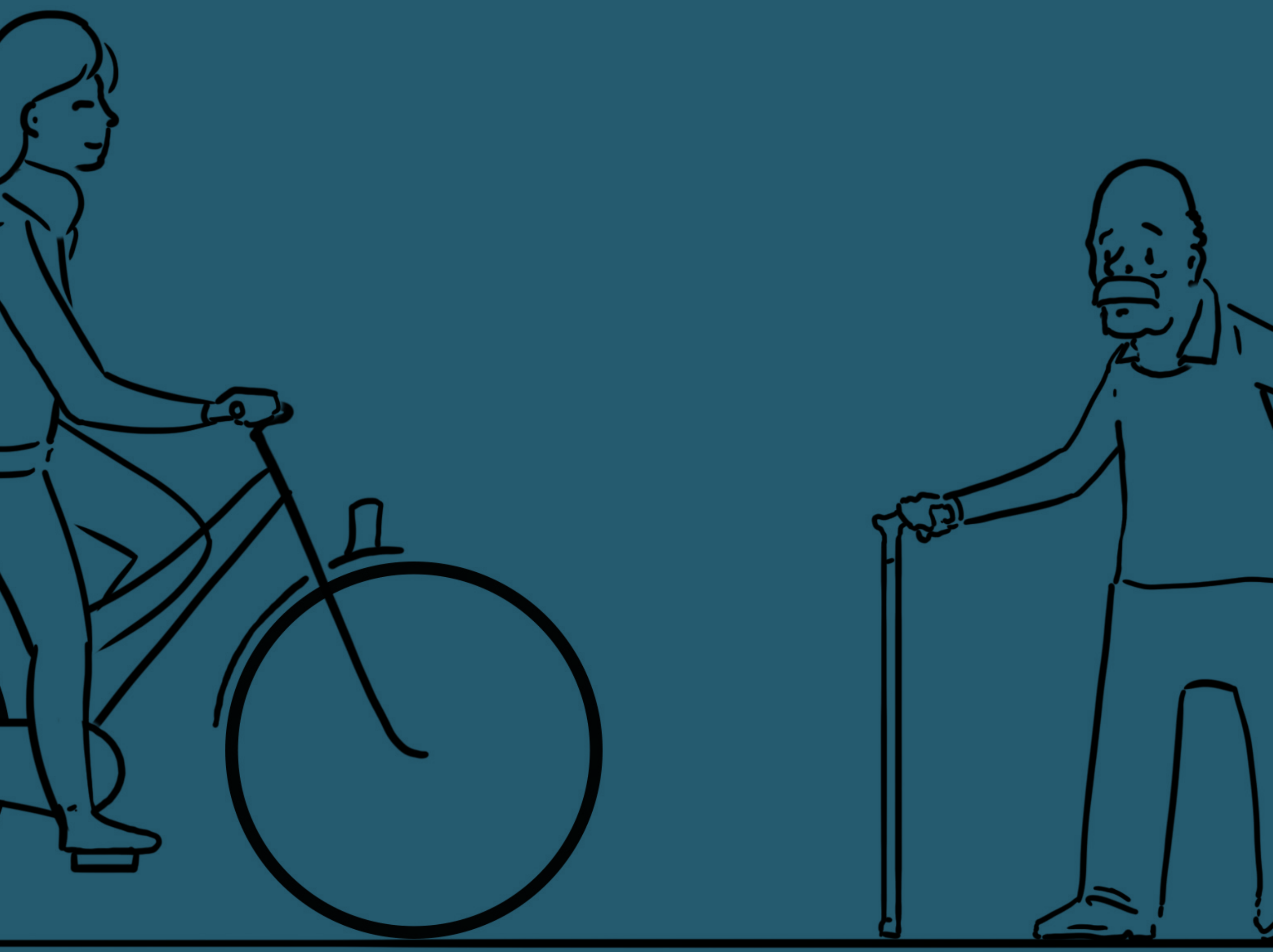
These THA patient information tools aimed at supporting the process of knowledge exchange and expectations management for THA patients, both before and after surgery. Both projects contained suggestions to personalize the information exchange, for instance by segmenting the THA patient population into user, or customer, profiles or by providing customized information services based on accumulation of patient-specific characteristics (such as psychological characteristics and communication preferences).

To scientifically explore the potential of using customer profiles to design tailored products and services that improve the THA patient experience, the HiPP partnership was extended into a consortium and a joint PhD project. The project was funded by The Dutch Foundation for Scientific Research (Nederlandse Organisatie voor Wetenschappelijk Onderzoek, NWO) as well as Zimmer Biomet Inc. The consortium acted as an advisory board, which met every six months to discuss progress. In addition, each partner fulfilled a specific role. The TU Delft guaranteed the scientific approach and validated outcomes. The Reinier de Graaf hospital, which includes four hospital locations in the area of Delft, coordinated the participation of patients and medical professionals in the various studies. Design agencies Panton and VanBerlo were responsible for the usability and usefulness of the results for the creative industry. Zimmer Biomet was responsible for the added value of the outcomes for industry, both in a local and global context.

Two PhD projects were carried out. In a parallel project by Tessa Dekkers, she investigated whether it is possible to segment the THA population into subsets of user profiles or ‘patient profiles’, and how to assess which profile best matches an individual patient. In this PhD project I explore how this knowledge on patient profiles can be translated to tailored product and service design for THA. The patient profiles were embedded in the design of an information tool for THA patients that is based on BiConnect and BioCoach. This thesis reflects on both the design process and its outcomes, which resulted in guidelines for the creative industry and healthcare providers. A detailed account of the patient profiles, the process of establishing them, and the tools that may be used to identify them are described in the thesis of Dekkers.[3] The joint knowledge of both PhD projects, including an extensive comparison of patient characteristics for the profiles (thesis of Dekkers) and design guidelines and examples (this thesis), is summarized in an online tool (www.medisigntudelft.nl/research/patientprofiles).

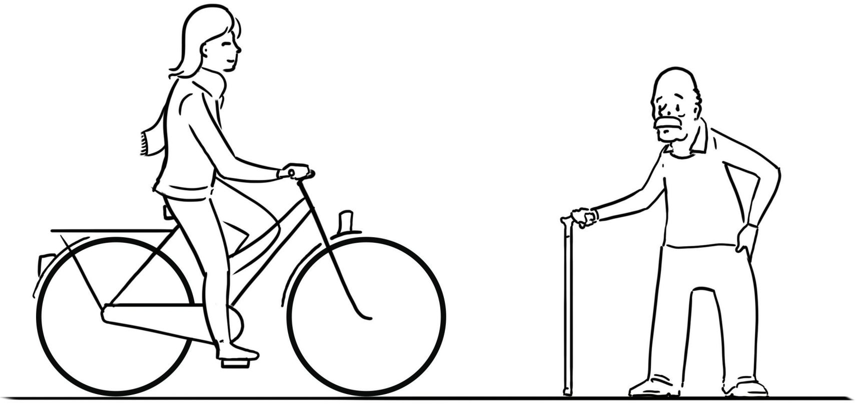
Bob Groeneveld

Delft, January 2020



1. Introduction

1.1. The cases of Jane and Carl

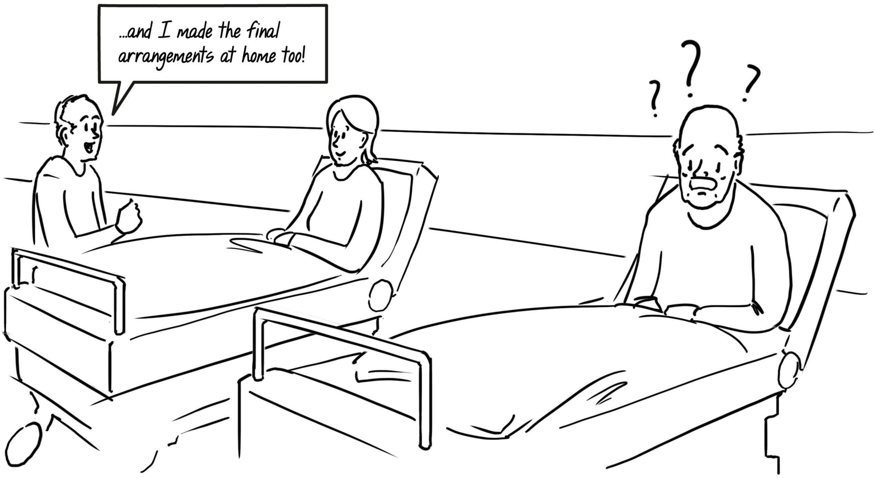


Jane is 63 years old. On her daily cycling commute she started to feel a pain in her hip. This makes her worried about whether she will be able to keep cycling in the future. Carl is 78 years old. He has had a hip surgery years ago due to a medical complication, and he now starts to feel a wear in his other hip. Last time he had some bad experiences, so he is anxious about a possible second hip replacement.

Jane searches the internet for information and visits the GP for advice. Eventually, she ends up at the orthopedic surgeon's office to discuss a hip replacement. Jane's surgeon is quick to make the decision for surgery, to which she wholly agrees. She even asks whether the surgery can't be done sooner. Carl is reluctant but his GP won't listen to him well, so in frustration he asks for a referral to the hospital. Eventually, he only agrees to have a second surgery because he has no other option. But he needs to be sure that the pain treatment will be better than last time. The surgeon invests some extra time to reassure him, which he greatly appreciates and makes him a bit more confident.

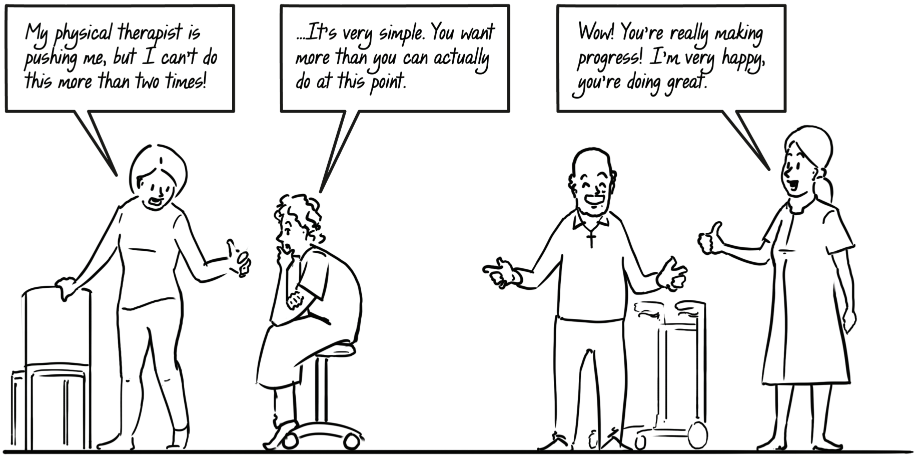
Both Jane and Carl are put on the waiting list, and in preparation they go to a meeting organized by the hospital with peers to receive information about the surgery. They notice large differences in how involved people are: Some just sit in the room and seem nervous, while others have many questions and keep talking forever.

After several months of waiting, the surgery takes place successfully for both Jane and Carl. The day after surgery they are both more or less pain free, but for Carl this is much more of a relief. However, while Jane is looking forward to the return to home and her partner, Carl has many questions and uncertainties because he is alone at home.



Luckily, the transfer nurse and a volunteer help Carl along and explain to him that he can go to a care hotel. He is very happy with this information, but also shocked that he did not know this earlier. Carl receives intense guidance in the care hotel and also draws strength from his religion during the rehabilitation; in all, his post-surgery experience was not as bad as he had expected.

On the other hand, Jane is discharged from the hospital after a day straight to home, and the transfer to home is smooth. She is lucky to have her husband at home to take care of her in the first weeks, but the period of recovery outside the hospital comes with many uncertainties. She wonders, “am I on track with my rehabilitation? Is it normal what I’m experiencing after several weeks?” Her physical therapist gives advice, but at a post-surgery consultation the surgeon says something different.



Over time, both patients recover well. Jane is reasonably satisfied with the surgery, but she does feel that some parts of her patient journey could have been better informed. Especially during her recovery, when differences between expectations and reality started to arise, she would have liked to have more guidance. In contrast, Carl was much more anxious before surgery and found it difficult to remember all the instructions, but he was less uncertain after surgery.

1.2. Background

Jane and Carl are fictional examples of people who receive a Total Hip Arthroplasty (THA). However, their experiences are adapted from actual observations and interviews with patients at Reinier de Graaf Hospital (Delft, the Netherlands). Their experiences are exemplary for the approximately 24.000 people who opt for a THA on a yearly basis in the Netherlands.[4]

For THA patients, communication and information provision has been shown to be particularly important.[5,6] THA is an elective procedure and therefore an intentional and carefully planned choice. Patients with osteoarthritis often opt for a hip replacement at some point in time, usually after deliberation with an orthopedic surgeon, and therefore the surgery as well as recovery period are usually well-planned. This makes management of patient expectations pre-surgery and expectation fulfilment post-surgery particularly important, and it is shown to be strongly linked to patient satisfaction after surgery.[7]

From the perspective of patients like Jane and Carl, each phase of the THA patient journey comes with specific challenges. In each phase, differences between patients can also be observed in aspects such as their information needs, communication preferences, or emotional state.[8] However, as was observed in the clinical context, logistic challenges such as a shared group meeting and packed consultation schedules put these individual needs under tension sometimes. In addition, THA is increasingly followed by fast discharge to home after one or a few days in the hospital.[9,10] This trend is driven by a clinically proven benefit on the one hand: Most patients recover safely and more efficiently in fast-track (FT) THA trajectories.[10,11] On the other hand FT THA also provides increasing patient turnover, which is relevant in the context of financial pressure faced by many hospitals today.[9] In any case, this trend limits the amount of face-to-face contact between care providers and patients directly after surgery.

After discharge from the hospital, post-surgery contact with care providers in the hospital is also scarce. For example, the surgical wound is checked two weeks after discharge by a nurse, and an X-ray and consultation with the surgeon may occur in the sixth week. In-between these consultations, patients carry out the recovery by themselves, sometimes supported by a physiotherapist, informal caregivers, or products and services such as educational booklets provided by the hospital.

This standard FT THA post-operative procedure works for most patients and is feasible. Still, no two patients are identical. During consultations, research has shown that orthopedic surgeons take into consideration a patient's abilities, autonomy, and interpersonal behavior, and that they intuitively tailor their communication accordingly.[12] While this intuitive tailoring approach by the surgeon may have its imperfections, indirect communication (such as information on web sites, and in flyers or booklets) usually has a static, one-size-fits-all format that cannot take into account any differences between patients at all. So THA (and particularly FT THA) with few post-surgery consultations may be successful on a clinical level, but a challenge remains to meet individual patients' varying perioperative information and support needs.[8,11] Within this context, there seems potential in offering tailored communication through printed or digital information channels in order to improve patient-centered communication or the patient experience in general.

1.3. Patient experience, Patient-centered communication, and Tailoring: definitions

The concepts of patient experience, patient-centered communication, and tailoring are central in this thesis. The patient experience is taken as an overall outcome measure: Improving the patient experience and accommodating patients' preferences is an established way of improving healthcare.[13] Next to quality improvement, a focus on patient experience has also been linked to competitive advantage for care institutions.[14,15] Patient experience is defined as 'the sum of all interactions, shaped by an organization's culture, that influence patient perceptions across the continuum of care'.[16] It spans across the entire care process and is strongly linked to expectations and expectation management. Assessing patient experience should therefore go beyond survey results and satisfaction alone.[14]

Patient-centred care and communication (PCC) is taken as an intermediate outcome measure, as it is a way to improve the patient experience. In patient-centred care, the patient is seen as a person with his or her own needs and characteristics; patient-centred communication (or interaction) is realized when care providers actively seek and discuss the patient's perspective.[17] Research has shown that PCC contributes to patient satisfaction,14,18 positive health outcomes,[18] and efficiency of care.[13,18] This makes PCC a key quality indicator of healthcare quality and PCC is thus also of competitive advantage for healthcare providers.[14,18,19]

In turn, tailored communication can be used to realize or support PCC (or to directly improve the patient experience). Tailored communication was originally described by Kreuter, Strecher, & Glassman[20] as "intended to reach one specific person, based on characteristics that are unique to that person, related to the outcome of interest, and derived from an individual assessment." Tailored communication has been conceptualized as a specific adjustment to the individual, rather than targeted communication which is adapted to groups of people.[20] For instance, a specific THA information flyer can be targeted at people with diabetes. This is a segment of the THA patient population. Conversely, in a one-on-one session a physical therapist (PT) may provide instructions that are relevant only to the patient receiving the information, because it is based on the PT's observation of that specific person at that specific point in time. This can be seen as tailored communication, and—next to face-to-face communication—it may also be mediated by technology (e.g. website chat function, e-mail, SMS).

In the context of computer-tailored information, Hawkins et al.[21] argue that it is more useful to view tailoring as a process of segmentation (dividing a generic target population into subgroups) and customization (making person-specific adaptations within each subgroup). The more communication is adapted in this way to recipient characteristics, the more it can be seen as tailored.[21] In effect, this may mean that an automated system provides information to a patient because she is in the segment of patients with diabetes, and the information may be customized because the patient entered specific data related to her recovery that only apply to her at that moment. Figure 1.1 illustrates the tailoring process based on the definitions of segmentation and customization.

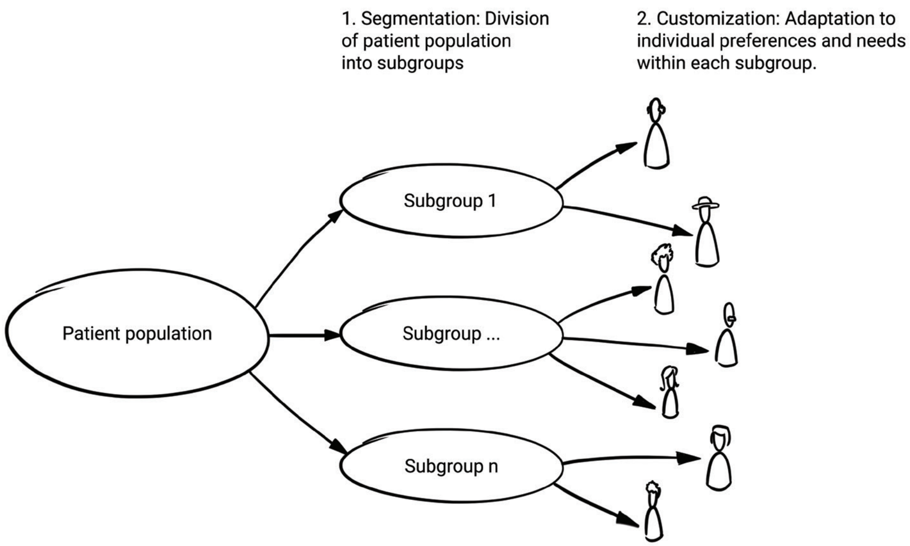


Figure 1.1. Visualization of the tailoring process based on the definitions of segmentation and customization.[21]

1.4. Tailored information tools for THA: State-of-art

Computer-tailored interventions have been studied for several decades, especially on the subject of lifestyle and habitual health behavior. Several reviews and meta-analyses of these tailored interventions provide insights and considerations for designing tailored communications for lifestyle adjustment.[22–24] For example, in the review of Noar et al.[24] into tailored print health behavior change interventions higher effect sizes were found in multiple contact interventions with so-called ipsative feedback (relating current responses to those given earlier by a participant). They also recommend tailoring to 4 to 5 theoretical concepts, e.g. attitudes or social support. In contrast, Lustria et al.[23] describe that multiple assessments do not result in a larger effect on health behavior change than a single assessment, and that interventions targeting the general public were more effective than those targeted at specific patient groups.

However, the lifestyle interventions included in these reviews are designed to prevent health decline. As described above, THA is an elective procedure followed by a relatively well-defined period of physical rehabilitation. This context calls for information provision and support that is fundamentally different from the indeterminate nature of preventive health behavior interventions.

In a scoping review[25] we therefor explored the current state-of-art in tailored information interventions or tools for THA patients. Specifically, the review included studies into tailored information provision and support in THA through printed or online channels. The search and original reporting was based on the PRISMA checklist.[26]

Our review revealed a total of four studies of tailored information tools for THA patients described in literature. Saunders et al.[27] describe a protocol for a randomized controlled trial (RCT) to evaluate the effectiveness of an eHealth program for people undergoing THA. The program provides timely information based on the date of surgery, as well as daily exercise recommendations. In the prospective RCT 50 patients will use the application; several clinical outcomes as well as website usage and patient satisfaction with the web site will be assessed.

Fortina et al.[28] describe a prospective observational study (n = 365) of a tailored guidebook for patients recovering from THA. However, the booklet mostly contains generic information and only the recommended sets and repetitions for exercises seem to be tailored to the individual patients. Patients are satisfied with the booklet overall and show a significant increase in Harris Hip Score (HHS) at three months after surgery compared to discharge, but due to the absence of a control group it is uncertain whether this effect can be attributed to the tailored booklet.

Tappen, Whitehead, Folden, & Hall[29] used a series of tailored videos as part of a video-based education program. At home, a patient can watch back his or her own exercises including the feedback from a physical therapist. The results from an RCT (n = 82) indicate that compared to care as usual patients using the tailored videos enjoyed a benefit in physical functioning only, mainly at week 1 post-discharge.

Finally, Jeong and Kim[30] outline an adaptive information website based on patient input of e.g. Body Mass Index (BMI). The user is directed to specific web pages based on their answers to certain questions. This way, the website differentiates in range, topics, and depth of information by algorithm. The study describes the development and expert evaluation of the website. Experts who evaluated the website saw potential usefulness for patients, but they indicated that aesthetic improvements were needed.

Summarizing the search results, the number of studies (n = 4) on tailored information provision strategies in FT THA is small and conclusions about effectiveness are limited. This indicates that more evidence and examples of tailored communication are needed in this specific population. In addition, authors of the existing studies seem to be unaware of reporting standards for tailored communication interventions[21,31] and none of the resources explicitly apply the segmentation and customization mechanisms to realize tailoring. Concluding, there is a knowledge gap on computer-tailored information tools for THA that are based on segmentation and customization, and this calls for new tools to be developed and evaluated in a systematic way.

1.5. Research Questions (RQs)

Based on the above, the main research question of this thesis was: *How can a segmentation of the Total Joint Arthroplasty (TJA, both knee and hip surgery) patient population be used to design tailored information tools for THA patients?* The framework in figure 1.1 was used to answer this question: a set of patient profiles provided the segmentation starting point, and in this thesis customization mechanisms were added to realize tailored communication. The segmentation was established in another PhD project[3] and defined as a set of 'data-driven patient profiles'. Table 1.1 includes a summary of each of the profiles.

Table 1.1. Overview of patient profiles as established in a parallel PhD project.[3] Descriptions are taken from the online resource (www.medisigntudelft.nl/research/patientprofiles).

Profile nickname	Summary of characteristics
Optimistic profile	The optimistic profile is characterized by high preoperative health status, low anxiety, limited coping behavior, no preference for personal and emotional communication, and good communication skills.
Managing profile	The managing profile is characterized by low preoperative health, higher pain scores, use of multiple coping strategies (including seeking support and distraction), and the highest communication skills, preferences, and self-efficacy.
Modest profile	The modest profile is characterized by more anxiety, a higher tendency towards pain catastrophizing, a relatively high preference for emotional communication compared to participative and open communication, and lower communication skills and self-efficacy.

The secondary research questions (RQs) were as follows:

1. Given a set (or segmentation) of three profiles of TJA patients based on clinical, psychological and communication characteristics, which individual differences in patients' preferences regarding communication and information provision throughout the patient journey are relevant to customize tailored information tools for TJA?
2. What is the effect of applying the TJA patient profiles as a segmentation strategy in the design of tailored information tools for THA on patients, medical professionals, and the design process?
3. Based on the patient profiles and design insights, what design guidelines can be formulated for the design tailored information tools for each profile?

This project resulted in a set of design guidelines that can be used by creative industry—but also healthcare—professionals to tailor products and services for hip surgery. Based on the results, the thesis also provides general considerations and a critical reflection on the merits and risks of using patient profiles to design tailored health services.

1.6. Thesis outline

The chapters of this thesis are structured following the process described in figure 1.2. In short, the patient profiles[3] and insights from generative sessions with TJA patients (Chapter 3) provided the starting points for an iterative design process (Chapters 4, 5, 6). In each step, prototypes were developed and evaluated with patients and sometimes care providers. The insights from each evaluation were used to define and refine profile-specific guidelines for designing tailored information tools for THA patients.

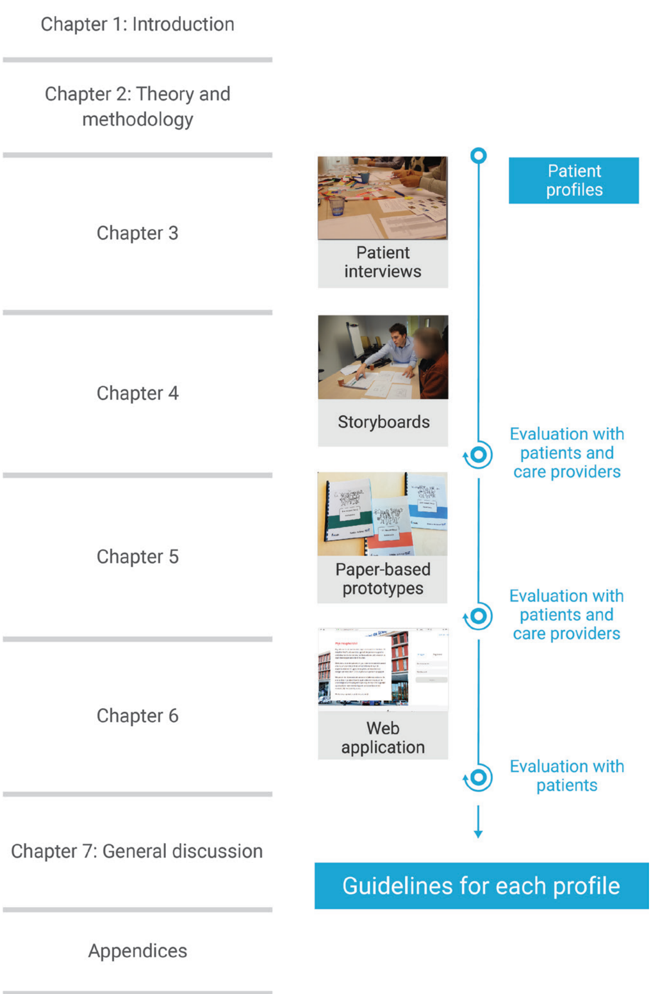


Figure 1.2. Thesis overview.

Chapter 1 provides an overall introduction to the thesis, including the general background, definitions, and project goal. Chapter 2 provides an overview of the theoretical foundation and research approach of this project. It is explained that this PhD project uses a Research through Design (RtD) approach, generating insights both from the development and evaluation of prototypes in the early design stage.[32] Chapter 3 describes a contextual inquiry[33] that was conducted with THA and TKA patients, in order to assess individual differences in preferences regarding communication and information provision (RQ1).

Chapter 4 provides the results from a storyboard evaluation with patients. Two scenarios were evaluated, and an initial set of design guidelines was developed for each subgroup based on participants' comments. Generic preferences were also indicated by patients, and this formed the basis for creating the next design iteration. Chapter 5 provides a detailed account of the development and evaluation of a paper prototype with patients from each subgroup. Chapter 6 outlines the development and evaluation of a digital THA patient information tool that was subsequently developed. This chapter focuses on the use and evaluation of the web application by patients (n = 20). (RQs 2 and 3)

Chapter 7 gives a general discussion of the thesis, including a reflection on the design outcomes as well as the design process, and recommendations for future research. This chapter also summarizes the guidelines for each profile. In addition, Appendix I provides a published overview of challenges for design researchers in healthcare that was published in parallel to this PhD project. Finally, appendix II provides a more detailed technical description of the web application, which was submitted to a Medical Research Ethics Committee (MREC) as part of the final study (Chapter 6).

1.7. References

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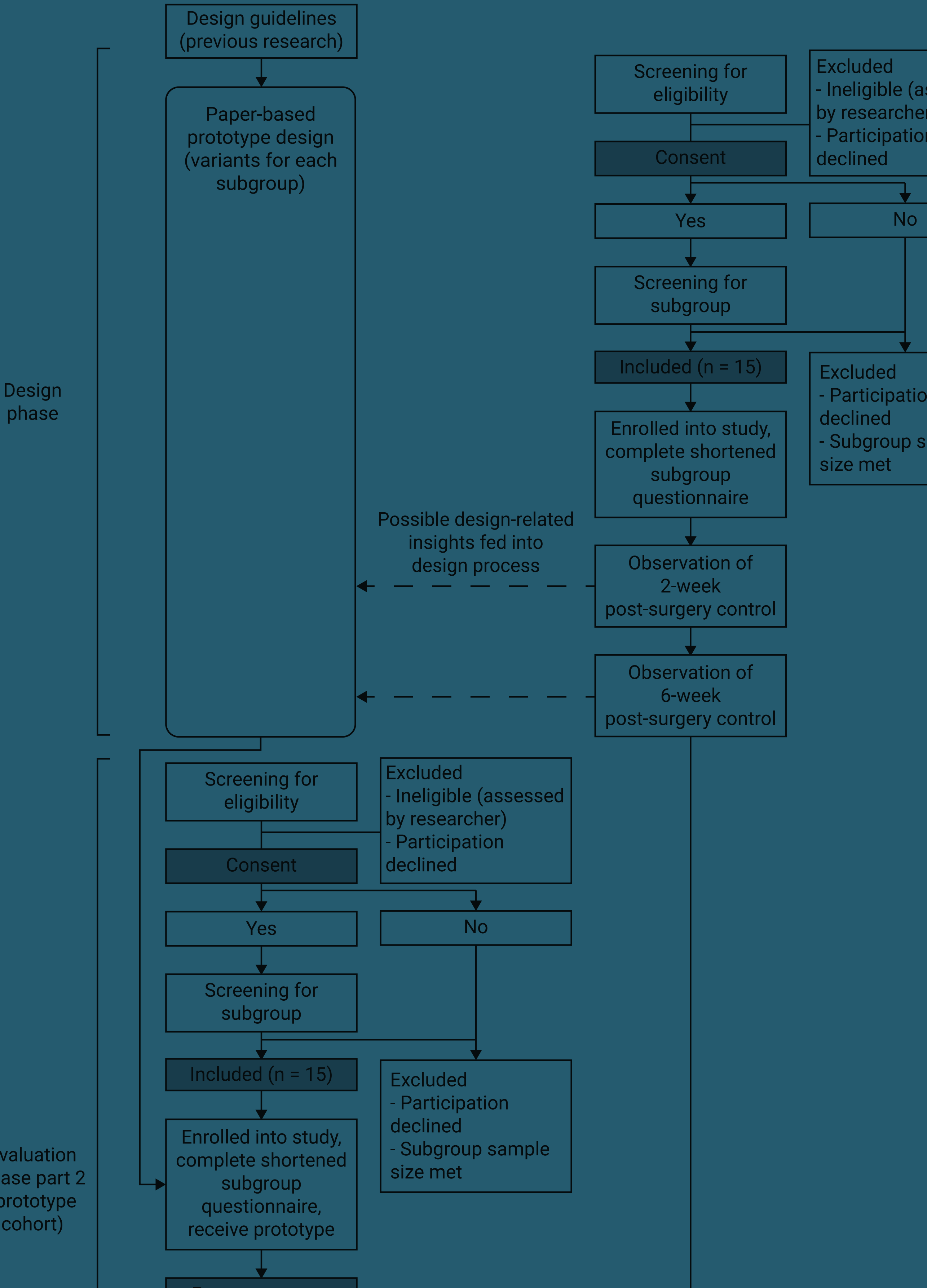

Design guidelines (previous research)
Paper-based prototype design (variants for each subgroup)
Design phase
Screening for eligibility
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Screening for subgroup
Included (n = 15)
Excluded
- Participatio
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- Subgroup s
size met
Enrolled into study, complete shortened subgroup questionnaire
Possible design-related insights fed into design process
Observation of 2-week post-surgery control
Observation of 6-week post-surgery control
Screening for eligibility
Excluded
- Ineligible (assessed by researcher)
- Participation declined
Consent
Yes
No
Screening for subgroup
Included (n = 15)
Excluded
- Participation declined
- Subgroup sample size met
valuation
ase part 2
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cohort)
Enrolled into study, complete shortened subgroup questionnaire, receive prototype

2. Developing digital applications for tailored communication in orthopaedics using a Research through Design approach

This chapter provides an overview of the theoretical foundation and research approach of this project. It is explained that this PhD project uses a Research through Design (RtD) approach, generating insights both from the development and evaluation of prototypes in the early design stage.

This chapter was originally published as a study protocol, with a focus on patient-centered care and communication (PCC) as the outcome measure. The introduction of this chapter provides an explanation of the overall theoretical background and approach of this thesis, which is why it was included in the thesis as the second chapter. However, the remainder of the protocol focuses on the design and evaluation of paper-based prototypes for patients of each profile, which was also based on input from Chapters 3 and 4. As such, the study that followed this protocol is described in Chapter 5. Minor adaptations were made to the original publication in order to incorporate it into this thesis (use of present instead of future tense, several references to other thesis chapters included.)

Groeneveld BS, Melles M, Vehmeijer S, Mathijssen N, Dekkers T, Goossens RHM. Developing digital applications for tailored communication in orthopaedics using a Research through Design approach. *Digital Health*. 2019; 5: 1–14. doi: 10.1177/2055207618824919.

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Abstract

Objective: Tailored communication and information provision is expected to contribute to patient-centred care (PCC) in total hip arthroplasty (THA). In previous research, three profiles of THA patients were identified that are similar in their clinical, psychological, and communication characteristics. Preliminary profile-specific design guidelines were also formulated. Using these insights as a starting point, a theoretical framework was developed for tailored information provision and communication using digital applications. This project aims to refine the framework as well as profile-specific design guidelines for digital applications.

Methods: This study uses a Research through Design (RtD) approach, generating insights both from the development and evaluation of prototypes in the early design stage. This chapter pays specific attention to a protocol using paper-based prototypes for each profile that were evaluated with patients and care providers. Semi-structured interviews are held with participants exploring their experiences with the prototype. A quasi-experiment with a non-random control cohort is used to validate the qualitative findings. Post-surgery consultations with and without prototype are videotaped and scored using a structured instrument.

Results: A design diary is used to summarize design decisions and considerations. Feedback from participants is analysed inductively. Adaptations in profile-specific guidelines is based on comparison of verbal feedback and descriptive statistics from consultations with and without prototype.

Conclusions: Although mixed-method feasibility studies of digital health interventions are common, this protocol also considers the utility of the early design process and the designer’s perspective for realizing PCC and tailored care.

Keywords

Patient engagement, patient education, prototype evaluation, design knowledge

2.1. Introduction

The utility and value of patient-centred care and communication (PCC) is widely recognized. In patient-centred care, the patient is seen as a person with his or her own needs and characteristics; patient-centred communication (or interaction) is realized when care providers actively seek and discuss the patient's perspective.[1] Research has shown that PCC contributes to patient satisfaction,2,3 positive health outcomes,[2] and efficiency of care.[2,4] This makes PCC a key indicator of healthcare quality and PCC is thus of competitive advantage for healthcare providers.[2,3,5]

This study focuses on PCC in relation to patients receiving Total Hip Arthroplasty (THA, or a hip replacement). For this patient group communication and information provision has been shown to be particularly important,[6,7] because THA is an elective procedure and therefor a conscious and carefully planned choice. Patients with osteoarthritis opt for a hip replacement at some point in time, usually after deliberation with an orthopaedic surgeon, and the surgery as well as recovery period are well-planned. So in order to manage patient expectations pre-surgery and expectation fulfilment post-surgery, communication in THA can and should be patient-centred.[8] However, differences between patients in a variety of factors can influence what a patient might perceive as 'good' communication or information provision. Refining the process of patient care and communication in a way that reflects these differences is central to further advancing PCC and improving the patient experience in THA.[3]

Definition of THA patient subgroups or 'profiles'

Although no two patients are identical, we can expect that there will be commonalities in terms of a patients' characteristics, preferences, and needs, in relation to the THA process. To investigate how we could utilise such commonalities—and subsequently group THA patients according to such factors—we distributed a survey among 191 patients who had recently undergone a total knee or hip replacement surgery. Hip and knee surgery patients are similar in their communication needs,[7] and were pooled together to increase sample size. In the survey, we assessed patients' clinical, psychological, and communication characteristics using a series of validated questionnaires measuring quality of life,[9] self-perceived health status,[9] pain,[10] anxiety,[11,12] tendency to catastrophize pain,[13] coping style,[14] communication skills,[15] communication preferences,[16] and self-efficacy for health information.[17] We used the resulting data set to identify clusters of patients in a series of unsupervised and supervised machine learning methods, including cluster analysis[18,19] and recursive partitioning.[20,21] This process, described in further detail in the thesis of Dekkers,[22] resulted in the identification of three subgroups or ‘profiles’. The ‘managing’ profile (subgroup A, 44% of the study population) consisted of individuals with poor preoperative clinical status, who reported a diverse set of coping styles (e.g. active coping, planning, seeking support in others, self-distraction) and strong preferences towards communication, particularly discussing personal circumstances. The ‘optimistic’ profile (subgroup B, 33%) had a good preoperative clinical status and quality of life, reported limited strategies for coping and found patient-provider communication of lesser importance, with the exception of a need for open information. The ‘modest’ profile (subgroup C, 24%) was significantly older and more anxious. They reported coping behaviour that was distinct from other patients (e.g. coping through religion) and were less skilled and self-efficacious in communication about health.

Framework for tailored communication and information provision in THA

Based on the identified patient profiles and earlier inquiries into the needs and experiences of THA patients (see also Chapter 3),[23] we developed a theoretical framework to be used as a blueprint for digital applications (such as a website or smartphone application) that support tailored communication and information provision for these patients. Fig. 2.1 illustrates this framework. It consists of two steps: segmentation and customisation. In Step 1 (segmentation), the patient completes a digital questionnaire (developed by Dekkers). Based on the responses, the application determines which profile is the best match for the patient. The patient then receives access to a variant of the application designed for this specific profile. Adaptations in the application include the way that information is presented, labelled, or structured. We expect that this will increase the initial relevance of the application for the patient, and enhance engagement with the application as a result. In Step 2 (customisation), the patient is offered self-tracking functions (such as textual or audio diaries, daily step count monitoring, or daily pain experience indication) to record their experienced recovery and specific questions that they may have for healthcare providers based on their experiences. This customised input is expected to enhance PCC through the interaction between patients and care providers. For instance, the care provider can give information and feedback during a consultation based on patient-specific data that the patient gathered in the week before that consultation.

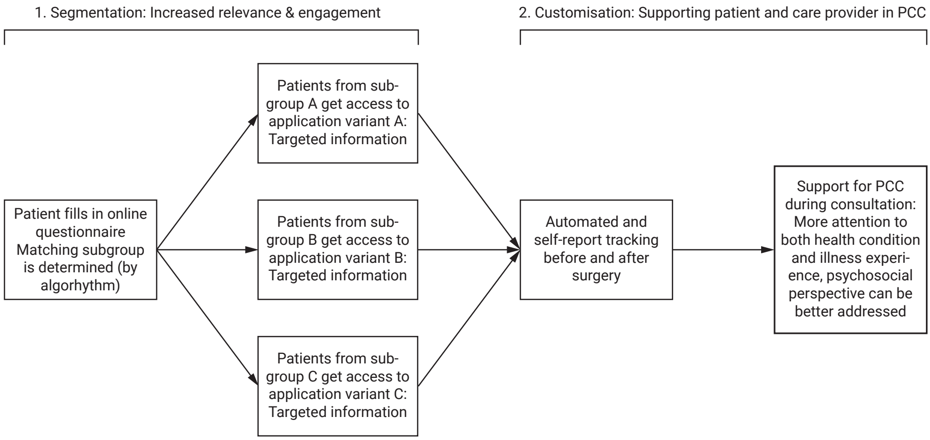


Figure 2.1. Framework for tailored communication and information provision in THA. (Profiles are described as subgroups A, B, and C in this figure.)

Our framework is based on patient segmentation (the division of a generic target population into smaller groups), followed by customisation (specific adaptations for individual members of each subgroup), in order to tailor to the needs of an individual patient. In this case, the THA patient population is segmented into three profiles, and the application is subsequently further customised for each patient based on their input over time. Traditionally, distinction is made between communications that are targeted towards groups of people and those that are tailored towards specific individuals. However, Hawkins et al.[24] argue that the concepts of segmentation and customisation are more useful than this model of labelling communications either as 'targeted' or 'tailored' because a clear distinction between these levels of adaptation is problematic. In our framework, segmentation is applied to increase the initial relevance of the content, which is intended to facilitate engagement of patients with the application.[24,25] Next, by using the self-tracking functions of the application, patients can reflect on their recovery process and customise the content of the application. During consultations, this information can promote the patient's perspective on the recovery, which is seen as one of the pillars of PCC.[26] Healthcare providers can use this information to give individualised feedback or specific information; functions which can be considered as tailoring strategies.[24]

Research approach

In order to refine the framework described above (Fig. 2.1) as well as profile-specific design guidelines for digital applications, this study uses a Research through Design (RtD) approach. RtD is an appropriate research approach to study the features, acceptance, and impact—three factors that are highly interdependent—of a design (in our case, a digital application). RtD is defined as knowledge generation through development as well as user evaluation of prototypes.[27] In addition, the research process is an iterative one, and evaluation of a first prototype allows new insights in order to subsequently modify and improve the design.[28(p96-104)] In our study, the prototype development process itself will lead to new insights, questions, and issues surrounding the use of patient profiles in the design of tailored healthcare communication.[27] Other social or ethical issues surrounding the development of digital applications may also arise, such as a negative association with patients being divided into profiles or issues surrounding data ownership and sharing.[29] Through studying how these are addressed in the design process, such issues may be better anticipated in future projects.

In this RtD project, User-Centred Design (UCD) principles are applied to create and evaluate prototypes. End-user needs and characteristics are considered from the start of product development, and users are actively involved throughout the design process.[30,31] The current framework is also iteratively developed and based on several rounds of preliminary designs and evaluations from target users (Fig. 2.2, steps 1 and 2).

In the study that this Chapter focuses on (Fig. 2.2, step 3), we make use of paper-based prototypes. Paper-based prototypes are often used in the early stages of digital user interface design, before the implementation of software starts.[32] The architecture and functionalities of a specific application are mostly undetermined at this stage, and paper-based prototyping allows developers to quickly define, test and refine a design. In this study, information and self-tracking options for each profile can be quickly tested and easily adapted, and this way a paper-based prototype is an efficient way of testing whether–and if so, under what conditions–the desired effects of segmentation and customisation described in Fig. 2.1 could be realised. Moreover, research has demonstrated that, usually, target users (in our case patients and care providers) provide the same amount and type of feedback to a paper-based prototype as compared to a digital prototype.[33,34]

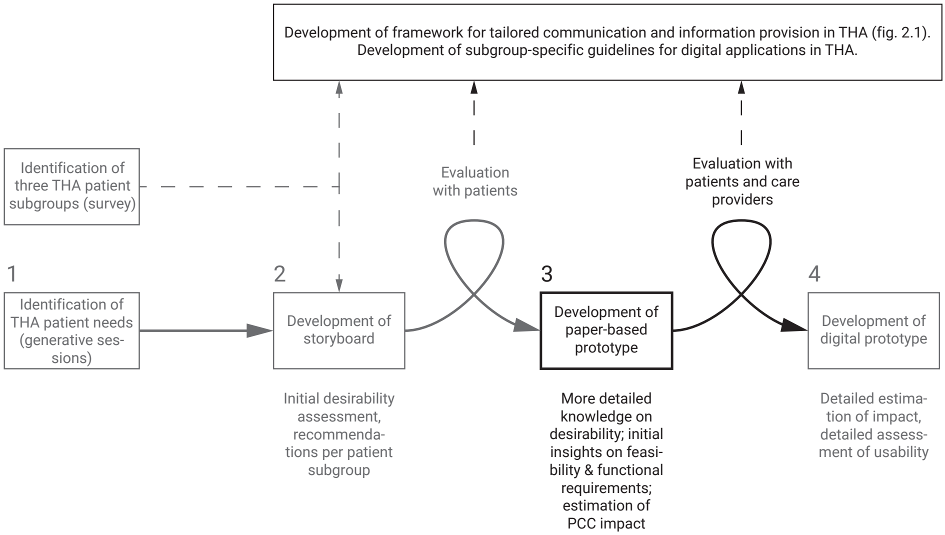


Figure 2.2. Development process of a digital application for tailored communication in THA. See also Chapter 1, paragraph 1.6. *Thesis outline*. The current Chapter focuses on step 3 in the design process.

The study outlined in this Chapter provides insight into which design features are necessary and appropriate, serving as a basis for developing a digital prototype (Fig. 2.2, step 4, Chapter 6). The results of this study are presented in Chapter 5. Usability of the digital application within specific criteria for human-computer interaction (such as discoverability of functions, flow and structure of a digital application) will be evaluated at a later stage (Chapter 6).

Study objectives

This study aims to refine 1) the framework for tailored communication and information provision in THA by digital applications (Fig. 2.1), and 2) the profile-specific design guidelines for digital applications in THA. To reach this goal, we create and evaluate paper-based prototypes of a digital application for tailored information provision and communication in THA, based on segmentation and customisation strategies. Specifically, we define and implement several profile-specific features in the prototypes, and evaluate the acceptance of the prototypes as well as their impact on Patient-Centred Communication during post-surgery consultations.

2.2. Methods

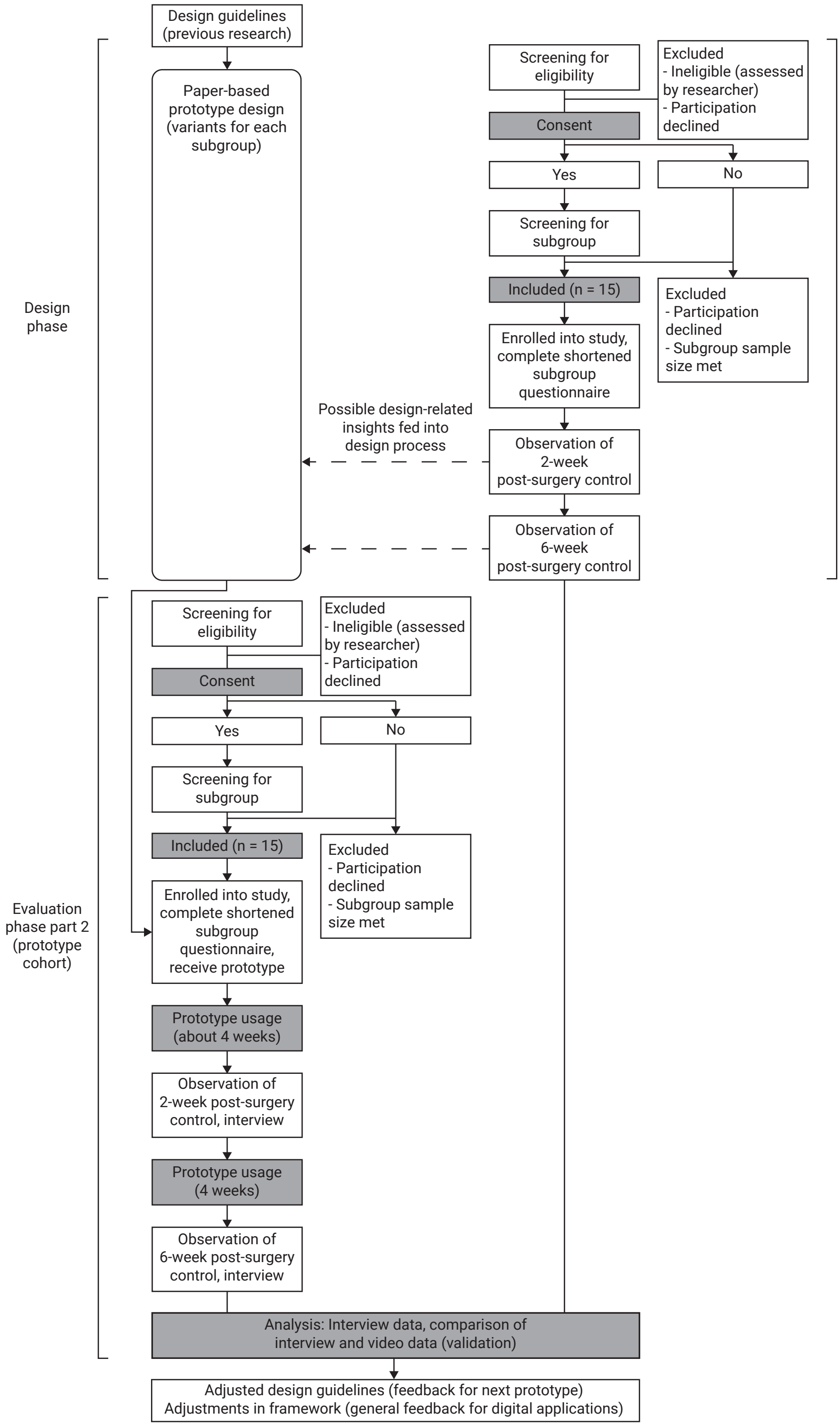
Study design

This study uses a Research through Design approach consisting of two phases; a design phase and an evaluation phase. Fig. 2.3 shows the study flow diagram illustrating these phases and the different activities within each phase. In the design phase, three paper-based prototype variants are created that match characteristics and preferences of each THA profile, following the framework in Fig. 2.1. The prototypes consist of several features related to THA information provision and can be used throughout an extended period (i.e. several weeks). In the evaluation phase, 15 THA patients and 4 healthcare providers use and evaluate the prototypes after surgery. A partially mixed concurrent design is adopted[35] (see Fig. 2.3): Semi-structured interviews with participants constitute the primary source of data collection. The interviews are conducted following the consultations in week 2 and 6 after surgery, and they explore the user experience and perceived impact of the prototypes on the communication with healthcare providers.[36] This perceived impact is validated through triangulation[37] in a quasi-experiment with a non-random control cohort: Post-surgery consultations are video recorded in prototype users and a control group, and these observations are quantitatively compared in order to estimate the observed impact of using a prototype on PCC. This observed impact is contrasted to perceptions by patients and healthcare providers.

Ethical review

A Dutch version of this research protocol was examined by the Medical Research Ethics Committee of the province of South Holland, the Netherlands (file 17 – 146). It was decided by the committee (3 January 2018) that the Dutch law concerning research involving human beings (Dutch abbreviation WMO) does not apply to this protocol, and the need for formal approval was waived.

Figure 2.3. (Right) Study flow diagram. In the design phase, paper-based prototypes are designed for each profile. In the evaluation phase, 15 THA patients and 4 healthcare providers will use and evaluate the prototypes before and after surgery. A quasi-experiment with a non-random control cohort is performed to validate (through triangulation) the impact of using the prototype on care provider behaviour. The control cohort runs parallel to the design phase (see paragraph "Evaluation phase" for the rationale for this).


Design guidelines (previous research)
Paper-based prototype design (variants for each subgroup)
Design phase
Screening for eligibility
Excluded
- Ineligible (assessed by researcher)
- Participation declined
Consent
Yes
No
Screening for subgroup
Included (n = 15)
Excluded
- Participation declined
- Subgroup sample size met
Enrolled into study, complete shortened subgroup questionnaire
Possible design-related insights fed into design process
Observation of 2-week post-surgery control
Observation of 6-week post-surgery control
Evaluation phase part 1 (care as usual cohort)
Screening for eligibility
Excluded
- Ineligible (assessed by researcher)
- Participation declined
Consent
Yes
No
Screening for subgroup
Included (n = 15)
Excluded
- Participation declined
- Subgroup sample size met
Enrolled into study, complete shortened subgroup questionnaire, receive prototype
Evaluation phase part 2 (prototype cohort)
Prototype usage (about 4 weeks)
Observation of 2-week post-surgery control, interview
Prototype usage (4 weeks)
Observation of 6-week post-surgery control, interview
Analysis: Interview data, comparison of interview and video data (validation)
Adjusted design guidelines (feedback for next prototype)
Adjustments in framework (general feedback for digital applications)

Study setting

The study is carried out at the Department of Orthopaedics of the Reinier de Graaf hospital in Delft, the Netherlands (481 beds). This hospital is part of a more extensive network in the province of South Holland, providing services to around 450,000 people in the region. This non-academic training hospital has a strong focus on research and teaching activities. The department primarily serves THA patients that live in the region, but also regularly receives patients from other parts of the country that opt to have the procedure done in Delft.

Design phase (Paper-based prototype development)

In the first phase of this study, paper-based prototypes are developed. Three variants are created that match the characteristics and preferences of the three respective THA patient profiles. This phase is discussed in more detail below.

Main features of paper-based prototypes

Previous inquiries into the needs of patients (Fig. 2.2, phases 1 and 2, described in Chapters 3 and 4) led to a rich array of design-related insights, which resulted in the starting points and main features of each paper-based prototype: 1) A timeline providing an overview of the rehabilitation process after surgery (impression in Fig. 2.4); 2) weekly information for the first six weeks after surgery; and 3) weekly questions and fill-in fields for the first six weeks after surgery (impression in Fig. 2.5). Table 2.1 details the features of the prototypes, including an explanation and the intended effects of each feature. The content of the prototypes is based on a generic patient information handout used at the study setting. A detailed account of how the previous design phases informed and inspired these features and starting points can be found in Chapters 3 and 4.

Each paper-based prototype contains the features outlined in table 2.1, but there are differences among each prototype in how the features are implemented. A prototype for one profile may for instance contain a more informal framing of the weekly information (feature 2) and the fill-in fields (features 3) may be more structured compared to the prototypes for other profiles.

Table 2.1. Main features of prototypes, explanation, and intended effects. Variants of each feature are implemented in each prototype, to match preferences and characteristics of each profile.

Prototype feature	Explanation of feature	Intended effects
1) Overview timeline depicting the rehabilitation process after surgery.	Patient and care provider can discuss the timeline of rehabilitation and patient expectations beforehand.	Manage patient expectations through feedback; answer specific questions.
2) Weekly information based on frequently occurring problems and questions (first six weeks after surgery).	Each week, the prototype offers relevant information concerning rehabilitation and recovery.	Emphasise that rehabilitation takes time; provide relevant information at the appropriate time.
3) Weekly questions and prompts (first six weeks after surgery).	Questions and prompts are provided for the patient to record and track their progress and experiences over time.	Facilitate self-monitoring and reflection in patients; illustrate patient recovery over time.

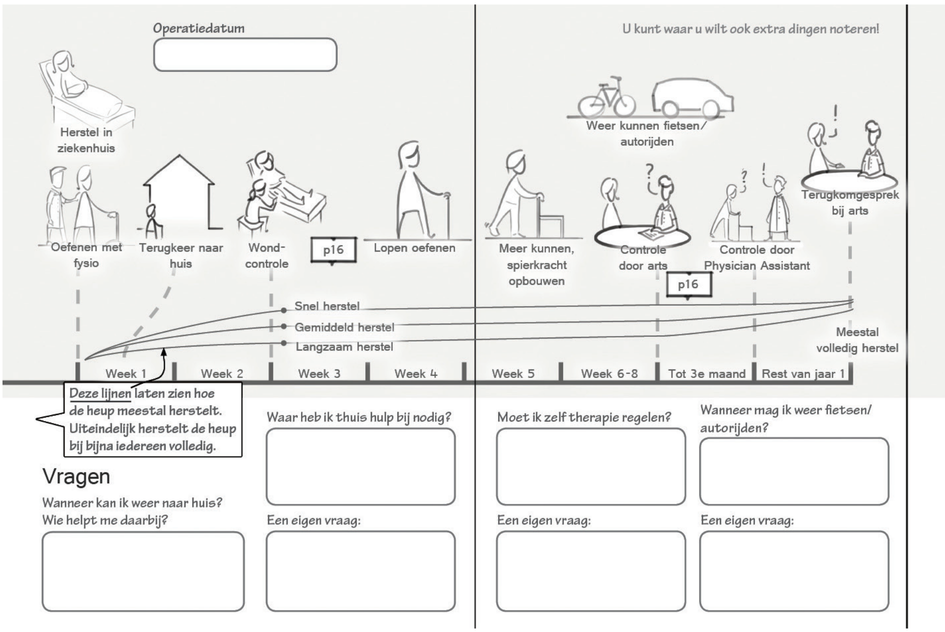


Figure 2.4. Impression of timeline in the paper-based prototype for subgroup B (Table 2.1, design feature 1). The aim of this timeline is to support patient-care provider communication regarding patient expectations in preparatory consultations before surgery. In the top half, the timeline visualises the process of recovery up to one year after surgery. In the lower part there is room to fill in predefined questions.

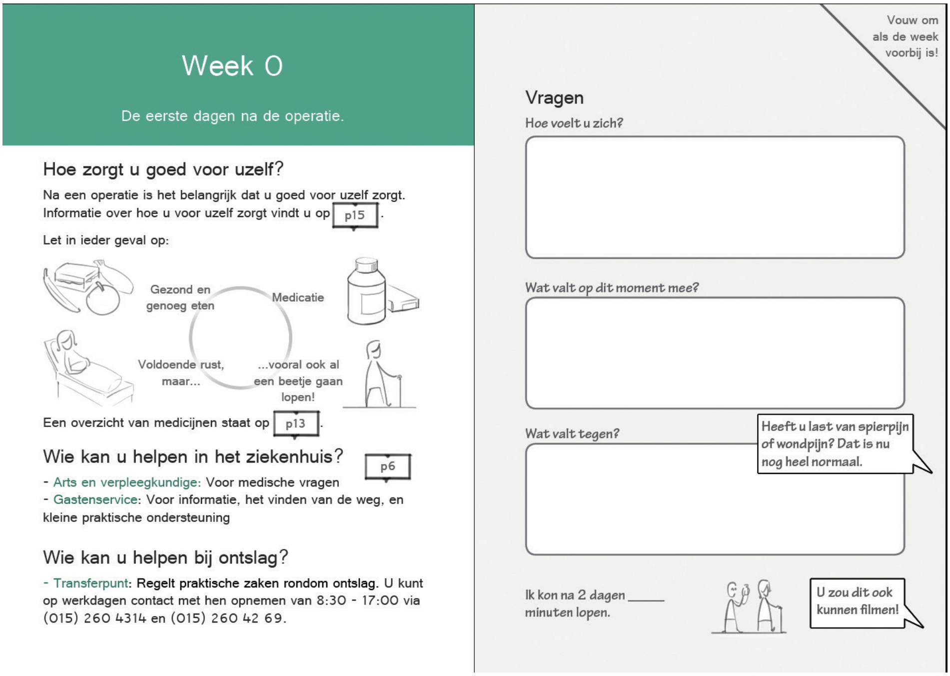


Figure 2.5. Impression of weekly information (left) and log book questions (right) form the second part of the paper-based prototype for subgroup B (Table 2.1, design features 2 and 3 respectively). During the first six weeks after surgery, the prototype may contain information and questions for each week. The logbook aims to facilitate self-monitoring and active feedback seeking in patients, allowing them to track their progress. Impressions of the other design variants are given in Chapter 5 (figures 5.4 and 5.5.)

Procedure

Three variations of the paper-based prototype are designed, with adaptations per profile. (See Chapter 5, figures 5.4 and 5.5 for impressions of the design variants.) These adaptations are based on predefined characteristics identified from the survey study (see Definition of patient subgroups or 'profiles' in Introduction), as well as patient feedback (n = 12) on a storyboard version of the design (Fig. 2.2, Step 2, described in Chapter 4). The insights gathered in these steps were summarised into preliminary guidelines for adapting each prototype variant to the preferences of the corresponding profile. Guidelines are formulated for the design in general, as well as the timeline (Table 2.1, feature 1) and log book (Table 2.1, features 2 and 3). The specific guidelines are listed in Chapter 4.

Outcomes

One outcome of the design phase is formed by the three paper-based prototypes, corresponding to the needs and characteristics of the three THA patient profiles, as well as an overview of considerations that underlie this design output. Additionally, in order to formulate potential design opportunities, constraints and reflections based on the process of prototype development, a structured diary is used. For the type of project described in this protocol, a structured diary is an acceptable option for detailed data collection.[38] Data entries are made following pretested guidelines, and entries are made for each day that design activities are carried out, with links to design materials where relevant. Data is prepared for analysis by numbering and labelling each entry in terms of a content analysis encoding scheme.[39]

Design diary entries and metadata (entry number and initial activity type code) are logged in a spreadsheet using Microsoft Excel. The diary is reread and critical events are listed. Based on further analysis of entries, the predefined set of category codes is adapted where necessary.[39] A general inductive approach is used to summarise and explain design activity code-by-code. Particular attention is paid to suggested options and opportunities for design features, as well as pitfalls or criticisms of the prototype design.

Evaluation phase

In the evaluation phase, the prototypes are given to THA patients of each corresponding profile. Feedback by patients and care providers on the prototypes provided by means of semi-structured interviews is used to explore the acceptance and estimated impact of the design in general, as well as specific design features. Video observations of post-surgery consultations are analysed and compared to care as usual, in order to validate the estimated the impact of the prototype on patient-centred communication.

Sample

Two consecutive samples of patients are recruited for the study, one for control observations and one for prototype use. Both cohorts will consist of 15 patients. Each cohort consists of five patients from each profile. We considered to set up a small-scale randomized trial with simultaneous recruitment and randomized allocation into either prototype or control group; however, we reasoned that additional design-related insights might emerge from the observations of care as usual, so the control cohort for care as usual is recruited and observed first.

For the prototype cohort, five patients of each corresponding profile use a corresponding prototype. As a rule of thumb, it is good practice in user evaluations to include at least five participants from each homogenous group in formative testing (i.e., testing with unfinished designs in order to improve the design).[32(p92)] As we have defined three groups, the sample for one prototype evaluation should consist of at least 15 patients. In addition to patients, four care providers (two orthopaedic surgeons, two medical consultants) are included to observe interactions with patients.

Recruitment

Eligible participants are elective THA patients who opted to undergo surgery at the study setting. For both cohorts, surgery should take place a maximum of two weeks before recruitment. Exclusion criteria for patients include insufficient comprehension of the Dutch or English language or insufficient mental capability to fill out a 10-minute questionnaire, as assessed by the researcher. Eligible healthcare providers are professionals involved in the THA patient journey in the post-surgery recovery period until week 6 after surgery.

The first author has responsibility for the recruitment of participants. In consultation with hospital partners, the first author or selected healthcare providers (e.g. medical consultant or research nurse) inform patients about the study and ask if they can be contacted for participation. Non-respondents are called again after three days.

Screening and assignment to a profile

A screening instrument is used to make an initial classification of respondents, and a shortened version of the survey described in the introduction (paragraph "Definition of THA patient subgroups or ‘profiles’") is then used to make the final classification of patients into profiles. Only patients that are included by the screening instrument fill in the shortened survey, which reduces patient burden. For instance, if sample size requirements are met for two of three profiles and inclusion is only needed for one more profile, we can exclude individual patients based on the screening instrument if this instrument indicates that the patient does not seem to belong to the ‘incomplete’ profile.

The screening instrument and shortened survey were developed in a way such that they only included the variables that best distinguished between profiles. In the screening instrument, these variables are measured using three questions, asking respondents to signify a presence/ absence of 1) coping by planning ('I've been trying to come up with a strategy about what to do.'), 2) feeling helpless when in pain ('When I'm in pain, I feel I can't stand it anymore.'), and 3) preference for completely open information provision ('Your physician should always tell you everything about your illness, even if it is unpleasant.'). The screening instrument was 76 per cent accurate to classify patients into profiles and performed slightly better in the classification of patients from the managing and optimistic profiles (subgroups A and B) compared to the modest profile (subgroup C).

For the shortened survey, the subset of variables includes age, anxiety,[11,12] pain catastrophising,[13] coping style,[14] skill in active-disease related communication,[15] and preference for open communication.[16] Eliminating non-discriminating variables reduced the survey length from 40 to 10 minutes.

In the case that a patient is allocated to a group which has already reached its sample size requirements, participation is discontinued; the patient can still be kept informed about the study if they wish to be. The above process is continued until enough participants are allocated to each group.

Procedure

The prototypes are embedded in the THA care pathway at Reinier de Graaf hospital in an as unobtrusive manner as possible. The prototype will impose no restrictions to optimal or usual care. This also means that patients and care providers are free to use, or discontinue using, the prototype during consultations or at home. Participants are also free to use whichever features of the prototypes they deem relevant. Participants are however requested to report discontinued or altered use to the researchers. Reasons for discontinued, incomplete or altered prototype use are taken into account in iterating and improving the design.

To stimulate intervention adherence (i.e. the use of the prototype), a researcher shortly explains the use of prototype to participants, and is also present in meetings where the prototype is used.

Outcomes

Outcomes include qualitative and quantitative insights regarding the use and evaluation of the prototypes. Interview data is gathered to obtain insights into both patient and care provider evaluation of booklet usability and perceived impact on the consultation.[40] To validate the perceived impact, interactions between patients and healthcare providers are observed using a structured instrument to estimate the impact of the prototype on PCC. We expect the prototype to positively impact PCC, as it is likely that the patient and care provider will more actively discuss the patient's recovery experience when using the prototype before or during a consultation. Recognition of the patient perspective in such a way is considered one of the pillars of PCC.[26]

Interviews with patients and care providers

After each consultation where a prototype is used (in week 2 and 6 after surgery, see also Fig. 2.3), patients are interviewed about their experiences with the prototype. Patients are asked about their general experience and impressions at first ("How did you experience using the prototype so far?") Subsequently, specific questions are asked regarding the different features described in Table 2.1 ("What do you think are strong or weak aspects of this feature? What points for improvement can you think of for this feature?" etc.). Follow-up questions are asked based on answers given by participants ("Can you elaborate on the answer you just gave regarding [general experience with prototype/a specific prototype function or feature]?") Patients are also asked to estimate the impact of using the prototype on their communication with the healthcare provider during the consultation ("To what extent do you think the prototype did or did not influence the conversation in your post-surgery consultations? What makes you think this?").

Healthcare providers are asked to evaluate the use of the prototype and the overall interaction across all cases, and they are asked to shortly explain this evaluation through similar questions as those described above.

Video-based observations of consultations

For both the control and prototype cohorts, consultations in week 2 and week 6 after surgery are videotaped. These observations are coded using the patient-centred behaviour coding instrument (PBCI).[1] This instrument can be used to code physicians' explorative communication behaviour in a consultation;

specifically, it can be used to assess the behaviours that inhibit or facilitate patients to share their perspective on their health condition. There is a clear conceptual link between the behaviour that this instrument captures and the intended impact of the design and paper-based prototypes. In addition, the psychometric properties of this instrument seem to be favourable compared to other instruments.[41]

Data management and analysis

Each participant is assigned a study code to allow an anonymised comparison of results across profiles and cohorts. Survey responses are digitised in IBM SPSS® version 22 for Windows; profile assignment is done with a custom script written in R for Windows. Observational and interview data are processed using Microsoft Excel. Observational data is collected with video recordings and researcher notes, and interviews are audio recorded. Transcript excerpts will be double checked by the corresponding author and a second researcher for accuracy.

Interview data is analysed inductively, in accordance with the guidelines of qualitative content analysis.[42] Each transcript is segmented into 'meaning units', containing words, sentences or paragraphs that are related in terms of their content and context. To summarise the content, all meaning units are condensed and interpreted. These condensed meaning units are grouped into categories, which are then grouped into themes. Themes are generated inductively, and may for instance concern prototype features, the interaction between the patient and the care provider, and patient or care provider experience of their interactions in general. Structures and themes are identified for each profile. The perceived impact on the consultation (from interview data) will be analysed separately as well.

To analyse the video observations, care provider behaviours are analysed using the categories defined by the PCBI.[1] Individual behaviour counts are weighed based on categorical principal component analysis,[43] and the weighted sum scores represent overall care provider performance in terms of 'facilitating' or 'inhibiting' behaviour during the consultation. Consultation length is controlled for by transforming the scores into behaviour rates per minute. Descriptive statistics and confidence intervals are generated to estimate differences in facilitating and inhibiting behaviours for both post-surgery interactions.[44] Quality of data coding is promoted as follows: Transcript excerpts or observational data are coded by a second author for 10 per cent of data. These analyses will be compared and discussed until agreement is reached (as much as possible). This will both be done to refine the observation coding (in a formative stage) and to assess interrater agreement.

Participants' interview responses are then validated using the quantitative comparisons of care provider behaviour. We use triangulation to determine whether there is agreement, partial agreement, or disagreement between the qualitative and quantitative results.[37] For example, patients may be very enthusiastic about the prototype and estimate that it positively impacts their communication with a care provider, but this impact may not be reflected in higher estimated PCC rates in videotaped consultations, compared to care as usual. Table 2.2 details various triangulation scenarios, and implications for adapted design guidelines.

2.3. Discussion

This project uses a Research through Design (RtD) approach in order to refine a framework and design guidelines for tailored information provision and communication applications in Total Hip Arthroplasty (THA). Specifically, this Chapter focused on the research step in which insights into the required features, acceptability, and impact of the design are generated from both the development and evaluation of paper-based prototypes. Semi-structured interviews are held with participants concerning their experiences with the prototype and their estimated impact on post-surgery consultations, and a quasi-experiment with a non-random control cohort is used to validate the impact on PCC during consultations in week 2 and 6 after surgery.

To refine the framework (Fig. 2.1) and profile-specific guidelines for the design of tailored digital applications, these combined outcomes are critically reflected upon. This is common practice in design processes, where insights from prototype testing are used to improve a design.[28(p96-104)] Special attention is paid to criticisms from patients and care providers regarding ethical aspects or feasibility. In reflecting on the impact of the prototype on PCC, the comparison of perceived impact (qualitative interview data) and validation through video observations (quantitative video-observation data) are used to make the final recommendations for future design iterations. Various triangulation scenarios and implications for adapted design guidelines are detailed in Table 2.2. The results of this specific study are presented in Chapter 5.

Table 2.1. Meta-analysis and triangulation scenarios for study components in Evaluation phase.[37]

Qualitative results (interview data)	Quantitative results (video analysis data)	Possible conclusion	Possible implications for design guidelines
Patients/care providers are enthusiastic about the prototypes and/or feel that its use positively impacts communication	Clear difference between control and prototype groups in PCC (i.e. higher facilitating and/or lower inhibiting behaviour rates)	Agreement: Prototype performs as expected	Little or no adaptations to guidelines needed
Patients/care providers have many remarks on prototype, and/or do not feel that its use impacts communication during post-surgery consultations	Clear difference between control and prototype groups in PCC (i.e. higher facilitating and/or lower inhibiting behaviour rates)	Disagreement: Prototype performs as expected, but this is not perceived as such by users	Use same features in next prototype, but expand them or frame them differently
Patients/care providers are enthusiastic about the prototypes and/or feel that its use positively impacts communication	No (clear) difference between control and prototype groups in PCC (i.e. similar facilitating/inhibiting behaviour rates)	Disagreement: Prototype does not perform as expected, but users are satisfied with it	Expand features and functions in next prototype, in order to increase its impact
Patients/care providers have many remarks on prototype, and/or do not feel that its use impacts communication during post-surgery consultations	No (clear) difference between control and prototype groups in PCC (i.e. similar facilitating/inhibiting behaviour rates)	Agreement: Prototype does not perform as expected	Formulate new features or functions (perhaps even different objectives) for next prototype

This protocol shows similarities with relatively common mixed-method protocols to study the feasibility and acceptability of digital interventions. Recent examples include a study using Facebook as a tool for people with serious mental illness,[45] an application for women with pregestational diabetes,[46] or the use of digital technologies by patients with musculoskeletal conditions in the waiting room.[47] In addition to this type of study, our RtD approach considers the early stages of design and the perspective of the designer as valuable sources of knowledge. Reflections made in this early process by the designer, as well as users, can result in high-quality guidelines for creative practice. These types of insights are sometimes defined as 'strong concepts' or 'intermediate-level knowledge',[48] i.e. specific types of interactions and design recommendations for specific target groups that can also be applied and evaluated in other (similar) contexts. A paper-based prototype is an efficient means to gather these insights at this early stage and can still result in valid user input for digital prototypes and the final application. Moreover, evaluating a digital prototype at this stage may confound the results as target users may, in general, prefer (or dislike) the concept of digital information provision.

This study also bears much similarity to the person-based approach for health behaviour change intervention development.[36] This approach uses in-depth qualitative research in an iterative fashion throughout the development process, in order to make health behaviour change interventions more convincing and persuasive for users. Goal-based design guidelines are also set up from the early stages, to steer the development process. The approach goes beyond usability or feasibility testing, also looking at how users implement the behaviour change techniques. Similarly, in our Evaluation phase we examine the experience of users with the prototype in terms of both acceptability and impact on PCC. However, we also make use of a quantitative validation of the perceived impact, through video analysis of post-surgery consultations. In addition, even in early development stages we apply basic (paper-based) prototypes to evoke specific feedback and responses by end-users. Moreover, we let patients evaluate storyboard of design features in order to create the initial set of guidelines (Fig. 2.2, step 2, see also Chapter 4). This prototype-led research setup is not necessarily part of the person-based approach from the earliest stages. So while the person-based approach is a highly relevant and valuable addition to theory-based and evidence-based intervention development, the RtD protocol outlined in this Chapter seems to add several elements to this approach.

The study that this Chapter focuses on has several limitations. Intensive observation and follow-up interviews with patients about the prototypes may introduce bias in behaviour during consultations and feedback on the prototypes. Also, sample sizes in this study are relatively small, which limits the generalisability of findings to the overall THA population and other contexts. Moreover, the use of a paper-based prototype for a digital application is useful in this design stage, but specific aspects such as navigation through the application should be tested with a digital prototype. This can be found in Chapter 6.

Nevertheless, we expected that this study would produce valuable and actionable insights for tailoring communication and information around THA using digital applications. As THA patients particularly value this aspect of care delivery, we expected that these applications would positively impact patient-centeredness.

2.4. References

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3. Communication preferences in Total Joint Arthroplasty: Exploring the patient experience through generative research

Chapter 3 describes a contextual inquiry that was conducted with Total Joint Arthroplasty (TJA, both hip and knee surgery) patients, in order to assess individual differences in preferences regarding communication and information provision (RQ1). These individual differences were expected to be useful to customize information and communication services for TJA patients, complementing the segmentation vantage point provided by the patient profiles. This Chapter is centered around the TJA patient experience; the results therefor provide direction on how to customize tailored services, but also provide general inspiration for TJA service development.

The Chapter has been accepted for publication in the journal Orthopaedic Nursing.

Abstract

Background: Improving communication and information services for people receiving a total joint (knee or hip) arthroplasty (TJA) depends on the differences in patients' communication needs and capabilities. A survey study of 191 participants identified three TJA patient subgroups with distinct clinical, psychological, and communication characteristics.

Purpose: To further examine individual differences in TJA patients' preferences regarding communication and information provision.

Methods: 19 Patients participated in generative research, which meant they actively reflected on their TJA experiences and communication preferences through creative exercises (e.g. collage-making). Audio-transcripts of their shared reflections were qualitatively analysed through an inductive approach.

Results: Some participants wanted full information, others did not. Participants also reported different support needs, e.g. at hospital discharge or during rehabilitation. Moreover, participants' preferences for social connections with care providers differed.

Conclusions: An individual patient's mind-set, his or her social support needs, physical condition, and medical history should guide the provision of tailored services.

Keywords

Interactions; Patient perceptions; Contextual inquiry; Qualitative methods; Person-Centeredness; Design

3.1. Background

Improving patient experience and accommodating patients' preferences is an established way of improving healthcare.[1] Next to quality improvement, the focus on patient experience has also been linked to a competitive advantage for care institutions.[2,3] Patient experience, defined as 'the sum of all interactions, shaped by an organization's culture, that influence patient perceptions across the continuum of care',[4] spans the entire care process and is strongly linked to expectations and expectation management. Assessing patient experience should therefore go beyond survey results and satisfaction alone.[2]

This study focuses on the patient experience of those receiving a Total Joint Arthroplasty (TJA; a Total Hip or Total Knee Arthroplasty). In the Netherlands (for example in the case of study partner Reinier de Graaf hospital, Delft) a fast-track TJA protocol is implemented for most patients and TJA in an outpatient setting (discharge from the hospital on the day of surgery) is available for selected patients.[5] Patients receive preoperative education in a class or an individual format, rehabilitation and mobilization are initiated on the day of surgery, and discharge criteria are checked more often. This has reduced the length of hospital stay (LOS) for most patients to one night, with most patients being discharged and sent home.[6] Post-surgery contact with care providers after discharge is limited. For example, a nurse checks the surgical wound after two weeks, and a follow-up consultation with the surgeon (including X-ray) occurs in the sixth week. Patients independently manage their recovery between these consultations. Some are supported by a physiotherapist, informal caregivers, or products and services such as educational booklets provided by the hospital.

Pre- and postoperative patient education can play a role in meeting TJA patient's expectations, which is strongly linked to the TJA patient experience.[7,8] Patients themselves also have knowledge expectations regarding TJA, and decreasing the disparity between expected and received knowledge remains a key issue in empowering patients and improving outcomes.[9,10] A recent overview of patient perspectives specifically emphasizes the need for individualized patient education and support, especially in the months after surgery.[11]

Improving the TJA patient experience through patient education is complicated, as personal factors influence each patient's individual needs. For instance higher knowledge expectations are found in patients with higher education levels, or for those individuals in a depressed state.[12] Furthermore, the rehabilitation after TJA, an important phase after TJA surgery, should also be personalized to improve patient experience, for example by taking comorbidities, physical condition, and pain control needs into account.[7,11,13] To further improve the TJA patient experience before and after surgery, care providers should systematically account for differences between patients, resulting in tailored approaches to communication and information provision.[11,14]

Subgroup division, or segmentation of the TJA patient population, offers opportunities to tailor and improve patient experience. In an earlier survey study of 191 patients, the authors showed TJA patients can be clustered into three groups based on similarities in their clinical, psychological, and communication characteristics.[15] These characteristics were chosen because of the importance of communication and information provision for TJA patients, and because care providers use them to intuitively adapt their communication with patients.[16] Each subgroup had a distinctive attitude or 'role' they assumed in the patient journey. The first subgroup (possessing a 'managing' role or attitude) consisted of individuals with poor preoperative health who reported many different coping styles and strong communication preferences. The second subgroup (an 'optimistic' role) showed the best preoperative health and quality of life, had fewer coping strategies, and noted a lower priority for patient-provider communication. The third subgroup (a 'modest' role) was significantly more anxious and older than patients in the other two groups and reported distinct coping behaviour (e.g. religious coping), as well as lower self-efficacy and competence in their communication about health. Healthcare providers can use a shortened version of the survey to determine the subgroup that best matches to a patient, or they can use a screening instrument consisting of three questions to estimate the subgroup. A more detailed summary of the subgroups and their determination is described elsewhere.[15,17]

The subgroup division offers opportunities for personalizing and therefore improving the TJA patient experience. However, adapting to group-level characteristics could be seen as a targeted, rather than a tailored communication approach.[18] In the definition of tailored communication by Hawkins et al.[19] the subgroup division is analogous to the 'segmentation' of a target audience. For instance, the segmentation proposed by the TJA subgroups could be used to increase the initial relevance of patient information, so that patients engage more with the material.[19,20] But to achieve tailored care, 'customization' to individual preferences within each segment (or subgroup) of the target population is also necessary.[19] Figure 3.1 shows the distinction between these tailoring components, and the relation to previous and current research.

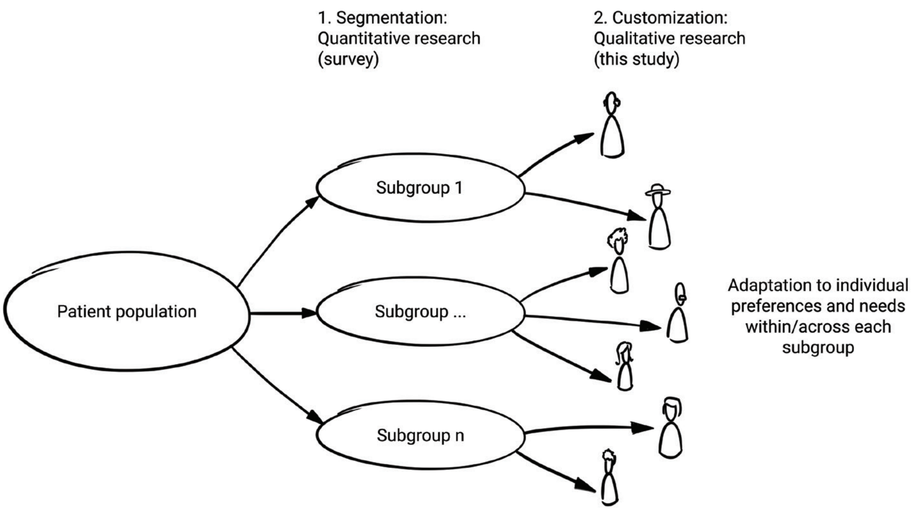

Figure 3.1. Framework for tailoring based on definitions by Hawkins et al.[19] The results from the survey study (step 1)[15,17] are used to segment the TJA patient population. To achieve tailored health services, customization (step 2) is needed.

Additional insights and nuances regarding individual differences between TJA patients throughout their care path, i.e. the patient experience journey, can be gathered through qualitative research (Fig.3.1, part 2). Moreover, detailed qualitative knowledge about individual patient perceptions of TJA can be used to design more relevant, persuasive, or appropriate health services.[21] In addition to the recent overview in TJA,[11] researchers have explored patient perceptions in chronic illness,[22] cancer,[23] and diabetes,[24] and they offer actionable recommendations.

3.2. Purpose

The overall purpose of the research this study is part of was to improve the TJA patient experience using tailored information and communication services for this patient group. In order to customize these services, this study aimed to qualitatively examine the individual differences in TJA patients' preferences regarding communication and information provision throughout the patient journey.

3.3. Methods

Total Joint Arthroplasty (TJA) patients took part in a generative design research study.[25] Generative design research is defined as "an approach for co-designing and co-creating that is focused on the front end of the design development process".[26(p25)] In generative sessions, participants are seen as "experts of their own experience"[25] and fulfil an active role in reflecting on their experiences, memories, and hopes for the future. In this study, participants collected photos and created both a timeline of their TJA patient journey and two collages describing their current experience and future ideal. The creation of and reflection on these visual artefacts allow for the elicitation of tacit or even latent knowledge about their experiences—more than, for example, regular interviewing or observations would—which, in turn, leads to a better understanding of the user experience.[27] In this study, the generative approach was used for discovering individual differences in TJA patient's preferences and for designing services such as patient information provision. Such generative techniques allow people (or patients) without design training to be more involved in this design process.[26(p25)]

The study was conducted from February to May 2017. After review, the local Medical Research Ethics Committee (MREC) decided (5 January 2017, file 17-008) that this study falls outside the scope of the Dutch law concerning research involving human beings (Dutch abbreviation *WMO*).

Participants

Eligible participants were patients from the TJA population at Reinier de Graaf hospital (Delft, the Netherlands) who had participated in the previous survey study (see Introduction). These participants had undergone surgery between October 2015 and October 2016 at the study site. Patients were eligible for inclusion in this survey study if they 1) were of adult age (>18 years), 2) were proficient in Dutch, 3) were capable of providing informed consent, and 4) had undergone only one TJA surgery at the start of the study. Eligible patients were contacted in chronological order of surgery date, to reduce selection bias. 191 Patients were included in the survey study. A subset of study participants was recruited for the current study; these patients were also contacted in chronological order of surgery date (for the same reasons as the survey study). The initial sample size was set at 10 percent of the survey sample (n = 19). Additional recruitment would have occurred to reach data saturation, but this was not necessary.

Procedure

The study procedure consisted of two parts: an individual part including a set of preparatory exercises followed by a group session. Each participant completed the preparatory exercises in the week prior to their scheduled session. The group sessions were organized at the participating hospital with the exception of one session which was held at Delft University of Technology, faculty of Industrial Design Engineering (Delft, the Netherlands). All participants provided written consent prior to inclusion. Prior to consent, participants received information about the study including safety measures. It was clearly stated that they were free to choose what information to share during the exercises, and that they were free to cancel participation at any time. It was also explained that participant data was coded so that it could be used anonymously, and that participants' information and data were safely stored at the study location accessible only to researchers.

Preparatory Exercises

Each participant received two preparatory exercises one week before their session date. The exercises were given to participants to let them actively and broadly think about their personal preferences and their TJA patient experience before attending the group session, so that they were better prepared for diverse and creative thinking during group sessions. It is considered essential to include these assignments in protocols for generative research.[26(p55)]

To let participants think about their personal preferences in daily life, participants completed Exercise A. The instructions for this exercise were as follows: "Please take up to three photographs of things from daily life that you generally like or dislike. These can be favourite pastimes, objects, or anything else that comes to mind. Write a short description of each photograph. You can take pictures with your smartphone or camera, or collect pre-existing images. Please send the images by e-mail, or bring them to the group meeting."

To help participants think about their overall TJA patient experience, exercise B consisted of a timeline template that was sent by regular mail. This template is shown in figure 3.2. The following instructions were given: "Please put the most important moment [of your TJA patient experience] in the timeline. You can use keywords or shorts sentences to do so. We would also like to ask you to mark the best and worst experience of the entire process. Bring the timeline to the group meeting."

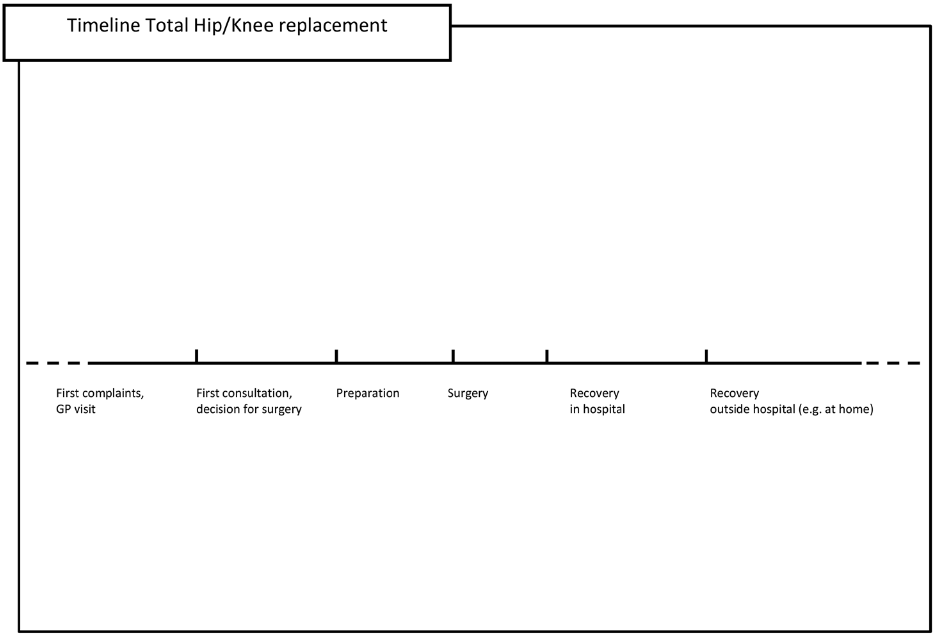

Figure 3.2. Timeline template sent to participants four days before the session, using a patient journey's structure (originally in Dutch).

Group Sessions

Based on guidelines for generative research we included between five and seven participants per session as this provides enough opportunity to exchange experiences, while keeping group dynamics manageable for the session leader.[25]

During the session, participants visualized or described 1) a part of the patient journey they had not looked forward to, but that had turned out better than expected and 2) an 'ideal' experience of the TJA experience, within physical limits (e.g. recovery time). Visual and textual stimuli (stickers with adjectives or generic shapes and colours) were provided to facilitate diverse visualisations or descriptions. Figure 3.3 gives an impression of the materials and tasks carried out by participants. After each creative act, participants individually presented their materials and the group was invited to compare their experiences and perspectives, evoking a discussion on differences and similarities between individual experiences. One researcher acted as the session leader, while the other assumed the role of note taker. In total, the session was planned to last two hours. Table 3.1 gives a detailed outline of the generative session.

Figure 3.3. Impression of the materials used and activities carried out by participants in the generative session.

Table 3.1. Detailed outline of the generative session.

Step (duration)	Activity	Participants' actions	Remarks	Goal
1 (10-15 min)	Introduction	Introduce themselves, receive explanation about session setup		
2 (15 min)	Constructing past experience	Visualise or describe a part of the patient journey they had not looked forward to, but that had turned out better than expected	Visual and textual stimuli were provided to inspire participants	Each participant has a personal account of a key experience
3 (15-30 min)	Discussing past experiences	One participant was asked to present his or her creation; other participants were subsequently invited to elaborate or indicate differences and similarities based on their own experiences.	One researcher moderates the discussion, the other takes notes	Unravel e.g. emotional aspects of the experiences in-depth; gain insights into similarities and differences among patients
(10 min)	Break			
4 (15 min)	Imagining ideal TJA experience	Individually envisioned an 'ideal' experience of the TJA procedure, within physical limits (e.g. recovery time)	Similar setup to step 2	Each participant has a personal account of an ideal experience
5 (15-30 min)	Discussing ideal experience	Similar to step 3	Similar to step 3	Similar to step 3
6 (10 min)	Closing			

All participants received a gift card (20 euros) as a token of appreciation for their participation. Participants were also given a stamped postcard addressed to the researcher, to note any additional thoughts they had after the session and to share these with the researchers.

Analysis

Directly after each session, the session leader and note taker discussed what they viewed as the session's most important statements and aspects. In addition, each session was audio recorded and transcribed. The transcripts were used as the main data source for the analysis. The stories that participants told to explain the timeline and collages they created and their shared reflections on differences and similarities were particularly rich and useful for designing services,[25,28] such as tailored information provision. The analytic framework was similar to a Grounded Theory approach[29] in the sense that structures and patterns in data were discovered without pre-set expectations. Rather than being hypothesized in advance, such patterns were discovered during analysis. To this end, data was abstracted and interpreted to produce information and eventually, knowledge about the subject being studied.[26,30(p200-201)]

Specifically, this meant that the researchers reread the transcripts several times in order to become familiar with the data. Qualitative Content Analysis (QCA) was used to extract categories and themes from the transcript.[31] Several measures to promote trustworthiness of this study are outlined below.

To promote credibility of the results, the first author coded the full transcripts of three sessions, which included sorting and interpreting meaning units. This resulted in a preliminary set of themes and data categories, an example of which is given in Table 3.2. Peer debriefing between the first and second author was used to check and refine this preliminary outcome.[32(p245)] Finally, data saturation was checked using transcript data from the final session. That is, we used this transcript to verify no new categories of data were formed by additional meaning units.[32(p221)] Verbatim quotes from the transcripts ensured mutual exclusivity between categories of data.

To ensure the dependability of the data collection process, all four sessions were organized within a limited period of time, and specifically focused on the differences and similarities in patient preferences regarding the TJA patient experience. Finally, to provide insight into the transferability of the findings, specific details regarding the study setting and participant characteristics were summarized (see Discussion, subsection 'Limitations of this study and further research').

Table 3.2. Example of QCA for a subset of data for the theme of 'Differences in information and communication needs'

<table>
<tr><th>Meaning unit (excerpt)</th><th>Interpreted meaning unit</th><th>Category</th><th>Theme</th></tr>
<tr><td>"[The surgeon] had already told me you could get infected during surgery [...] so yeah" (S3).</td><td>Participant experienced the info given as open</td><td rowspan="2">Some participants prefer open and full information about TJA and adjacent procedures</td><td rowspan="3">Contrasting needs regarding information provision and communication</td></tr>
<tr><td>"[...] I have no one at home who can take care of me, so [the fact] that a rehabilitation ward is available here in the hospital, that was never … they refused to tell me that" (S2).</td><td>Participant had the feeling that information was deliberately withheld</td></tr>
<tr><td>[Participant recalling the discussion with the surgeon about surgery:] "I don't know anything about that. I just said, I hope you have a sharp knife." (S2)</td><td>Participant is not interested in knowing all the details of the surgery</td><td>Some participants place less value on detailed TJA-related information</td></tr>
</table>

3.4. Results

A total of 19 TJA patients participated in the four sessions which were organized between February and May 2017. Sessions 1 and 2 had five participants, session 3 had six. These patients had undergone TJA on average 7 months before their participation (SD 1.6 months, range 4.6 – 10.7 months). In the last session, only three patients participated due to unexpected cancellations. Participants' background characteristics are presented in Table 3.3.

The accounts of participants' experiences were rich and vivid, and participants actively responded to each other's experiences and opinions at each session. Data analysis of the last three participants did not result in any new themes or categories, which means data saturation was achieved. The following themes were found: 1) Participants indicated differences in information needs: some participants wanted open and full information, while others valued this less. 2)

Participants reported differences in their support needs post-surgery, such as hospital discharge or rehabilitation. 3) There were differences in participants' preferences for a social connection with care providers. These themes are discussed in detail below; Table 3.4 provides an additional summary. Quotes in the text are provided with a session number, abbreviated as (S).

Table 3.3. Participants' background characteristics, including comparison to the survey study population.

Characteristic	n (%) or MEAN ± SD (range)	
	Current study sample (n = 19)	Survey sample (n = 191)
Sex: Male	7 (37)	74 (39)
Age: Years	67 ± 7.5 (46-76)	71 ± 8.7
Type of surgery: Total Hip Arthroplasty (THA) (otherwise: Total Knee Arthroplasty, TKA)	13 (68)	106 (55)

Differences in Information Needs

Participants reported contrasting needs regarding *information provision from care providers*. Several participants were pleased that they had received detailed information from care providers. This included a participant who could monitor her own (minor corrective) surgery (S1), or one participant who was clearly informed about the risks of surgery: "[The surgeon] had already told me you could get infected during surgery […] so yeah" (S3). In this case it helped the participant to accept a post-operative complication. Giving specific information after the operation about the amount of blood loss was also valued by one patient (S3). Some participants also had the feeling that processes were not communicated well or that information was even deliberately withheld: "[…] I have no one at home who can take care of me, so [the fact] that there is a rehabilitation ward available here in the hospital, that was never … they refused to tell me that." (S2). At least 5 participants seemed to find *open and full information provision* important. In addition, examples were mentioned of care providers using terms and phrases that patients were unfamiliar with, causing confusion (S3). One patient stressed the need for dispersed and repeated information provision "because people never remember everything" (S3).

Others (n = 2) placed less value on receiving open and full information. For instance, one participant recalled saying, when discussing the operation with

Table 3.4. Themes regarding individual differences in TJA patients' needs and preferences.

Theme	Specification	Examples
Differences in information needs	Varying needs for open and honest information	Some patients want open and full information, others need fewer details and try to have faith in the surgeon
	Assessment and adaptation of communication	Shared responsibility of care providers and patients to assess communication preferences and adapt accordingly
Differences in support needs post-surgery	Different needs and preferences regarding hospital discharge	Suggested creating a checklist for discharge based on medical conditions, home circumstances, social support
	Adaptation to personal wishes in rehabilitation	Adapt rehabilitation to patient's wishes, capabilities, physical status, and medical history
	Extent and type of guidance in rehabilitation	Some patients need little guidance in rehabilitation, others want or may need more than what is currently being provided; related to complications, social connections, physical fitness
Differences in preference for a social connection with care providers		Some patients find social connection or rapport with the surgeon more important than others

the surgeon, "I don't know anything about that. I just said, I hope you have a sharp knife" (S2). Several other participants felt that it was also important to just *have faith in the surgeon* and the process, leading to disagreement on this topic between participants (S3). Some participants (n = 2) thought that the need for open, full information is also dependent on the person's own attitude and previous experience: "I also have trust, but through experience I have, if you have worked in this field, you know a bit more about how this works, really." (S3) This critical attitude was also mentioned as a disadvantage because patients could make the process harder for themselves.

In light of the above, the presence of formal (hospital-provided) information was satisfactory for at least two patients, but three patients thought that this information should be better adapted to their personal circumstances, such as the presence of social support and possible complications. As such, participants mentioned that care providers should *assess and adapt their information provision* to patients to accommodate these kinds of individual differences (S3). Three participants indicated that it is the *patient's responsibility* to discuss their questions and preferences: "Listening is important, but [...] as a patient, you also need to indicate yourself where you have pain, what you're feeling, what your attitude in life is." (S1) However, it was added that "this may be pretty hard" for some patients, as "everyone has the right to know everything [about the operation] but not everyone can [indicate] this." (S3)

Differences in Support Needs Post-Surgery

Participants also reported differences in their post-operative support needs. Specific comments were made regarding the guidance around and criteria for hospital discharge; participants also indicated different personal preferences for their rehabilitation. These aspects are discussed below.

Different Needs and Preferences Regarding hospital discharge

Six patients believed that the period to discharge and transfer to home should be more flexible (S3, S4). One patient (S3) was frustrated by the rigid use of protocol for discharge from the hospital: "So I was still in the hospital, and the bed was soaked [with wound fluid]. [...] So, I said, but that's not OK, right? 'Yes, but you can walk a bit, right? [...] well, then you can go home.'" (S3) In this case, the patient had to undergo corrective surgery due to a bacterial infection. Another participant indicated that being alone at home was especially hard the first days after discharge: "That was worse than I had imagined, to really manage on your own at home. [...] Or you would need a spouse at home or a partner, but [for me] that wasn't the case." (S2) For a participant (S4) without a partner, practical support at home was hard to arrange. This participant really valued being allowed to stay in hospital longer (S4). Reflecting on these experiences, in one session (S1) a checklist for discharge was suggested that took a patient's medical conditions, home circumstances, and the presence of peer support into account.

A lack of communication about the transfer home was also particularly stress-inducing for several patients: "It's unclear when you go into hospital how that will go. There's a decent person that knows the way who takes care of it. But you only see them once you go home. And that causes much uncertainty." (S2) In this case, the transfer nurse played an important role, but there was also need for more information about this person.

Adaptation to Personal Wishes in Rehabilitation

At least 4 patients indicated that flexibility throughout rehabilitation is important. For example, a patient argued that "it's very important that […] both physician and physical therapist, […] and that you look very critically at what goals you want to reach." (S2) She also argued that "they shouldn't [adapt rehabilitation] to your age category, but to your fitness." Conversely, one patient was negative about 'standard rehabilitation' that did not account for his specific needs. In some cases, patients could indicate what they wanted: "Yes, I told them myself what I like and what I need. […] I benefited quite a bit from [doing this]." (S2) To summarise the discussions on this subject, it appears that the rehabilitation plan should include a patient's wishes, capabilities, physical status, and medical history.

Extent and Type of Guidance in Rehabilitation

Patients also differed as to how much and what kind of guidance they preferred during rehabilitation. Several patients (n = 5) reported that the rehabilitation process was smooth and that little guidance was needed. For instance, one participant recalled: "I needed to do those [exercises] and that helped me […] Well, I just did that and it only got better, only better" (S2). One patient thought that all the instructions after surgery made rehabilitation seem "like boot camp" (S4), and she exercised casually after surgery.

Most patients indicated that the physical therapist (PT) provided clear feedback on exercises and physical behaviour (S1, S2, S4). For instance, one participant especially valued that the PT clearly indicated that an activity was off-limits: "At some point I said, I could cycle again. […] and he was like, 'don't do that!' So I thought the physical therapist was very clear about that." (S1)

There were also participants who independently supported or arranged their own rehabilitation. One patient noted, "that PT I went to, she said […] 'just do the exercises with the cycling and your legs and all. So, I said, well, then I'll just go to [the gym] […]. Then I'll do it myself." (S3) Another participant (S2) purchased a step counter to keep track of his progress and made adjustments in his home. Some participants (n = 2) adapted their own pain medication, or found alternative means of managing post-operative pain (S4). These participants seemed to only need a little guidance from care providers during this phase.

In contrast, other participants (n = 7) reported problems or struggles relating to rehabilitation, and implicitly or explicitly indicated that more guidance was needed (n = 5). In one extreme case, a lack of clear information on recovery led to a long period of distress, "When you meet with the Physician Assistant after six months, you're like, Oh, I'm no good, I'm still limping. And then that man says, 'completely normal. You're doing great. It's really normal that it hurts.' And here I was, thinking all the time that I should be running around all fit." (S2) Another participant expressed "I find this hard, my limits… what I can and can't do. [My surgeon] is not in favour of physical therapy, he just prefers walking and that's it. […]; I want to have some more guidance." In this case, the therapy could have been adapted to the patient's wishes, but still she felt that "the rehabilitation process is a process of searching. […], that's the only thing that disappoints me, so to say." (S1) This was a participant who had always been very physically active and who valued her independence. However, it was also said that more guidance was especially needed for patients who weren't very motivated to start moving again (S1).

Finally, whereas some participants managed modifications in their homes independently, in Session 2 it was noted that these adaptations should be guided by care providers. In all, there were considerable differences in how patients *managed* the rehabilitation process versus *what they expected* of it, which seemed to be related to their own goals, post-operative complications, personal circumstances, and social connections, as well as physical fitness. As one participant said: "If you've been [fit and active] your entire life, then you just don't know better. […] and then [rehabilitation] takes a bit more energy" (S1).

Differences in Preference for a Social Connection with Care Providers

The *importance of a social connection* between patient and care provider was valued differently. One participant indicated that, "sometimes [communication] could be a bit lighter, more humorous, I think. […] Of course, it's, […] in fact it's very enjoyable, that you can walk again. I would [put] more humour in the process." (S2) The sociability of a surgeon was specifically valued by an S4 participant, and another participant (S3) even indicated that he switched to this surgeon because he felt he had a "better connection" with him. Another participant disagreed, arguing that "it's great if the physician is nice, but […] if they are just functional and have good professional knowledge, that comes first" (S3).

3.5. Discussion

This study aimed to qualitatively examine the individual differences in TJA patients' preferences regarding communication and information provision throughout the patient journey to customize health services for this patient group. Participants indicated differences in these needs: they differed in whether they preferred open and full information. Participants also reported differences in their support needs throughout the care process; specifically, the moment of hospital discharge should be more flexible, and patients should be able to have more influence on rehabilitation goals. In addition, while some patients need little guidance in rehabilitation and mostly manage themselves, others want or may need more guidance than currently provided. This need was influenced by post-surgery complications, social connections, and physical fitness. Finally, there is a difference as to how participants value social connection or rapport with care providers.

As shown in previous research,[9,11] the preferences for information provision differed between individual participants. Participants' current statements reveal additional contextual factors such as a patient's previous experience, attitude towards care processes, and social support that determine a patient's information needs. Regarding the hospital discharge, patients in the current study indicate that the presence of social support should be taken into account, as this is known to influence the post-discharge experience for TJA patients,[13,33,34] Patients without a partner/carer at home may need more support, for instance in adapting the home to physical limitations following the operation. The role of a discharge planning mentor was mentioned,[33] and this study emphasises the importance of clearly communicating the presence and role of such a person, if available. Patients' personal rehabilitation goals and expectations need to be managed,[7,34] but the participants in this study also stated that they wanted to influence the goal setting process and that their personal factors needed to be taken into account. Socio-cultural factors are also indicated as important determinants for a successful return to desired physical activities,[13] but in this study, these were only mentioned in the context of guidance and feedback during rehabilitation. The need for more intense feedback and guidance on recommended levels of physical activity has also been mentioned,[33] and this study also notes factors (such as postoperative complications and social connections) that influence this need for guidance.

Implications for Nursing Practice

First, this study points to the limits of a class or generic approach to TJA patient education. Second, beyond the TJA patient subgroups defined in the earlier study (see Background), this follow-up study provides insights into and elaborates on differences in personal preferences that can be used to customise healthcare services. For instance, results suggest that TJA rehabilitation could be specifically adapted to an individual patient's physical activity goals, physical status, and medical history. In general, an individual patient's mindset, social support, physical condition, and medical history should guide the tailoring of services for TJA patients.

In the development of these services, novel information technologies could be useful for organizational optimization and better access to healthcare services.[35] Examples can be found of technology-supported patient education in orthopaedic settings,[36] but the use of technology should be expanded for it to support tailored information provision. For instance, physical activity goals have been mentioned in calls for personalized rehabilitation;[7,13] results from this study can be used to design processes that incorporate these personal differences. Figure 3.4 provides an impression of this process ideated by the first author, based on participants' comments. In the two scenarios, patients and healthcare providers shape the rehabilitation programme together based on a patient's personal wishes, supported by technology. In this light, it was interesting that one participant bought a step tracker to monitor progress independently, suggesting that such devices may be acceptable to at least some current and future TJA patients to support their rehabilitation. Daily step counts have already been suggested as an objective measure in orthopaedic rehabilitation.[37]

Although this study specifically focuses on differences in personal preferences regarding the style of communication and information provision, it should be noted that participants also mentioned care provider behaviours and dispositions that are important for all patients: having an attentive attitude and treating patients kindly; taking patients and their physical complaints seriously; and behaving flexibly and responsively to patients' needs. These aspects are also mentioned as generic components of compassionate care[38] or patient-centred TJA care.[34] Leaving efforts to personalize the patient experience aside, the importance of these generally valued behaviours and the need to improve these should also be stressed.[39]

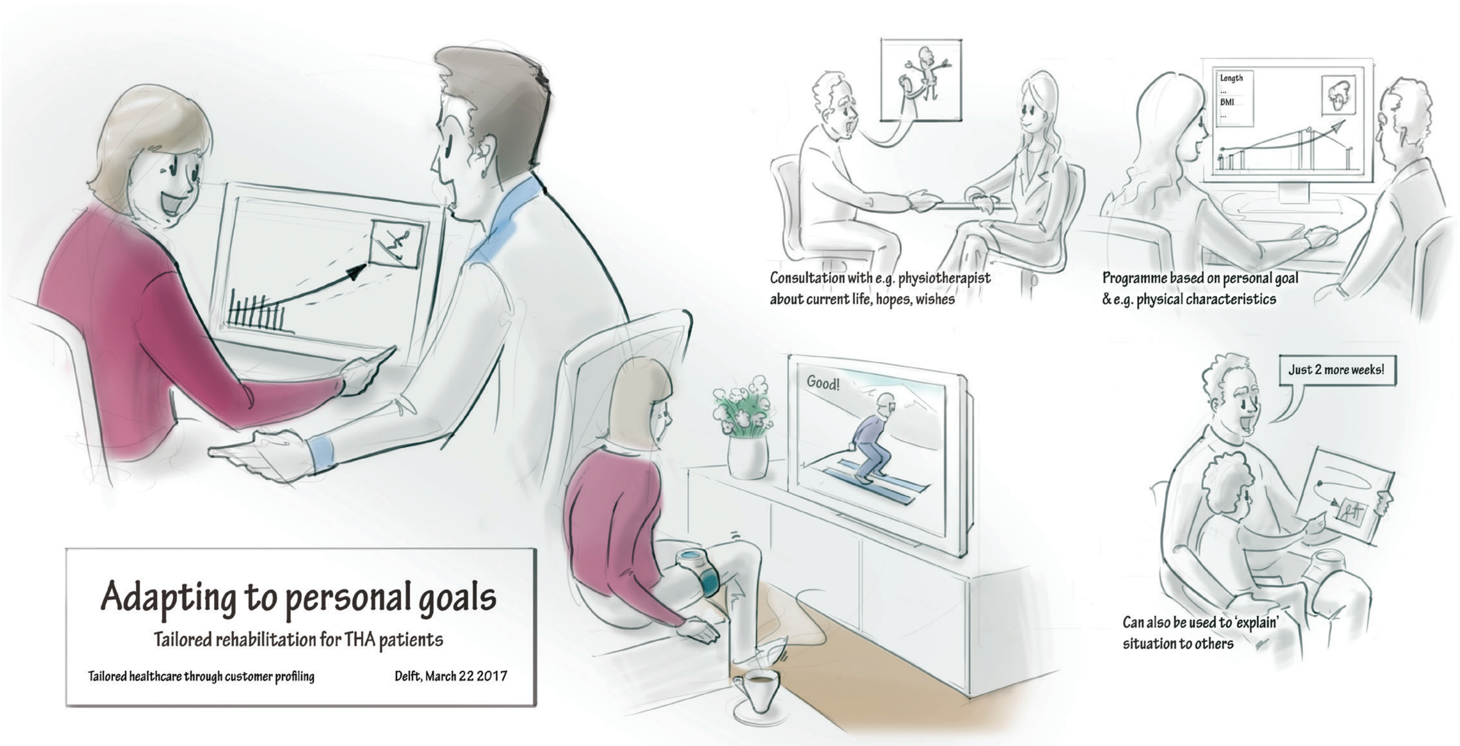

Figure 3.4. Two scenarios for tailored rehabilitation based on adapting to personal goals. Left: A patient has indicated to a physical therapist (PT) that her personal goal is to be able to go skiing again. The PT gives contextualized information based on this goal and at home (bottom), the patient uses a rehabilitation device to do exercises that are contextualized toward the skiing goal. Right: A scenario in which the patient discusses the goal of being able to safely lift his grandchild again. (These scenarios were drawn as a starting point to discuss medical feasibility with healthcare providers, i.e. whether it is safe and reasonable to specify contextualized exercise schemes for individual patients.)

Limitations of This Study and Future Research

First of all, because of the study design we were unable to evaluate patients' experiences over time and while patients were in the process of preparing for surgery or recovery. As for the credibility of the results, data saturation appeared to be achieved; in addition, 12 participants gave feedback on intermediate results and they mostly recognized themselves in the outcomes. However, it remains questionable whether knee and hip replacement patients can be pooled as their preferences and experiences may be too different,[7] although this did not seem to be the case during the group sessions. Most participants in this sample had undergone a THA, so credibility for TKA patients may be limited. A final limitation to the credibility of the findings lies in the possible recall bias of participants.

In addition, it could be that the specific study context limits the transferability of the results. That is, the experiences TJA patients outside the Netherlands (or even the specific study site) may vary because the typical TJA process may be different (e.g. if the hospital stay is longer, or if patients are discharged to a skilled facility more often). The sample of this study appears to be similar to the survey study sample, but a selection bias could have occurred because participation may have been appealing to a specific subset of patients (i.e. those eager to communicate about their experiences). Most participants in this sample also had a similar cultural background (native Dutch), which may limit transferability across cultures. For instance, in other cultural contexts than the one in this study there may be less room in general to adapt the rehabilitation to patients' personal wishes, or to develop a social connection with care providers.

Furthermore, it remains uncertain whether and how implementation of patients' suggestions will improve the patient experience: research and development of services for TJA patients that incorporate the insights from this study and the survey study[15] (Chapter 2) is thus needed. It also remains uncertain whether personal preferences (e.g. for open and full information) are more prominent in certain subgroups (e.g. the first subgroup, displaying strong communication preferences.) This could be further studied.

Finally, this study itself appeared to be beneficial for some participants. In all, at least three participants indicated that talking about their experiences and sharing them with other patients supported emotional closure of the events surrounding their TJA. This is in line with a therapeutic effect of participating in qualitative interviews found in other cases,[40] and further exploration of this effect may be worthwhile.

3.6. Conclusions

In TJA, processes like information provision and communication are key determinants of the patient experience. However, to optimise these aspects of care differences in patients' communication needs and capabilities need to be accounted for. Subgroups of TJA patients similar in their clinical, psychological, and communication characteristics can be used to create targeted information strategies. In addition, this study confirms that personal preferences should also be considered: an individual patient's mindset, social support, physical condition, and medical history should guide the tailoring of services for TJA patients. Beyond these factors, this study also provides patients' suggestions on how these factors could be incorporated into the TJA patient journey, both before and after surgery. These findings can be further validated by developing and evaluating tailored services for TJA patients.

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4. Establishing an initial set of profile-specific guidelines through storyboard evaluations

Chapter 4 presents the results from a storyboard evaluation with patients, in order to define an initial set of profile-specific design guidelines (RQs2 and 3). The storyboards were based on insights from previous design cases, which are shortly described in the introduction of this chapter (see also Foreword). As the chapter aimed to define an initial set of guidelines for the design of tailored services, the Chapter did not specifically focus on tailored communication in the context of patient experience or PCC. However, the realisation of tailored patient experiences and PCC are mentioned as the overall goals of the study.

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Minor adaptations were made to the publication, similar to Chapter 2 (several references to other thesis chapters were included.)

Groeneveld BS, Melles M, Vehmeijer SBW, Mathijssen NMC, Dekkers T, van Dijk L, et al. Tailored Patient Experiences: A Research Through Design Study. In: Bagnara S, Tartaglia R, Albolino S, Alexander T, Fujita Y, editors. *Proceedings of the 20th congress of the International Ergonomics Association*. Cham, Switzerland: Springer International Publishing AG; 2018. p. 198–207.

Abstract

To achieve optimal patient-centered care for people undergoing a Total Hip Arthroplasty (THA), communication should ideally be tailored. In previous studies, three clusters of patients or patient 'profiles' were identified based on communication preferences and clinical and psychological characteristics as a starting point for tailored communication in orthopedics. The current study aims to formulate initial guidelines for the design of tailored communication and information provision based on these profiles. Two design cases were each evaluated as storyboards with twelve patients (three, seven, and two patients of each profile, respectively). Generic and functionality-specific preferences were indicated by participants for both design proposals. Similarities in feedback per profile provided the basis for generating an initial set of profile-specific guidelines, that can be used to design tailored information and communication solutions.

Keywords

Interactions; Communication design, Healthcare, Patient experience

4.1. Introduction

People undergoing a Total Hip Arthroplasty (THA) find communication with healthcare professionals and information provision important.[1,2] To design effective communication support, a holistic, user-centered approach is essential.[3] However, most healthcare products or services that support information provision and communication are designed as one-size-fits-all solutions. Tailored solutions can contribute to patient-centered care,[4] this way enhancing patient engagement and quality of care.[5,6]

As a starting point for developing tailored solutions in hip surgery, previous studies determined clusters of patients who are similar in their needs regarding communication and in their psychological and clinical characteristics. Quantitative data was gathered in a survey (n = 191) and included socio-demographic, psychological, and surgery-related characteristics, as well as communication preferences.[7] This survey resulted in three subgroups or 'profiles' of THA patients: The 'optimistic' profile, the 'managing' profile, and the 'modest' profile. A subset of survey participants was included in subsequent generative research (Chapter 3); in four sessions, 19 patients in total constructed and shared their experiences in the past and hopes for the future.[8] The resulting qualitative insights were aggregated into individual preferences and design leads for information tools.

These insights are expected to be useful for designing products or services that are tailored to each profile. Next step is to investigate how these insights will benefit the design process. Furthermore, differences between individual patients still have to be done justice to in practice.[6,9] Finally, the resulting design should be acceptable for the healthcare professional as well.

This study investigates how patient profiles can be embedded in tailored products or services to support information provision and communication. Two design proposals are evaluated in a narrative way with patients from each patient profile. The insights gathered from these evaluations are summarized as design recommendations or guidelines for each patient profile and design case. In addition, we reflect on the differences and similarities between the guidelines for each design case.

4.2 Methods

In this study, the process of designing and doing user research (using prototypes, gathering data through interviews and observation) is combined in a so-called Research through Design approach.[10] Specifically, knowledge is gathered through creation of design proposals and evaluating these proposals with stakeholders. Two cases were studied: The first design is called BiConnect, which is an information application that supports the communication between patient and physician during consultations. It also aims to help in managing patient expectations of the period after surgery. The second design is a rehabilitation device called BioCoach. This product-service system supports outpatients by providing feedback on rehabilitation exercises at home. Exercise data generated by the BioCoach can also be used to support meetings with e.g. a physiotherapist. These interventions were developed on a generic embodied level in earlier research. An impression of these designs is provided in figure 4.1.

Fig. 4.1. Impression of BiConnect application (left), BioCoach application and leg band (right).

Further elaboration of both designs is done in an iterative process, where insights from user testing and evaluation are used to improve preliminary designs.[11] Prototype testing is key in this process. In the early stages of the design process such prototypes can be storyboards depicting interaction or use; many insights about patient preferences can be gathered through narrative evaluation of such storyboards.[12] This study focuses on storyboard evaluation of both design proposals.

Participants

Storyboards of both designs were evaluated with twelve THA patients, with multiple patients from each profile. Which profile a patient belonged to was determined using a survey developed in earlier research. Participants were selected deliberately to have as much variation in profiles as possible. Three patients were classified as having an 'optimistic' profile, seven patients as having a 'managing' profile, and two patients as having a 'modest' profile. Eleven of these patients participated in the survey and generative research described above; one additional patient was recruited as part of a graduation student's research project (student Lisanne van Dijk). This participant's surgery had taken place seven weeks ago, whereas all other participants had had their surgery at least six months ago. Five participants were male, average participant age was estimated at around 75 years.

Storyboards

The two designs were elaborated as storyboards depicting interaction and possible functionalities of the two design proposals.

BiConnect proposal

This design was adopted in a paper version as a booklet for patients, that informs the patients and can be used to keep track of his or her rehabilitation experiences. This booklet is adjusted based on survey responses to suit his/her preferences. (These adaptations are not yet specified in this scenario.) The following functionalities were incorporated into the booklet and evaluated:

1. A timeline to be used in consultations before surgery, aimed at aligning patient expectations.
2. Weekly information in the booklet (possibly augmented with online information) that the patient receives about his recovery after surgery, to align information provision with needs arising over time and to emphasize that recovery takes time
3. A log book to fill in during the first weeks after surgery, and the option to discuss this with a healthcare provider (e.g. physiotherapist). This is aimed at monitoring a patient's progress, and reassuring the patient that rehabilitation takes time and there's often no need to worry about this.

Figure 4.2. Storyboard for BiConnect proposal: A patient receiving a booklet (top left); using a timeline in consultation with a healthcare provider aimed to align expectations and answer questions (top right); examining information and filling in a log book in the first weeks after surgery (bottom left); and discussing log book insights with a healthcare provider (e.g. physiotherapist, bottom right)

BioCoach proposal

The storyboard developed for the second product focused on four different functionalities that the BioCoach fulfils:

1. Tracking and mapping exercise activity, aimed at promoting an optimal amount of exercises over time and to record activity progress
2. A dial on the product to indicate pain during or after exercises, including feedback (e.g. ‘is this pain level normal’); this function could support pain management
3. Opportunity for digital communication with peers or caregivers, aimed at discussing personal situation, progression and needs, and at providing motivation during rehabilitation.
4. Motivational feedback based on exercise patterns, to reinforce training behaviour and provide reassurance.

Figures 4.2 and 4.3 show the visuals that were used for the BiConnect and BioCoach scenarios respectively.

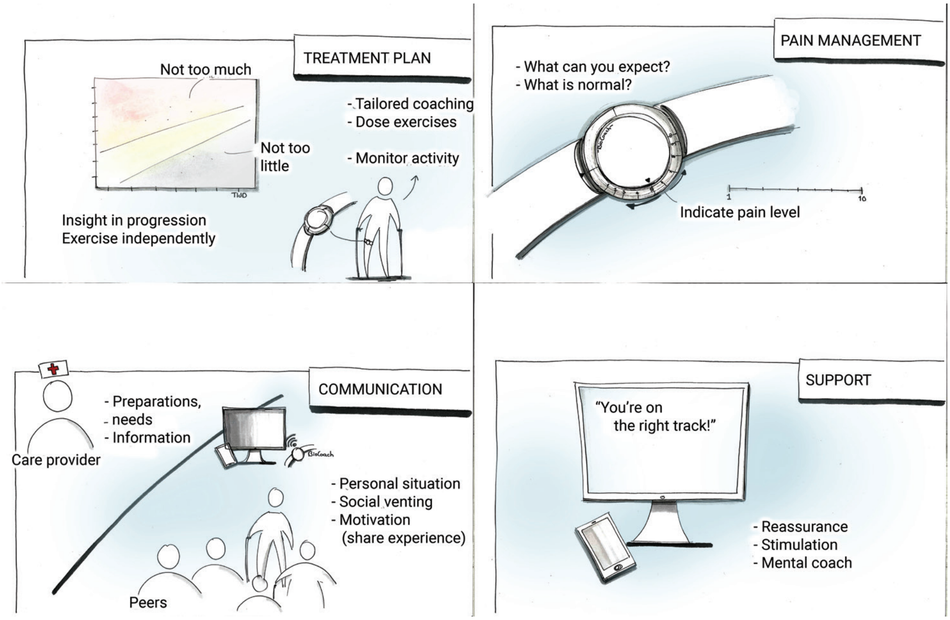

Figure 4.3. Storyboard for the BioCoach proposal: Tracking and mapping exercise activity (top left), a dial on the product to indicate pain during or after exercises, including feedback (top right), opportunity for digital communication peers or caregivers (bottom left), motivational feedback based on exercise patterns (bottom right; text replaced for legibility)

Both storyboards included several visuals to introduce context and the general idea behind both designs. A general 'THA patient journey' was also shown, in which these scenarios were contextualized. This overview served as an articulation of the researchers' assumptions and knowledge of the THA process, and as a starting point for conversation with the participant.

Procedure

Each scenario was introduced and shown to the participants, with a short explanation per slide; the BiConnect scenario was always shown first as this product was introduced earlier in the patient journey. In the BiConnect case, the entire scenario was shown first and then questions were asked to the participant. In the BioCoach case, several questions were asked after presenting each individual functionality. Questions included: "What is your overall impression of this product proposal/function? What do you think of [specific functionality] in this proposal? How would you like to use [specific function] in this proposal? How could we further adapt this proposal to your needs and preferences?" Participants could freely discuss any comments on the scenarios and other associations they had that were relevant to the presented materials. Figure 4.3 presents an impression of the evaluations.

Fig. 4.3. An impression of the scenario evaluations. On the right, a participant was joined by her neighbour who travelled together with her to the session.

Data analysis

A general inductive approach was used to analyse the data. For the BiConnect or patient booklet scenario, answers of each patient were digitalized in a table. Participant answers were grouped based on the three profiles and specific functions or generic preferences for e.g. communication style throughout the booklet. These aggregations were summarized into preliminary guidelines, and similarities and differences were compared between the profiles. For the BioCoach proposal, notes were digitalized and structured based on the four functionalities proposed (see also Fig. 4.2) as well as generic preferences and other comments. Detailed responses can be requested at the corresponding author.

4.3. Results

Overall, the conversations were experienced as vivid and rich. Participants seemed to enjoy the opportunity to provide feedback on the design proposals, and in most cases would like to use either (part of) one or both designs in future care. Tables 4.1 and 4.2 outline design guidelines based on user feedback for each product, functionality and profile.

Table 4.1. Generic and function-specific guidelines for each patient profile for the BiConnect proposal, based on participant feedback.

BiConnect aspect or function	Optimistic profile (n = 3)	Managing profile (n = 7)	Modest profile (n = 2)
Generic style or tone of communication in booklet	Use positive, but strict tone (e.g. 'You have to …, or else …'; 'keep going!'); Complement text with small visuals	Use upbeat, positive tone; emphasize positive stories; use cheerful visual style; emphasize that information is up-to-date	Include simple, straightforward information and humorous elements; Emphasize affective dimension of care & patient experience
Function 1: Timeline	Include recovery scheme for comparison: 'Am I on track'	Emphasize that recovery takes time; Avoid potentially irrelevant information	(Apply adaptations based on generic guidelines above)
Function 2: Weekly information	Encourage patient to ask questions when needed	Include pain management information (e.g. on medication)	Include stories of comparable patients
Function 3: Log book	Facilitate that patient can see his/her progression over several weeks	Include checklists for e.g. arranging transfer to home; Include open fields to write down experiences; Facilitate that patient can see his/her progression over several weeks	Use short questions/answers (e.g. more box-ticking or indications on scale)

Overarching Guidelines for Tailored Communication Tools

Generic and function-specific preferences were indicated by participants for both, leading to guidelines for communication tools tailored to the patient profiles; managing, optimist and modest. Several similarities were observed between the feedback of the three patient groups on both design proposals. These overarching guidelines are described below.

Table 4.2. Generic and function-specific guidelines for each patient profile for the BioCoach proposal, based on participant feedback. Text (in brackets) indicates low preference for the given functionality.

BioCoach aspect or function	Optimistic profile (n = 3)	Managing profile (n = 7)	Modest profile (n = 2)
Information level	Provide right amount of information, no overload; realistic view on recovery	Provide friendly formulated, sufficient information to be well-prepared	Provide clear, accessible information: Simple language and guidance.
Interaction qualities	Realistic, practical, positive	Controlled, trustworthy, friendly	Simple, consistent, guiding, empathic
Function 1: Tracking and mapping exercise activity	Create insight in progression: Motivate or slow down patient	Create possibility to exercise independently of others; give insight into treatment plan; also motivating or slowing down (similar to profile 1)	Give insight in progression, positive feedback
Function 2: Pain dial on product	(Give pain information when needed)	Provide information on medication. (Prepare for pain experience, showing what is 'normal')	Give advice about medication use. Prepare patient for pain experience.
Function 3: Opportunity for digital communication with peers or caregivers	(Facilitate peer contact)	Facilitate contact with one specific care provider when needed	Provide option to digitize advice of care provider, to see it again. (Peer experience sharing)
Function 4: Motivational feedback based on exercise patterns	(Use function 1 for reassurance and support; positive comparison with others may help. May also help with acceptance.)	Give confirmation and reassurance. Show positive stories to make rehabilitation more pleasant. (Send messages to limit uncertainty)	Provide support, security, limit feelings of anxiety. Show a face or positive visual icons during contact.

The 'Optimistic' Profile

For the 'optimistic' profile, participants would like products or services to feel positive, but realistic or at times strict in terms of information provision or interaction. Also, participants liked to gain insight into their rehabilitation process, and if possible the reassurance that they were 'on track'. In the design cases, if patients have the insight that they are doing well, they may simply require little further support.

The 'Managing' Profile

A friendly or upbeat interaction was preferred, but it also seemed that participants wanted accurate and up-to-date or trustworthy information. In this managing group, there seemed to be a slightly higher need to be clearly told that rehabilitation takes time; insight in the treatment plan might help to meet this need. Furthermore, for both design proposals patients indicated that they would like to have specific information when they need it; for instance when they experience high pain, have no spouse at home, or when they have specific questions for a care provider. It seems that these participants want to have initiative to determine which information they acquire, and when they do so.

The 'Modest' Profile

Finally, participants with characteristics from the 'modest' profile were also similar in their preferences for both design proposals. They preferred accessible information. The need to be taken seriously (proposal 1) and the need for guidance in rehabilitation (proposal 2) were also seen as similar, reflecting perhaps a need to be able to rely on care providers and to have them close-by.

4.4. Discussion

This study aimed to formulate initial guidelines for the design of tailored communication and information provision solutions in Total Hip Arthroplasty (THA) rehabilitation based on three patient profiles. Two design cases were evaluated as story-boards with twelve patients that, based on earlier research, could be grouped into three different profiles (three, seven, and two patients of each profile, respectively). Generic and function-specific preferences were indicated by participants for both design proposals; This lead to a preliminary set of generic guidelines for the development of communication products and services that fit the preferences of the different patient profiles.

Several similarities can be observed between the feedback of the three patient groups and earlier research.[7] (See also Chapters 1 and 2.) For the ‘optimistic’ profile, findings seem to align with low reported feelings of anxiety and perhaps little need for coping in general, as they already seem quite satisfied with care. Patients in the ‘managing’ profile appear to have high communication abilities and needs, and they experience more pain and higher anxiety; this seems to be in line with the initiative and insights they seem to desire in both design proposals. Finally, participants with characteristics from the ‘modest’ profile stressed the need for accessible information which can be related to relatively lower education levels. Both the need to be taken seriously (proposal 1) and the need for guidance in rehabilitation (proposal 2) can be seen as reflections of their relatively high anxiety, and the related higher need for emotional support by healthcare providers. This might also explain why they preferred the pain management function in the BioCoach to prepare them for the experienced pain after surgery, and why they would like to receive positive feedback in this design (functions 1 and 4) as well.

Limitations and Further Work

Whereas it was possible to formulate design guidelines for the three patient profiles find similarities between the two proposals for each profile, this study has several limitations. First, sample sizes of individual profiles were small, especially for the ‘modest’ profile with only two participants interviewed. This was a formative user evaluation in which insights collected are part of a design process so there is no formal requirement for sample sizes, but it is suggested to involve around five participants from a homogenous group in such studies.[12(p92)] Furthermore, it is uncertain whether these guidelines lead to design proposals that patients from each profile actually prefer. This will be evaluated in future research through user research with working prototypes.

4.5. Conclusion

In healthcare, one-size-fits-all communication is not necessary. But the wheel can’t be reinvented for every single patient as well. This study suggests design guidelines for three different THA patient profiles, to adjust information products to differences between patients meaningfully. This will contribute to tailoring communication in healthcare, which should be beneficial for patients and the healthcare system alike.

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5. Expanding the profile-specific guidelines and general recommendations: Development and evaluation of paper-based prototypes

Chapter 5 aimed to expand and validate the guidelines of Chapter 4 and to provide general recommendations and considerations for developing tailored information tools (RQs 2 and 3). It provides a detailed account of the development and evaluation of a set of paper prototypes, for and with patients from each profile. The protocol for this study was described in Chapter 2, but a short version was included in the introduction and methods section of Chapter 5 for readability and publication purposes. As stated in Chapter 2, this study focused on tailored services (or specifically, information tools) in the context of PCC. The profile-specific guidelines presented in Chapter 5 provided further guidance for the next design iteration, described in Chapter 6.

The Chapter has been submitted.

Abstract

Objective: In previous research, three profiles of total hip arthroplasty (THA) patients were identified based on similarities in clinical, psychological, and communication characteristics. This study investigated the use of these profiles in a tailored information tool, which is expected to contribute to patient-centered care and communication (PCC).

Methods: This study used a Research through Design (RtD) approach, generating insights from the development and evaluation of prototypes. Paper-based prototypes were developed for each profile, including features for expectations management and self-monitoring. Semi-structured interviews with participants explored their experiences with the prototypes. To validate these findings, consultations with and without prototype were videotaped and compared using a structured instrument.

Results: In the design process, variations in content and framing for each profile were realized to a limited extent. Beyond this point, patient feedback was needed.

The evaluation revealed profile-related differences in preferences: The optimistic profile recommended positive, but strict information and checklists; the managing profile preferred a Q&A format for information and detailed recommendations on pain and activity levels; and the modest profile wanted stories from other patients and more room for writing down experiences. The impact of the prototypes on PCC during post-surgery consultations was most likely absent.

Conclusions: In the early stages of developing tailored information tools based on patient profiles, it is complicated to define relevant functions for tailoring and develop profile-specific variations of these functions. The profile-specific guidelines in this study can guide future design iterations. In general low-fidelity prototypes and several early iterations are recommended.

Keywords

Patient engagement, patient education, prototype evaluation, design knowledge, mixed-methods study

5.1. Introduction

People Patient-centered care and communication (PCC) is a key quality indicator of healthcare that positively impacts patient satisfaction,[1,2] health outcomes,[1] and efficiency of care.[1,3] PCC entails that healthcare providers see the patient as a person with his or her own characteristics and needs, and actively seek to surface the patient's perspective.[4] For healthcare institutions, PCC has also been mentioned as a source of competitive advantage.[1,2,5]

The current study reports on the design and evaluation of an information tool that aims to promote PCC for people that receive a Total Hip Arthroplasty (THA). The background and methodology of this study were detailed in Chapter 2; a summary will be provided below.

THA patients find communication and information provision of particular importance,[6,7] because THA is a conscious and carefully planned choice associated with certain expectations and fulfilment of these expectations after surgery. To successfully manage patient expectations adopting PCC is essential.[8] However, for PCC to be effective care providers need to take into account differences in patients' needs and abilities.[2] In other words, there is a need for tailored communication and information tools in THA.

To guide tailored communication in THA, a sample of patients was divided into profiles that have similar clinical, psychological, and communication characteristics.[9] In a survey study (n = 191) three subgroups or 'profiles' of patients were defined:

1. An 'optimistic' profile that needed few active coping strategies, and did not find patient-provider communication of particular importance. These individuals had good preoperative clinical status and quality of life.
2. A 'managing' profile formed by individuals that reported many different coping styles as well as strong communication preferences. This group showed a poor preoperative clinical status.
3. A 'modest' profile that had a higher age and anxiety compared to the other profiles, reporting distinctive coping behavior (e.g. coping through spirituality) and lower competence as well as self-efficacy in their health communication. The preoperative clinical status of this group was similar to the managing profile.

These data-driven patient profiles are starting points for the development of tools that support tailored communication and information provision in THA. Fig. 5.1 presents a framework for such tailored information tools in THA using the patient profiles as part of the tailoring process. The mechanisms of segmentation and customization form the basis of this framework; these are argued by Hawkins et al.[10] to form the main components of computer-tailored information. For example, a digital questionnaire can be used to assign a patient to a profile and adapt information in the application according their communication preferences and other relevant characteristics. That is, information that is similar in content may be differently labelled, presented, or structured for each profile. Next to this, self-tracking options such as diaries or daily step count monitoring can be offered to provide patient-specific, customized, feedback on recovery. As Fig. 5.1 shows, a digital tool that contains these functions uses the questionnaire to achieve segmentation, and self-tracking options to realize customization.

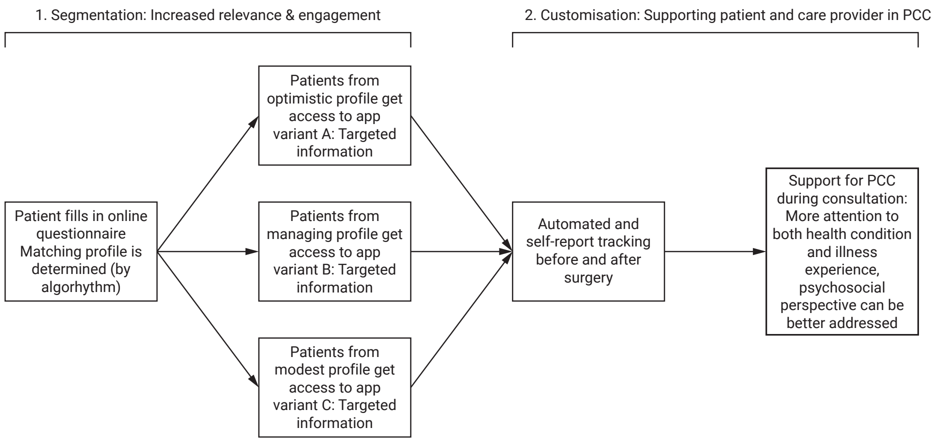


Figure 5.1. Framework for tailored information tools in THA, adapted from study protocol.[11]

The profiles and tailoring framework in Fig. 5.1 provide a starting point for realizing tailored information tools in THA. However, it is still unclear how surgery-related information should be adapted to characteristics and preferences of each profile. It is expected that profile-specific guidelines are appropriate, and these were broadly formulated in previous research[12] (Chapter 4) but still require further validation. The use of profiles as a segmentation strategy in realizing tailored communication for THA is also novel in itself: A review of existing tailored tools for THA patients revealed that there are few examples in general, and none make use of the concepts of segmentation and customization.[13] (See also paragraph 1.4.) So the process of developing tailored tools using data-driven patient profiles may lead to new insights, questions, and issues regarding computer-tailored communication in THA.[14] These generic recommendations and considerations, as well as profile-specific guidelines, will support the design and development of tailored tools that positively impact PCC.

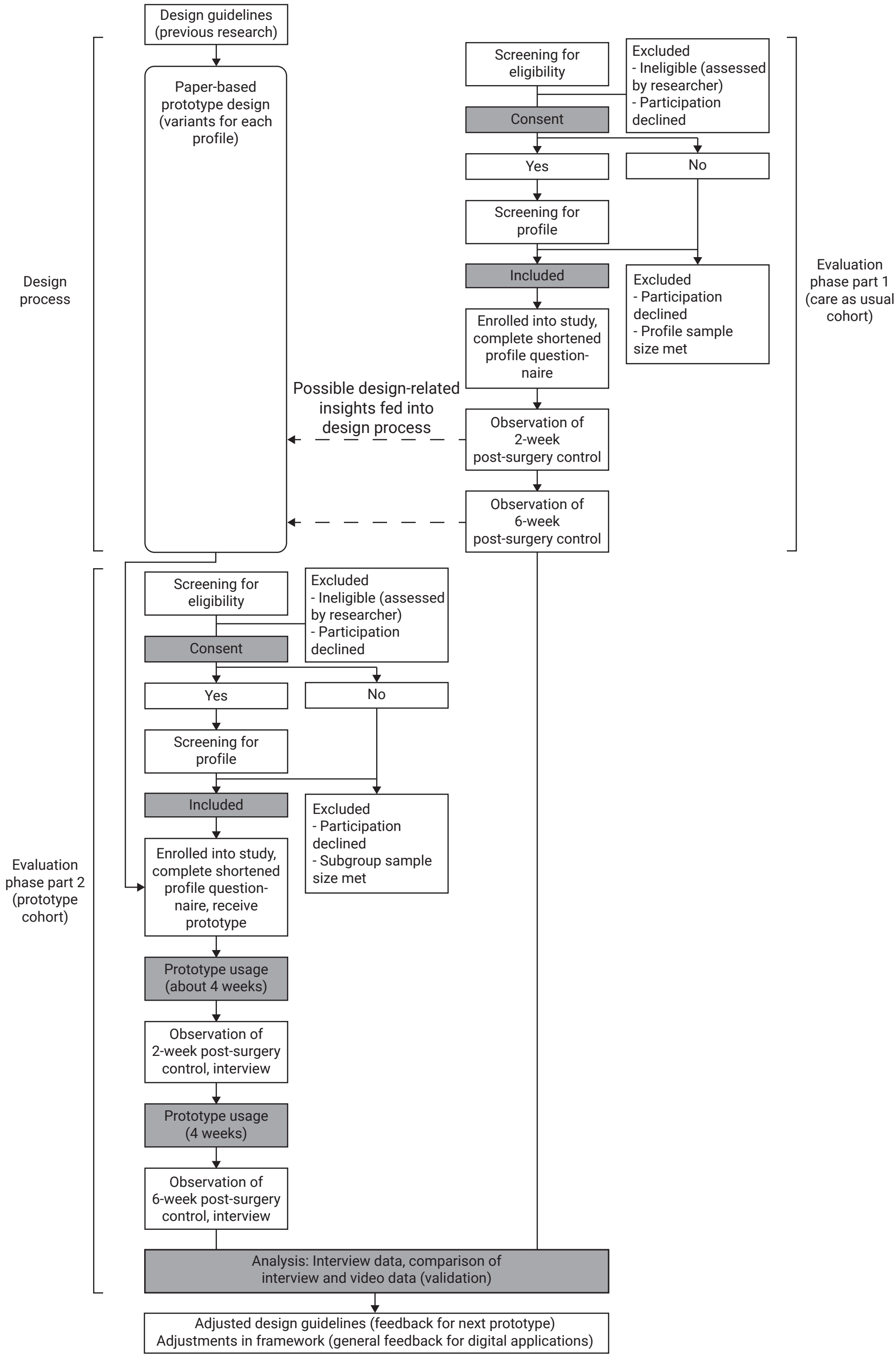
This study aims 1) to validate and expand profile-specific guidelines for three profiles of THA patients (i.e. optimistic, managing, and modest profiles), and 2) formulate general recommendations and considerations for designing tailored information tools for THA patients using these profiles and guidelines.

This study used a Research through Design (RtD) approach. In RtD knowledge is generated through the process of developing prototypes as well as evaluating these prototypes with users.[14] Insights that emerge during prototype development (i.e. the design process) are, next to the evaluation results, explicitly considered as results as well. (Details of the approach, including a more elaborate description of the theoretical background and methodological considerations, are provided in Chapter 2.)

5.2. Methods

This study consisted of two parts: a design process and a user evaluation of the set of prototypes. Fig. 5.2 shows the study flow diagram illustrating both parts and the different activities within each part. First, features were defined and incorporated in profile-specific versions in three prototypes variants. Next, the acceptance of the prototypes as well as their impact on Patient-Centered Communication during post-surgery consultations was evaluated. From earlier user evaluations, appropriate functionalities and components were broadly determined.[12] In this early stage of our (digital) product and service design process, prototypes were paper-based, which is common in advance of the implementation of software.[15(p92)]

The Medical Research Ethics Committee (MREC) of the province of South Holland, the Netherlands, waived ethical approval of this study. On 3 January 2018, the committee ruled that the Dutch law concerning research involving human beings (Dutch abbreviation WMO) does not apply to this protocol (file 17 – 146). All participants provided written informed consent.



Design guidelines (previous research)
Paper-based prototype design (variants for each profile)
Design process
Screening for eligibility
Excluded - Ineligible (assessed by researcher) - Participation declined
Consent
Yes
No
Screening for profile
Included
Excluded - Participation declined - Profile sample size met
Enrolled into study, complete shortened profile question-naire
Possible design-related insights fed into design process
Observation of 2-week post-surgery control
Observation of 6-week post-surgery control
Evaluation phase part 1 (care as usual cohort)
Screening for eligibility
Excluded - Ineligible (assessed by researcher) - Participation declined
Consent
Yes
No
Screening for profile
Included
Excluded - Participation declined - Subgroup sample size met
Enrolled into study, complete shortened profile question-naire, receive prototype
Prototype usage (about 4 weeks)
Observation of 2-week post-surgery control, interview
Prototype usage (4 weeks)
Observation of 6-week post-surgery control, interview
Evaluation phase part 2 (prototype cohort)
Analysis: Interview data, comparison of interview and video data (validation)
Adjusted design guidelines (feedback for next prototype)
Adjustments in framework (general feedback for digital applications)

Figure 5.2. (Left) Study flow diagram, adapted from study protocol (Chapter 2). A paper-based prototype of an information application was created in three variants during the design phase. To evaluate these prototypes, THA patients were given the prototypes throughout the intended period of use. Validation of qualitative insights was done through triangulation, using a quasi-experiment with a non-random control cohort. The control cohort ran simultaneously to the design phase (see Chapter 2 for the rationale for this).

Design process

The design process was executed between February and June 2018. In this part a User-Centered Design (UCD) process was adopted, which entailed that needs and characteristics of end-users were considered throughout the product development process, and that the envisioned users were actively involved in each stage.[16,17] Based on previous research,[12] (Chapter 4) the paper-based prototypes contained three main features related to THA information provision, intended to be used both before and the first weeks after surgery: A timeline, weekly information after surgery, and weekly questions and/or checklists after surgery. These features were incorporated to manage patient expectations and allow self-monitoring; this was expected to support PCC during post-surgery consultations as patients would be better prepared to share their rehabilitation experience. Table 5.1 lists the features of the prototypes as well as intended effect of each feature. For example, weekly information after surgery (Table 5.1, feature 2) was incorporated to manage patient expectations after surgery and provide timely guidance. Fig. 5.3 provides an impression of the paper-based prototypes (optimistic variant, features 2 and 3).

The design process was captured in a structured diary: this diary contained an entry for each day that design activities were carried out, and each entry consisted of a summary of the decisions taken and dilemmas or challenges faced in the design activities, if any.[18]

Evaluation

To evaluate the prototypes for acceptance and feasibility, THA patients were given the prototypes throughout the intended period of use (around 9 weeks). The goal was to recruit at least 5 patients from each of the three profiles evaluate a corresponding prototype variant. Participants completed a questionnaire to assign a profile to each patient.

Table 5.1. Summary of prototype features, including an explanation and the intended effect. Each prototype contained a variant of each feature, corresponding to each profile.

Prototype feature	Feature explanation	Intended effect
1) Timeline that depicts preparations for and recovery after surgery.	The timeline can be discussed by patient and care provider before surgery.	Answer patient's specific questions; Management of patient expectations before surgery.
2) Weekly information for the first six weeks after surgery.	Relevant information is offered by the prototype each week, e.g. regarding rehabilitation and patients' frequently experienced uncertainties.	Manage patient expectations after surgery; provide appropriately timed, relevant information.
3) Weekly questions and/or checklists for the first six weeks after surgery.	Using the questions and prompts, a patient can record and track his progress and experiences throughout the initial recovery period.	Support a patient in self-monitoring and reflection; create insight into a patient's recovery over time.

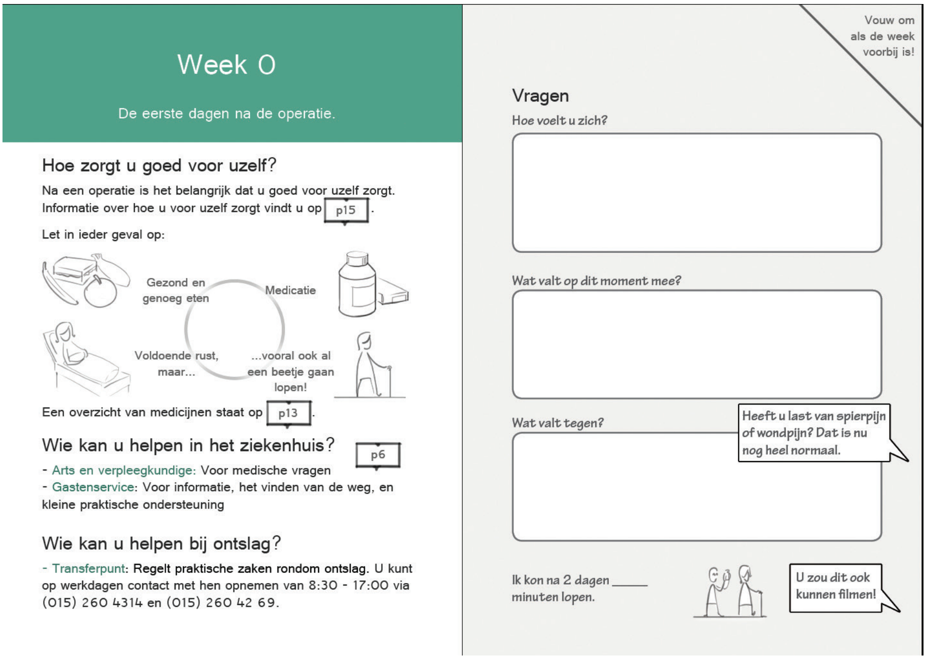


Figure 5.3. Impression of paper-based prototype (booklet): Weekly information (left; Table 5.1, feature 2) and weekly questions (right; Table 5.1, feature 3). The prototype contained information and questions for each week during the first six weeks after surgery.

For the evaluation phase a partially mixed concurrent design was used.[19] That is, semi-structured interviews with patients resulted in the main source of (qualitative) data. The interviews took place after the consultations in week 2 and week 6 post-surgery. Explored themes included the user experience and perceived impact of using the prototype on post-surgery consultations.[20]

Validation of this perceived impact was done by triangulating the qualitative data[21] in a quasi-experiment with a non-random control cohort: Prototype users' post-surgery consultations were video recorded and quantitatively compared to video recordings of a control group. A structured instrument[4] was used to classify care providers' behaviors that were facilitating or inhibiting the patient perspective, which is argued to be one of the pillars of PCC.[22] To estimate the interrater agreement of this sample, a second rater classified behaviors of a random 10 percent of data. The Kappa Statistic was used to determine interrater agreement,[23] using a weighted average that accounted for the duration of each consultation. Descriptive statistics were used to explore differences in rates of facilitating and inhibiting behaviors between groups.[24] (Profiles were pooled for this purpose.)

Further explanation of the rationale, data gathering methods, and data analysis is provided in the expanded protocol.[11] (See also Chapter 2.)

5.3. Results

First, the main insights from the design process are described, followed by results from the evaluation of the prototypes.

Design process

The first author carried out the design process, occasionally supported by the co-authors and other members of the project group. Throughout this results section, references are made to entries into the design diary that was used as source material for this phase. These references are indicated as (entry x).

First, the design and prototype was developed for the optimistic profile. Starting from this prototype adaptations were made to accommodate to the characteristics of the managing and modest profiles (entry 2). This was decided when the first prototype variant was finished: Each prototype needed the same set of features but in different variants, and it was most straightforward to make variations in the existing materials rather than designing new content from scratch. There were also no grounds at this point to assume that this was necessary.

The content of prototypes was determined using existing information materials (i.e. brochures) from the study site. Input on the framing of the information came from feedback on earlier prototypes (i.e. storyboards) that were evaluated with patients in a previous research round,[12] (Chapter 4) as well as summaries of characteristics of the patient profiles (similar to the descriptions in the introduction).[11] Several specific additions were made based on demographic data of the patient profiles, as well as specific observations in the control cohort. For example, most patients in the modest profile were retired, so information on returning to work after surgery was omitted from their prototype variant (entry 1). Table 5.2 summarizes design adaptations for each prototype listed by feature. Considerations for each feature are discussed in detail below. Figures 5.4 and 5.5 provide an impression of design variants for features 2 and 3.

Table 5.2. Summary of design adaptations for each prototype variant.

Prototype feature	Design adaptations		
	'Optimistic' variant	'Managing' variant	'Modest' variant
1) Timeline	Neutral visualization of process after surgery	Neutral visualization of process after surgery	Visualization of process after surgery including patients' thoughts and feelings
	Simplified clinical recovery patterns	Detailed clinical recovery patterns	Recovery patterns omitted
	Open questions on specific topics as well as room for other questions	Open questions on specific topics as well as room for other questions	Check-box questions and suggested themes for discussion with care providers
	(No additional prompts)	Additional prompt to call hospital in case of questions	Additional prompt to call hospital in case of questions

(Table 5.2. Cont'd)

Prototype feature	Design adaptations		
	'Optimistic' variant	**'Managing' variant**	**'Modest' variant**
2) a. Weekly information: Framing	Positive tone	Friendly, positive communication style	Information framed as story from a fellow patient
	Strict tone ("You should …, or else")	Focus on what patients can do instead of what they should do	(no specific adaptations on this level)
	Text complemented with small visuals	Text complemented with small visuals	Prominent illustration of a fictional patient included for each week
2) b. Weekly information: Content	(No specific information added or omitted for this group)	Additional information about pain and pain medication	Information regarding return to work omitted
3) Weekly questions and/or checklists	Open spaces for writing down experiences	Open spaces for writing down experiences	Short questions and tick-box answers; limited space for making notes
	Limited amount of checklists	A checklist every week (e.g. for current abilities and arrangements at home)	Limited amount of checklists
	Occasional advice	Occasional advice	Occasional advice
	Encouragement to take multiple photos or videos over time to record progress	Encouragement to take multiple photos or videos over time to record progress	Encouragement to take multiple photos or videos over time to record progress

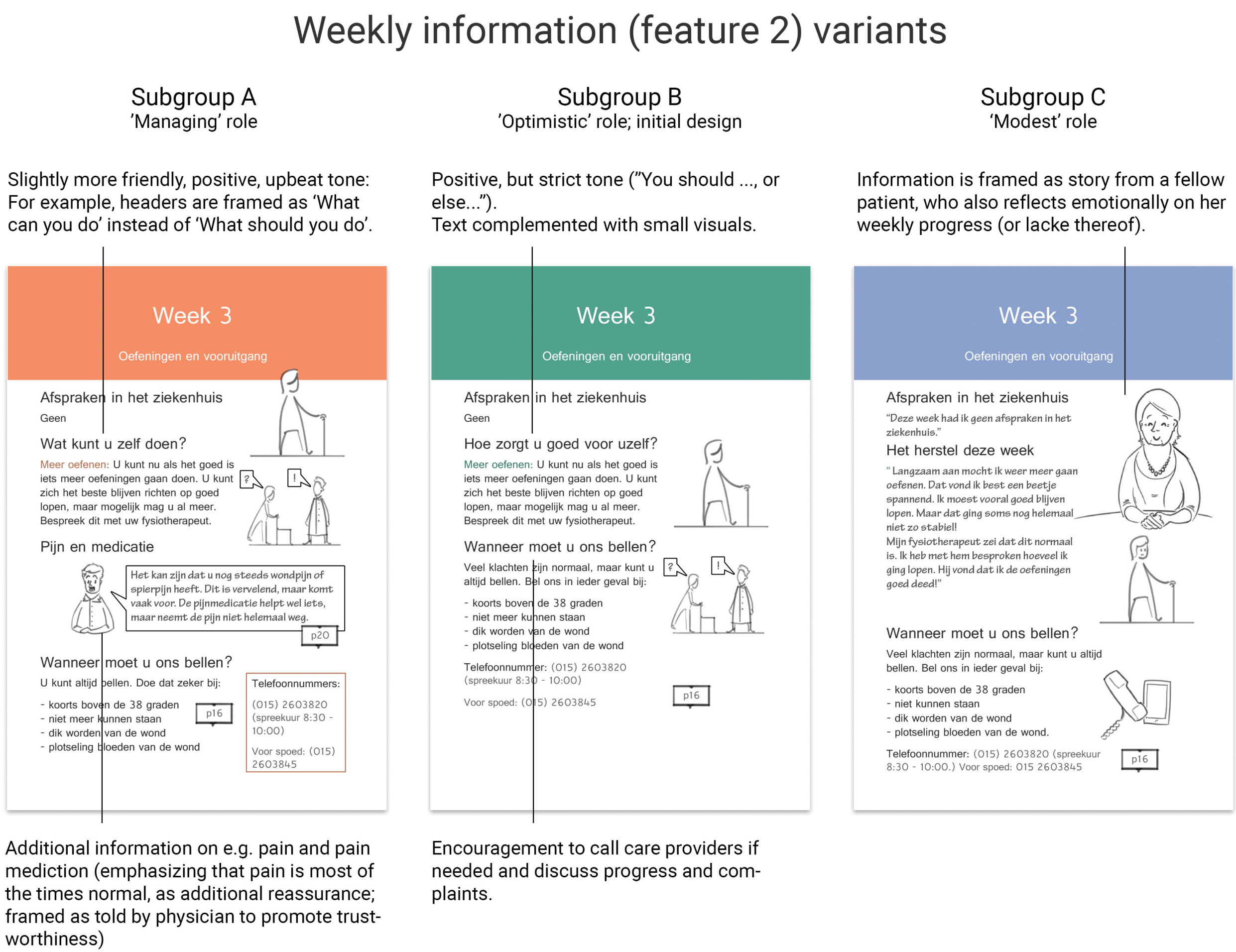


Figure 5.4. Impression specific design variants of feature 2, with explanations of adaptations for each subgroup.

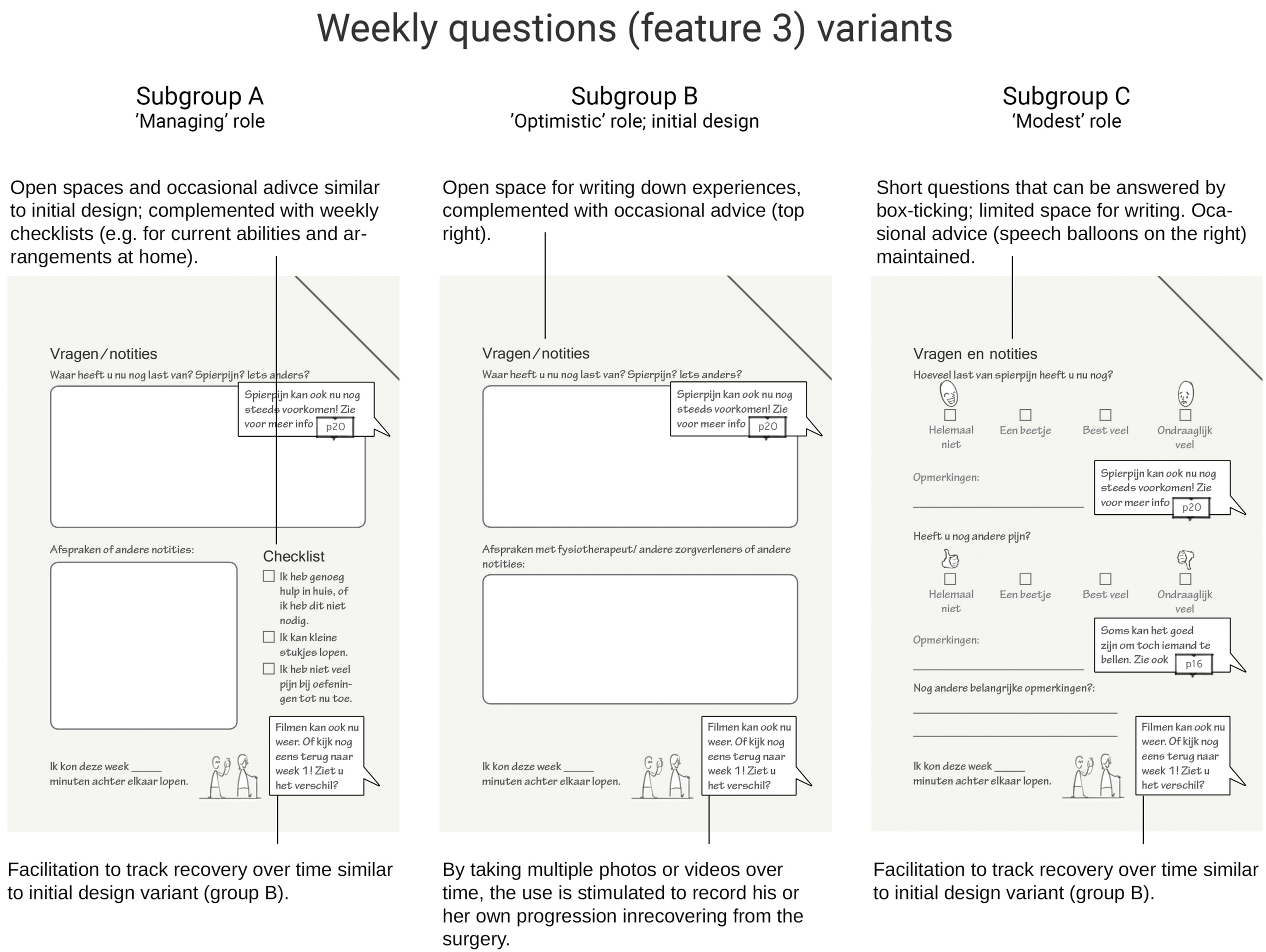


Figure 5.5. Impression specific design variants of feature 3, with explanations of adaptations for each subgroup.

Features: development and design choices

Timeline

Starting from the timeline for the Optimistic profile, the timeline was simplified for the Modest profile, and made more specific for the Managing profile. The most important addition for the managing profile was to specify recovery patterns directly from research data, rather than indicating recovery in a simplified way as was done for the optimistic profile. For the modest profile, the recovery lines were omitted as a whole.

For the managing and modest profiles, a prompt was added to have them call the hospital in case of questions about the prototype in general or about specific topics. It was assumed that patients in these profiles may have a specific need for direct contact with a care provider, either because of anxiety over symptoms (in the modest profile), or because of need for control (in the managing profile) (entries 14, 15). In addition, several ideas were considered to vary the questions below the timelines for each profile, but there was insufficient information to make considerable changes for the managing profile (entry 15). The themes of the questions were also kept the same for the modest profile, but they were presented as check-box questions with more guidance.

Weekly information: Framing

For the functionality of the weekly information, the prototype variant for the modest profile differed most from the other two. For this profile the information was framed as a story from a fellow patient (entry 7). Eventually, this fictional character was also given a specific name (entry 12). There was uncertainty about the acceptability and persuasiveness of this framing to patients in the modest profile (entry 6). Thus, it was concluded that this could only be established through feedback of patients in this profile (entry 7).

Between the managing and optimistic variants, the information framing (or tone of communication) was made only slightly different. The tone in the prototype for the managing profile was made less strict and more positive: for example, the weekly headers for this profile were changed from ‘what do I have to do’ (in the original prototype for the optimistic profile) to 'what can I do' (entry 12). There were also more sentences added like ‘everything will be all right!’ in the ‘managing’ variant, contrasting to the more strict, neutral directives in the ‘optimistic’ variant (entry 13).[12] (See also Chapter 4.)

Weekly information: Content

Beyond the adaptations in the information framing for each profile, several adaptations on the content were also made based on demographic data from profiles (based on survey results). For instance, only ten percent of the people in the modest profile were not retired yet. Information regarding return to work was therefore removed from the prototype for the modest profile, and replaced with more information on patient experiences and advice from healthcare providers (entry 7). It was also tried to use demographics or other specific group data to make content adaptations for the managing group, but this information turned out to be too specific to justify content-related changes (entry 10). It seemed that the actual content of the information for the optimistic profile also matched the needs and characteristics of the managing profile (entry 11).

Weekly questions

Based on feedback of orthopedic consultants on a preliminary version, it was first decided for all variants to have patients shortlist their questions for post-surgery consultations. This was meant to focus the information needs of patients, as the healthcare providers feared that some patients would want to discuss all the questions and answers in the prototype (entry 1).

Additionally, patients in the managing profile received more checklists in the prototype as it was assumed that patients in this profile had a higher need for control and overview (entry 10). For the modest profile, more guidance in questions was assumed to be needed as patients had indicated previously that they wanted a simple way to enter information (e.g. tick boxes or only indicate a 'thumbs up').[12] (See also Chapter 4.) To this end, over time it was decided to replace the open fill-in fields mostly with semantic differentials (entry 12). This was assumed to be easier to fill in than open fields for this group. Visual elements were added to the scales to make the scales more understandable (entry 14).

Evaluation of the prototypes

In total, 34 participants took part in the evaluation of the prototypes. Table 5.3 provides an overview of participants' background characteristics for both cohorts. It was originally intended to also interview care providers in the evaluation phase.[11] However, it turned out that patients did not actively use the prototypes during the consultations. As such, care providers were unable to reflect on the use of the prototype during consultations and were left out from the evaluation.

Table 5.3. Participants' background characteristics.

Characteristic	Control cohort n or MEAN ± SD (range)	Prototype cohort n or MEAN ± SD (range)
Participants	18	16
Sex: Male	11 (61% of cohort)	5 (31% of cohort)
Age: Years	74 ± 9 (60-92)	71 ± 11 (41-90)
Optimistic profile	6	3
Managing profile	8	9
Modest profile	4	4

Patient interviews

In total, there were 16 patients in the prototype cohort that provided informed consent and were enrolled in the study. Two participants decided to stop using the prototype after several days and three weeks respectively (reasons are explained below). These participants did provide feedback on their prototypes. One participant did not receive the envelope that contained the prototype, and another participant did receive the envelope but lost it and was unable to evaluate it. These participants did not provide feedback on a prototype. Furthermore, one participant seemed to belong to the optimistic profile in the screening but was assigned to the modest profile by the questionnaire; upon receiving the prototype she indicated that she was very unsatisfied with it and did not recognize the description of the modest profile that she was supposed to be matched to. It was decided to give her a prototype for the optimistic profile, to see if this prototype was a better match, which turned out to be the case. As such, a total of 15 prototypes were evaluated.

Table 5.4 provides an overview of profile-specific guidelines that were extracted from participants' feedback. General comments from each profile are also summarized. None of the participants reported to have actively engaged with the timeline, so there were no guidelines formulated for this feature. The feedback from each profile on other features is discussed in further detail below.

Optimistic profile (n = 4)

Weekly information: Framing

Although a neutral but strict framing was used, several participants mentioned that the tone of communication was too childish (C37, C58). This was perhaps related to the visuals that were used to complement the text. One participant liked the recommendations for rehabilitation and daily activities in the prototype, but indicated that these recommendations and limitations could be even more clearly described in the prototype at times: “Walk outside with at least one crutch, or else…” (C37). Also, it should be clear that these recommendations come from a physical therapist (PT) or orthopedic surgeon. In general, several participants indicated that a care provider with medical authority giving certain recommendations was most “reassuring” (C27, C48). It was either indicated that additional reassurance from the prototype was not necessary, or that “[this] should really be given in a face-to-face conversation” (C27).

Weekly information: Content

Not all content was found to be relevant, especially by one participant who decided not to use the prototype several days after receiving it (C27). It was also indicated that there were some specific information statements that were useful at specific moments. For instance, the suggestion to sleep with a pillow between the legs was useful: “There I thought, ah! Smart! I hadn’t thought of that myself” (C58). The prototype could have contained more of these suggestions or they could have been described more specifically. For example, one participant indicated that it would be handy to have a more specific description of how many pain killers to use over time (C37). This participant added that the need for specific information was also dependent on his recovery: “I’m just doing very well, so I don’t need all that elaborate information” (C37).

Weekly questions and checklists

One participant made use of the questions in the prototype, and had mixed reactions about this. Several questions seemed “nonsensical” to her, and she was not motivated to follow the suggestions to take photos or videos of her recovery because she did not own a smartphone. However, the checklists in the prototype were a bit more useful to her: “I’m already aware [of my recovery], but this makes me a bit more aware. Can you do this, can you do that… Oh, that’s 4 weeks, if I can’t do that yet it’s not so bad” (C58). She also wrote down questions for the orthopedic surgeon in the prototype: “Because then I think, I should ask that, and then I immediately wrote it down in the prototype and I take that with me. I liked that” (C58). (There were no observations of this patient using the prototype during a consultation.) However, she indicated that she would have done that without the prototype as well.

Table 5.4. Summary of design guidelines for each prototype, based on patient feedback. Feature 1 (timeline) was not included because patients did not use this feature.

	Optimistic profile (n = 4)	Managing profile (n = 7)	Modest profile (n = 4)
2) a. Weekly information: Framing	Indicate recommendations clearly (e.g. “walk outside with at least one crutch, or else…”) Frame recommendations as if they are made by someone with medical authority (e.g. surgeon, PT)	Provide information in a Q&A format, OR Provide information on (ab)normal complaints as a weekly (check)list	Frame information as stories of multiple patients, to show different recovery scenarios (e.g. ‘slow’ and ‘fast’ recovery)
2) b. Weekly information: Content	Provide specific weekly suggestions (e.g. putting pillow in-between legs when sleeping)	Put emphasis on complaints / symptoms that are ‘normal’ or require contact with care providers Emphasize (more) that rehabilitation takes time Include information on pain killers Include PT recommendations Include specific recommended activity levels per week	Include both generic and specific information (e.g., general statements about pain vs. specific information on pain in certain situations), perhaps in a hierarchy

(Table 5.4. Cont'd)

	Optimistic profile (n = 4)	Managing profile (n = 7)	Modest profile (n = 4)
3) Weekly questions and/or checklists	Include weekly checklists only	Emphasize that answering questions is optional (but possibly mention expected benefits of doing so, e.g. as testimonial from a patient) Use open fill-in fields sparingly Include weekly checklists for possible arrangements (before surgery) or presence of symptoms or complaints (after surgery)	Emphasize that answering questions is optional Provide sufficient room for writing down experiences in addition to ticking boxes
Other comments and general remarks	Prototype provides slightly more awareness and reassurance in some cases (e.g. comparing own recovery to what's normal). Provide prototype as an optional service beyond generic hospital information, e.g. only for patients who experience problems during recovery	Specific information provided reassurance to some patients. For some patients, keeping track of recovery helps to prepare for post-surgery consultations. Provide prototype as an optional service beyond generic hospital information, e.g. only to provide general overview	Prototype is supportive/ reassuring in some cases; may complement meetings with care providers. Provide flexible knowledge resource (e.g. both generic recommendations and detailed information)

Managing profile (n = 7)

Weekly information: Framing

In terms of information framing for the managing profile, the Q&A format that was used for specific information was well received (C36). This format could be included more in the prototype. It was also suggested to present normal and abnormal complaints as a weekly checklist (C15). One participant found the style and contents unappealing and irrelevant, and stopped using the prototype even before his surgery (C14). Another participant from this profile that did engage with the prototype also complained about its style, which seemed childish to her: “Perhaps this is fun for a 12-year old.” (C15) However, she admitted that a neighbor that she showed the prototype to was much more enthusiastic about the style.

Weekly information: Content

In terms of content, the prototype for the managing profile also included more specific information on pain and pain management. One participant felt that these specific information elements were useful, such as the statement that wound pain is normal after two weeks. “This gives a bit of support.” (C7) In another case, a text balloon saying that some swelling in the leg is normal was experienced as “reassuring” (C15) and it prevented the participant from having to make a phone call to the hospital. The suggestion that patients should actually make a phone call in certain circumstances was appreciated as well (C7). The statement that “Recovery costs time” was also found useful (C36).

Participants also suggested that more details on using pain killers after surgery could be included (C17), as well as information from the physical therapist (C7). This may lead to redundant information, but one participant did not find this very bothersome (C7). Another participant decided herself that she could skip certain parts that were irrelevant to her (C17).

In addition, one participant added that the progression measurement could be made more specific by giving recommended activity levels (minutes or meters of walking, swimming, or cycling) per day (C17).

Weekly questions and checklists

Next to the open spaces for writing, checklists were provided for every week after surgery. Some positive reactions to the weekly questions and checklists were observed. For example, one participant found that even though she was still recovering well the prototype was useful to her (C17). This participant felt that keeping track of all the information was helpful, in both interview moments. She actively tried to engage and keep track of as much information as possible. "I really didn't have any idea what was coming for me. I didn't want to know. […] Then this is a huge aid, because otherwise I might have been on the phone [with the hospital] ten times" (C17). She also felt that keeping track of her questions helped to prepare for post-surgery consultations: "You can set your mind for it" (C17). Although less enthusiastic, another participant agreed on this aspect: "With some questions, you do start to think about things that you hadn't considered before." (C7)

On the other hand, one participant didn't really see the relevance of the questions, because she could verbalize her thoughts and needs without the need of such a support (C15). At a later stage, she kept indicating that because her recovery went well, most of the prototype parts were not useful to her. It was suggested to replace the open fill-in fields with simple fill in questions, and to remove double questions (C7), or to simply remove all questions and replace them with checklists: "What can you arrange before surgery, and what are normal complaints at any given time after surgery. That is very nice, if found that reassuring." (C15) Most participants agreed that the parts about taking photos and making videos should be removed (C7, C14, C15, C17).

Other comments

In general, three participants in the managing profile found useful elements in the prototype, sometimes after a while. One participant did not understand the value of the prototype before surgery (C7), but was a bit more positive in later interviews. In contrast, two other patients indicated that they didn't find the information very clear and relevant, so although they kept the prototype until the second interview after surgery, they did not engage with it very much. One of these patients did find that it was nice to go through the prototype right after surgery, "to see what I'm going to go through in the coming weeks" (C32). Yet another patient indicated that he didn't see the added value of this prototype beyond the original information flyer and the explanations by care providers during consultations. He did assume that additional repetition of information might be useful for some patients, "but not for me" (C21).

Modest profile (n = 4)

Weekly information: Framing

One participant was positive about the information framed as peer report, but she recommended to have multiple stories of several patients, to show that recovery can differ between individual patients (C34). This participant suggested to show extremes: A 'slow' and 'fast' patient, both sharing their experiences each week. This should be especially reassuring for patients that take longer to recover, for instance due to physical condition or comorbidities. She thought that "people can worry a lot about this" (C34). As in the other profiles, all participants in profile C indicated that the style of the prototype was 'childish' (C6, C34, C35, C58).

Weekly information: Content

The only adaptation on the content level for the modest profile was to omit information regarding return to work. No remarks were made about the adaptation (but participants were not aware that it was present in the other prototype variants.) One participant (C34) became more positive about the weekly information over time, especially about the content of the peer report: "You ask yourself, what is normal, what is not normal. This guideline is quite nice, to be able to follow that. […] You do look to it, see what [persona] is saying after [each] week… yes, that matches. [That is] reassuring" (C34). She said that the information also corresponds to the types of questions you have as a patient. Care providers would also answer questions during these meetings, but "[the prototype] is a nice support" (C34). For example, the statement in week 4 that the recovery takes time was reassuring for her to read, she used this type of information to gage whether she was on track with her rehabilitation. Another participant agreed, explaining that contact moments with care providers after surgery are scarce and this prototype fulfils a complementary profile (C35).

Another participant mentioned that short informative statements were mostly obvious: For instance, she already expected that she would have wound pain in the first weeks after surgery, but she wondered whether it was also normal if this pain caused her to wake up at night (C34). So she felt that this weekly information should be made more specific. In contrast, another participant said that this information on pain was useful to her (C35). This participant also liked the accuracy of the timeline and specific instructions about showering (C35). Moreover, another participant in this profile actually found the information in the prototype too specific. She indicated that the information in the generic flyer was enough for her, and mostly relied on the principle that she could do anything right away as long as she felt safe about it (C7). So it seemed that the principle of knowing what is part of a normal recovery is desirable for all three patients, but that they were different in the extent to which they needed this information to be worked out. It seems that both generic and specific information should have been included.

Weekly questions and checklists

For the modest profile, short questions and tick-box answering was mostly used. One participant was not really interested in answering all the questions, because some were obvious or unnecessary (C34). Two participants were not really interested in taking photos or making videos of themselves (C34, C35). Another participant indicated that her recovery went well so the questions were not really relevant to her (C7), which is similar to participants in the other profiles (C15 and C17). For these participants it may be useful to emphasize that answering questions is optional.

However, a third participant agreed that not all questions were relevant, but it was nice to keep track of her recovery a bit (e.g. how was she walking, how was she sleeping). This was also quite a good way to spend time in the first weeks after surgery, and she indicated that "this way I can remember myself how I [...] experienced it, so to say"(C35). Although she did not specifically write down questions for care providers, she did discuss the diary entries during consultations; she indicated that the prototype stimulated her to do this. She recommended to have more room to actually write down her experiences, rather than just being provided with tick-boxes.

Comparison of patient centered communication rates

Video data was captured in 18 control participants and 15 participants that had used a prototype. Several data points were missing, mostly due to unforeseen rescheduling of appointments. Table 5.5 lists descriptive statistics of the rates of care providers' behaviors that facilitated or inhibited the patient perspective. (Higher rates reflect higher degrees of behavior.) It is observed that the 95% confidence intervals of the facilitating and inhibiting rates largely overlap. One exception is seen in the facilitating behaviors of orthopedic nurses during the 2-week consultation: The average facilitating rate is higher for the prototype group, and there is somewhat less overlap in the confidence intervals. The weighted average Kappa statistic was calculated to be 0,65, which indicated substantial agreement for the selected random 10 percent sample of data.[23]

Table 5.5. Descriptive statistics of the rates of care providers' behaviors that facilitate or inhibit the patient perspective. (Higher rates reflect more presence of a given behavior.) Comparisons are between control and prototype cohort, separated for the first and second visit (at 2 and 6 weeks after surgery, respectively).

Outcome measure	Measurement (T)	Participant group	n	Mean	SD	CI
Facilitating rates	2-week consultation	Control cohort	17	1,65	,70	1,28-2,02
		Prototype cohort	12	2,17	,53	1,73-2,62
	6-week consultation	Control cohort	17	2,58	,45	2,34-2,82
		Prototype cohort	11	2,71	,76	2,08-3,35
Inhibiting rates	2-week consultation	Control cohort	17	,26	,17	0,17-0,35
		Prototype cohort	12	,32	,19	0,16-0,49
	6-week consultation	Control cohort	17	,26	,18	0,16-0,36
		Prototype cohort	11	,13	,12	0,02-0,23

CI = 95% Confidence Interval

Data triangulation

The qualitative and quantitative data from the evaluation phase was compared to the triangulation scenarios that were previously defined.[11] (See also Chapter 2.) The quantitative validation revealed that the impact of the prototype on patient-centered communication during post-surgery consultations was at best limited, but probably absent. This seems to confirm the assertion of several participants that the prototype has limited impact on the conversation with care providers, although there was disagreement about this among participants.

5.4. Discussion

This chapter described the results of a Research through Design study focused on the development of an information tool for people that receive a Total Hip Arthroplasty (THA). Using data-driven patient profiles to achieve tailoring, the tool aims to promote patient-centered communication (PCC). A paper-based prototype was developed in three variants intended for three profiles of THA patients with similar clinical, psychological, and communication characteristics. This study described the design and evaluation of the prototypes.

Summary of the design process

The framing of the information was based on feedback on storyboards that were evaluated with patients in previous research,[12] in combination with descriptions of the patient profiles. In addition, several specific additions were made based on demographic data of the patient profiles, as well as specific observations in the control cohort.

The author experienced unexpected difficulties in making design decisions, for instance on how to frame information in the prototype variants. Whereas the guidelines from previous research (Chapter 4) provided some direction, it was hard to estimate whether specific framing variations would be acceptable and persuasive to patients. Similarly, on the content level it was difficult to establish variations based on profile characteristics and descriptions. In some cases there were not enough grounds to change the content between profiles. As such, during the design process it was determined that feedback from patients on prototype variants was needed to establish which variations would be appropriate or necessary. This underlines the importance of a User-Centered Design (UCD) process and active involvement of users in each stage.[16,17]

Summary of prototype evaluation

In the evaluation phase, participants suggested improvements for the framing of the information, specific content areas, and for the weekly questions. Table 5.4 summarizes these suggestions, which shows that there are differences between participants' preferences across the profiles. Participants from all profiles also suggested to make the style of (visual) communication more professional, to make questions easier to answer (i.e. less open fill-in fields), and to omit the suggestions to take photos or videos and to paste prints of these in the prototypes.

In addition, several participants were enthusiastic about the prototype but a majority saw few benefits in using it in its current form. Quantitative validation showed that the impact of prototype use on PCC during post-surgery consultations is most likely absent. In all, the guidelines in table 5.4 provide additional directions to make variations of an information application so that they suit the preferences of each profile, but for a positive contribution to PCC a different set of functions or different forms of existing functions should also be considered. An account of the resulting digital design is described elsewhere.[13] (See also Chapter 6.)

Reflections on prototype fidelity and study design

In addition to the profile-specific guidelines in table 5.4, several reflections that are relevant to the design of tailored information applications for THA are provided. In the preceding phase of storyboard evaluations, most patients were positive about the prototype in its current form that was explained to them on a generic level.[12] So it could be seen as surprising that few participants in the current study were positive about the prototype, and that the effect of its use on PCC post-surgery was limited. First of all, the degree to which the current prototype was designed to fit into the current care process may have limited its impact. That is, patients were free to use the prototype at will, and there were no obligations for care providers to discuss the prototype during consultations.

The limited impact could also have occurred due to a poorly executed transition from the storyboard to tangible prototypes, which indeed turned out to be more challenging than expected. On the other hand, users' imaginative capabilities as to what the actual use of the prototype would have been like may have been limited, based on reviewing a storyboard alone. While low-fidelity prototypes such as storyboard may be useful to convey early design ideas[25(p104)] it is argued that users need to be able to review design concepts and assumptions in a tangible way.[26(p197-199)] So perhaps the storyboards were not specific enough for patients to be able to imagine using the actual product (or prototype). Possible shortcomings in the explanation of the study to participants of the storyboard evaluation could also have had in influence.

In addition, the actual low-fidelity format of the prototypes and their framing could have influenced the results. The prototypes were paper-based instead of digital, and they were given to participants by a researcher who emphasized that this was still 'work in progress' and criticism was welcomed. Perhaps a different framing of the prototypes might have made more sense: If the researchers or surgeon had given the prototypes to participating patients emphasizing its benefits, participants might have viewed the prototype more positively. On the other hand, to be consistent with the current framing of the paper-based prototypes they could also have been evaluated in a single interview with patients, without the implementation in the care process and the use over time. For patients, the current study set-up might still have implied too much that the prototype was finished. Still, the aim to gain insight into how users interact with the prototypes in their real-life context warrants the more intensive, longer-term user evaluation in the users' own environment.[20,25,27(p.118)]

Conversely, a digital and more refined prototype with similar functionalities may have been evaluated differently. But the functions in a digital prototype would have been very similar to the paper-based prototypes used in this study; from this perspective, the paper-based prototypes should give a good impression of patients' opinions of these functions. In all, in this design case it was challenging to define relevant and acceptable functions in an information application on one hand, and to create the right kinds of variations of these functions for specific profiles on the other hand. Using paper-based prototypes allowed to navigate the complicated interaction between these aspects against modest prototyping investments. On the basis of this study, using paper-based prototypes in the early stages of developing tailored information applications is thus recommended, but alternative research designs (such as focus groups) should be carefully considered.

The instrument used to measure PCC could also have impacted the observed effectiveness of the prototypes. An instrument was used that seemed to be widely adopted and showed good consistency[28] but it measured a relatively indirect construct in relation to the functions of the prototypes. It was reasoned that by using the prototypes, patients would communicate differently during consultations, which would also impact the care providers' PCC behaviors (assessed by the instrument). It is still arguable that using the prototype could have impacted PCC during post-surgery consultations, as several prototype functions address issues surrounding counselling and post-surgery expectations management observed by both THA patients and care providers.[29,30] But perhaps different quantitative measures, that assessed a patients' attitude or perceived patient-centered care, would have been more suitable.[22]

Considerations for theoretical framework

As the acceptance of the prototypes was limited and its effects on PCC were apparently absent, more research is needed to validate or further develop the theoretical frame underlying this study (Fig. 5.1). It did seem that an assignment to one particular profile was not really an issue for participants; one participant even indicated that this was "well explained" in the prototypes. However, based on patients' comments, perhaps the information provision should also depend on the specific recovery process of individual patients (e.g. fair or poor recovery).

Study strengths and limitations

As explained in the study protocol[11] (Chapter 2), this study bears similarities to traditional mixed methods evaluation studies. As such, a strength of the study lies in the triangulation of qualitative and quantitative evaluation data. Specifically, the use of a control cohort enabled a preliminary estimation of the impact of prototype usage on PCC, which increased the robustness of the quantitative part. An additional strength of this study is that the design process is added as a study result. The reflection on the decisions made and challenges faced during the design of the prototypes contribute to the general considerations for designing tailored information applications, and put the findings in the evaluation phase in perspective. Regardless of the risks suggested with the use of low-fidelity prototypes such as lower user comfort,[31] in this study they provided an efficient way to gather user insights and input for digital prototypes.

This formative study also has several limitations. The design case was carried out mostly by one researcher, so it would require more research to see if the use of other designers and design cases would lead to similar results. In addition, although the quantitative validation provides some insight into the impact of the prototypes on PCC after THA, participants were not randomized to a control or intervention arm. A randomized design (perhaps with larger sample sizes) would have enabled statistical inferences about this impact. Furthermore, participants gave feedback on the prototype variant that was given to them, which may have led to variations in participants' feedback due to the stimulus presented. So for example, it cannot be assumed with certainty that weekly checklists are only preferred by patients in the optimistic profile, or that stories of patients recovering quickly and slowly are only relevant to patients in modest profile. As such, the guidelines in table 5.4 are formative and provide guidance for the next prototype, but additional validation of these guidelines is needed.

5.5. Conclusions

Patient-centered communication may be enhanced by providing tailored communication and information to patients. This case study for THA patients provides design guidelines for designing tailored information tools for THA, based on three profiles of THA patients. In addition, general design considerations are provided. In the early design stages such as the one in this study, it is a complicated challenge to find a set of functions that is relevant to users and impactful on the care process on one hand, and to simultaneously develop profile-specific variations of these functions on the other hand. Moreover, while in-context evaluations have advantages in the early design stages, they are challenging to define and detail; other study designs should also be carefully considered. Nevertheless, the profile-specific guidelines presented in this study will provide more guidance for future design iterations, and in general the use of low-fidelity prototypes and several early-stage iterations is recommended. This way, tailored information applications for THA can be developed that contribute to patient-centered care and communication.

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6. Development and evaluation of a tailored information tool for Total Hip Arthroplasty patients

Chapter 6 presents the development and evaluation of a tailored digital THA patient information tool, with the aim to improve post-surgery support (RQs 2 and 3). This overall aim could be taken as a specific way to improve the patient experience, as participants in Chapter 3 indicated that in some cases there was room for improvement in in this part of the TJA patient journey. This chapter focused on the use and evaluation of the web application by patients (n = 20) and provides a final update on profile-specific guidelines. The digital information tool, which was based on insights from all previous chapters, is also discussed in detail.

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Minor adaptations were made to these sections after publication, similar to Chapters 2 an 3 (several references to other thesis chapters were included.) However, the discussion of the web application was expanded by providing an overview of its components, based on reporting standards for tailored interventions. This overview is included in Table 6.1.

Abstract

Background. People that receive a Total Hip Arthroplasty (THA) have little contact with care providers after surgery. However, most printed or digital Information tools that complement post-surgery consultations ignore patients' varying information needs and capabilities.

Aim. Investigate whether and how mechanisms for computer tailoring can be applied in an information tool for THA patients, to improve post-surgery support.

Methods. This study used a person-based approach to evaluate a tailored web application for THA patients. A sample of THA patients (n = 20) used and evaluated the application before and after surgery. Participants recorded their daily step counts, and received tailored information based on this input. In previous research, three different THA patient profiles (optimistic, managing, modest) were defined, and the application adapted to the participants' best-matching profile. Online usage metrics and qualitative feedback were analyzed separately for each profile.

Results. No patients in the optimistic profile were recruited. Patients in the modest profile accessed the application less often than the managing profile. Participants from both profiles wanted more options for input, and complained about step counter accuracy. Patients in the managing profile wanted more explanation of their information variant. Participants in both profiles experienced varying supportive effects on the rehabilitation, but most preferred the information variant matching their profile. Managing profile participants made more recommendations, while modest profile participants encountered usability issues more often.

Discussion. The profiles are an adequate starting point for designing tailored information tools in THA. Participant characteristics likely resulted in use and evaluation differences between the profiles, but the nature of the information variants may also have an influence. To increase the relevance of the tailored information, it should align with the course of recovery (e.g. complications). Resolving generic technical and usability issues is also essential.

Keywords

e-Health; Orthopedics; Design

6.1. Background

The elective procedure of a Total Hip Arthroplasty (THA) is increasingly followed by fast discharge to home. Historically, patients used to stay for up to seven days after surgery or even longer, whereas today patients are more often discharged from hospital after few days in the hospital or even on the same day.[1,2] This trend is driven in part by a clinically proven benefit: Most patients are able to recover safely or even more efficiently in fast-track THA trajectories.[2,3] However, it is also a way of increasing patient turnover, which is relevant in the context of financial pressure as well as staffing and facility limitations faced by many hospitals today.[1]

After discharge from the hospital, patients are largely self-responsible for their recovery. For example, at Reinier de Graaf hospital (Delft, the Netherlands) the surgery wound is checked after two weeks by a nurse, and an X-ray and consultation with the surgeon may occur in the sixth week. In-between these consultations, patients work on recovery themselves, often supported by a physiotherapist, informal caregivers, products and services, such as educational booklets provided by the hospital. This post-operative protocol may be safe for most patients and is still feasible for the hospital: that is, intensive and frequent contact with each and every patient after surgery cannot be realized, and is also unnecessary for most patients. Still, no two patients are identical. Orthopedic surgeons seem to account for differences between patients intuitively during the consultation, considering a patient's abilities, autonomy, and interpersonal behavior, and they also intuitively tailor their communication accordingly.[4] While this intuitive approach may have its imperfections, indirect communication (such as information on web sites, and in flyers or booklets) usually has a one-size-fits-all format and does not take into account any differences between patients at all. So THA with fast discharge and few post-surgery consultations may be successful from a clinical perspective, but a challenge remains to meet individual patients' varying perioperative information and support needs.[3,5] This is especially the case because fulfilment of expectations is an important determinant for patient satisfaction after THA.[6]

A human-centered design process can address this challenge, and it is likely to result in tailored information resources. Tailored communication is originally described as "intended to reach one specific person, based on characteristics that are unique to that person, related to the outcome of interest, and derived from an individual assessment".[7] In this definition, tailoring is a way to optimally embed human factors principles in the design of online or print materials, given the variance in patients' needs and characteristics. As such, tailored information tools can adequately support a large variety of patients in terms of information and support.

Tailored communication has been conceptualized as a specific adjustment to the individual, rather than targeted communication which is adapted to groups of people.[7] Hawkins et al.[8] argue that it is more useful to view tailoring as a process of segmentation (dividing a generic target population into subgroups) and customization (making person-specific adaptations within each subgroup). The more communication is adapted in this way to recipient characteristics, the more it can be seen as tailored.[8]

Various reviews and meta-analyses exist of tailored interventions for general physical health behavior and education, providing insights and considerations for designing tailored services for lifestyle adjustment.[9–11] However, these lifestyle interventions are designed to prevent health decline. In contrast, THA is an elective procedure followed by a relatively well-defined period of physical rehabilitation. Thus, the goals of information provision are also very different in the THA context, and insights from health behavior change interventions offer little guidance in this case.

On the other hand, literature describing tailored information provision and support in THA through printed or online channels is very limited; a total of only 4 studies available could be found by the authors. Tappen et al.[12] describe the recording of patients' own exercise videos for review at home, leading to short-term benefit in physical functioning; Fortina et al.[13] discuss a guidebook with tailored exercise, with which patients seem highly satisfied; Jeong and Kim[14] outline an adaptive information website based on patient input of e.g. Body Mass Index (BMI), and Saunders et al.[15] also describe a protocol to evaluate a web application with tailored exercise recommendations. In addition to this limited body of research, authors are unaware of reporting standards for tailored communication interventions[8,16] and none of the resources explicitly apply the segmentation and customization mechanisms described above to realize tailoring. Conclusions about effects of the interventions on patient satisfaction or physical outcomes are also either uncertain or limited.

To address this knowledge gap, we aimed to investigate whether and how segmentation and customization as described by Hawkins et al.[8] can be applied in an information tool for THA patients, to realize tailoring and create a perceived positive impact on post-surgery support. Specifically, we explored whether the theory of tailoring could be applied to create an information tool for THA patients that is relevant and convincing, providing added value to the recovery after surgery because of the tailoring mechanisms applied.

6.2. Methods

This study evaluates a tailored web application for THA patients. As part of a human-centered design process, we used a person-based approach for health behavior change interventions[17] to assess and improve the relevance and persuasiveness of the application for users. In addition to usability and feasibility testing, this approach also studies how users implement the prompts and advice from the application e.g. in their daily life. This way, we evaluated tailored components in a web application and refined guidelines for tailored ICT in healthcare.

Study setting, ethical approval

The study was carried out at the Department of Orthopedics of the Reinier de Graaf hospital in Delft, the Netherlands (481 beds). This hospital provides services to around 450,000 people in the region of South-Holland. This non-academic hospital has a strong focus on research and teaching. The Orthopedics department serves THA patients primarily on a regional level.

A detailed version of the research protocol for this study was examined by the Medical Research Ethics Committee of the province of South Holland, the Netherlands (file 19 – 025). Formal approval to carry out the study was given on April 9 2019. This protocol can be found in Appendix II.

Participants and procedure

A consecutive sample of THA patients was included. The participants used a high-fidelity prototype of an information application tailored to their needs from approximately one month before surgery to the sixth week post-surgery. Participants were interviewed about their experiences with the application and its perceived impact on their rehabilitation after two post-surgery consultations, in week 2 and 6 after surgery. The consultation in week 6 was also observed by the researcher (or assistant) to explore any impact of the application on the consultations (e.g. general subjects discussed, specific details mentioned by patients regarding the application, etc.). Finally, patients were shown all information variants of the application (further explanation in Text box 6.1), and were invited to indicate and explain which variant they would prefer to support their rehabilitation. In addition, web metrics were recorded for each patient to assess how many times they logged in over time, how much actions were performed, and how much time they spent on the application.

Tailored web application (prototype)

The application informs THA patients about recommended activity levels in the first weeks after surgery using daily step count thresholds that are individualized for each patient. The feedback given by the application is designed in three variants that match characteristics from three THA patient profiles from previous research. A summary of the development process and application characteristics is provided in Text box 6.1.

Data analysis

Web metrics

Descriptive statistics (means, standard deviations) were generated for the web application usage, separately for each profile. Confidence intervals were generated to estimate differences in usage between profiles.[25] (Sample sizes are too small for inferential statistics, but confidence intervals may be used to make such a preliminary assessment.) An intention-to-treat principle was adhered to in analysing usage data.

Interview data

Feedback (interview responses) from patients was analysed inductively, in accordance with the guidelines of qualitative content analysis.[26] Each transcript was segmented into 'meaning units', containing words, sentences or paragraphs that are related in terms of their content and context. To summarise the content, all meaning units were condensed and interpreted. These condensed meaning units were grouped into categories, which were then grouped into themes. Initial themes were 1) feedback on prototype features, 2) perceived impact on the care process, and 3) other comments or remarks. Structures and themes were identified for each profile inductively.

Text box 6.1. Detailed summary of tailored application (development and features).

Summary of tailored web application

Previous research

Fig. 6.1 provides an impression of the human-centered development process, which is described in more detail in Chapter 2.[18] The segmentation and customization mechanisms applied in the application are defined based on previous studies. Starting point of the development process were three patient profiles that were used to realize segmentation. 191 Patients who had recently undergone total lower limb arthroplasty completed a questionnaire consisting of a set of validated instruments to measure patients' communication preferences and psychological and clinical characteristics. Questionnaire responses were used in a series of supervised and unsupervised machine learning methods, to identify clusters of patients that are similar in these characteristics. Three 'profiles' emerged from this analysis: An 'Optimistic' profile, showing limited coping strategies, lower communication needs and good preoperative clinical status; A 'Managing' profile with a diverse set of coping strategies, strong communication needs and poor preoperative clinical status; and a 'Modest' profile, consisting of older people with higher anxiety and lower self-efficacy in communicating about health.[19]

A subset of these patients (n = 19) took part in generative sessions[20] (Chapter 3) to explore their experiences from the past and ideals for the future resulting in preliminary guidelines for the customization of information tools as well as inspiration for design directions. Based on in-depth qualitative insights from this study, generic storyboards of design proposals for supportive products and services were created and evaluated with another subset of patients from each profile (total n = 12; Chapter 4).[21] This was followed by the creation of profile-specific paper-based prototypes that were evaluated by a new sample of patients (n = 15) within the care process (Chapter 5). All studies were used to create and refine profile-specific guidelines for tailored ICT in THA.

(Text box 6.1. Cont'd)

Figure 6.1. Development process of a digital application for tailored communication in THA. More details on this development process are described in Chapter 2.[18] The final step (web application) is the current study.

Functionalities to realize tailored information

The web application starts with a digital questionnaire to determine the profile that is the best match to the patient. This is a shortened version of the questionnaire used in earlier research.[22] An algorithm is used to assign a profile based on the responses, and the web application is adapted accordingly. For instance, patients in the managing profile receive more detailed and abstract information, whereas patients in the modest profile are provided with simple, affective messages. This way, the segmentation mechanism is realized in the application.[8]

(Text box 6.1. Cont'd)

After completing the survey, the patient can keep track of daily step counts before and after surgery. Patients use a step tracker (Fitbit, Inc., San Francisco CA) to record daily step counts. To determine the average pre-surgery physical activity level, daily step count tracking is started approximately three weeks before surgery. After surgery, patients receive weekly feedback on their weekly average step counts. The feedback mechanism was established in consultation with an orthopedic surgeon and guidelines from physical therapy in sports.[23] In short, a gradual increase in physical activity is recommended. When a patient wants to intensify his or her walking too quickly, the application will recommend to lower the weekly average, and if the patient is walking too little compared to his or her own pre-surgery average, the application will respond oppositely. The exact thresholds for high or low activity are determined each week for each individual patient, and are based on the weekly averages of daily step counts as they develop over time. This can be seen as a customization mechanism, and it complements the profile-based segmentation.[8]

Specifically, the information in the application is adapted to the profile to which the patient belongs. To this end, insights from earlier studies were translated to three variants of the application, corresponding to characteristics and wishes of the three profiles. The adaptation in feedback mode is done in order to increase the personal relevance for the patient using the application, thereby enhancing the likelihood of elaboration on the message by the patient.[24] Figure 6.2 shows the difference between feedback for the three profiles. Patients in the optimistic profile receive a feedback message on whether they are currently doing OK or not; Patients in the managing profile view a detailed graph displaying the weekly average step counts as well as lower and upper thresholds; and patients in the modest profile receive a message written as a quote from their orthopedic surgeon. This quote (accompanied by a picture of the surgeon) contains the same information as for the optimistic profile, but is framed in a more personal and affective way.

Table 6.1 provides an overview of the characteristics of the application, based on terminology as defined by Harrington & Noar.[16] (Refer to this work for a more detailed description of the terms used in this Table 6.1.)

(Text box 6.1. Cont'd)

Table 6.1. Components of the application, based on reporting standards for tailored interventions.[16]

Intervention component	Web application for THA patients (current Chapter)
1. Variables/ constructs	Questionnaire responses; step counts
2. Theoretical foundation	Elaboration Likelihood Model:[24] increasing personal relevance by adapting information framing to subgroup assigned to patient. Guidelines for gradual increase of physical activity after surgery (or sports injury).[23]
3. Tailored messages	Personalization: Mentioning the participants name in de website, raising expectations (feedback message at the end of survey that website is adapted based on patient's responses). Feedback: Information given based on patient's daily step counts. It differs per group whether this feedback is descriptive (managing profile) or evaluative (optimistic and modest profile).
4. Tailoring system	Subgroup is assessed per algorithm, based on patient's survey responses. Feedback content (whether patients walk too much, just enough, or too little) is determined using dynamic thresholds for each week post-surgery; calculations based on Blanch & Gabbett.[23] This system is also automated.
5. Intervention channel, format, dosage, context	Web application, displaying messages that may change on a daily or weekly basis. Website shows some standard content such as frequently asked questions, contact information. General layout is the same for all patient groups.
6. Intervention implementation and assessment	Patients can log on to the website and enter or adjust daily step counts for any point in the past as often as they like; they may also view the feedback message as often as they like. Feedback (tailored content) is provided directly after assessment of step counts; feedback based on survey responses is implicit and indirect.

(Text box 6.1. Cont'd)

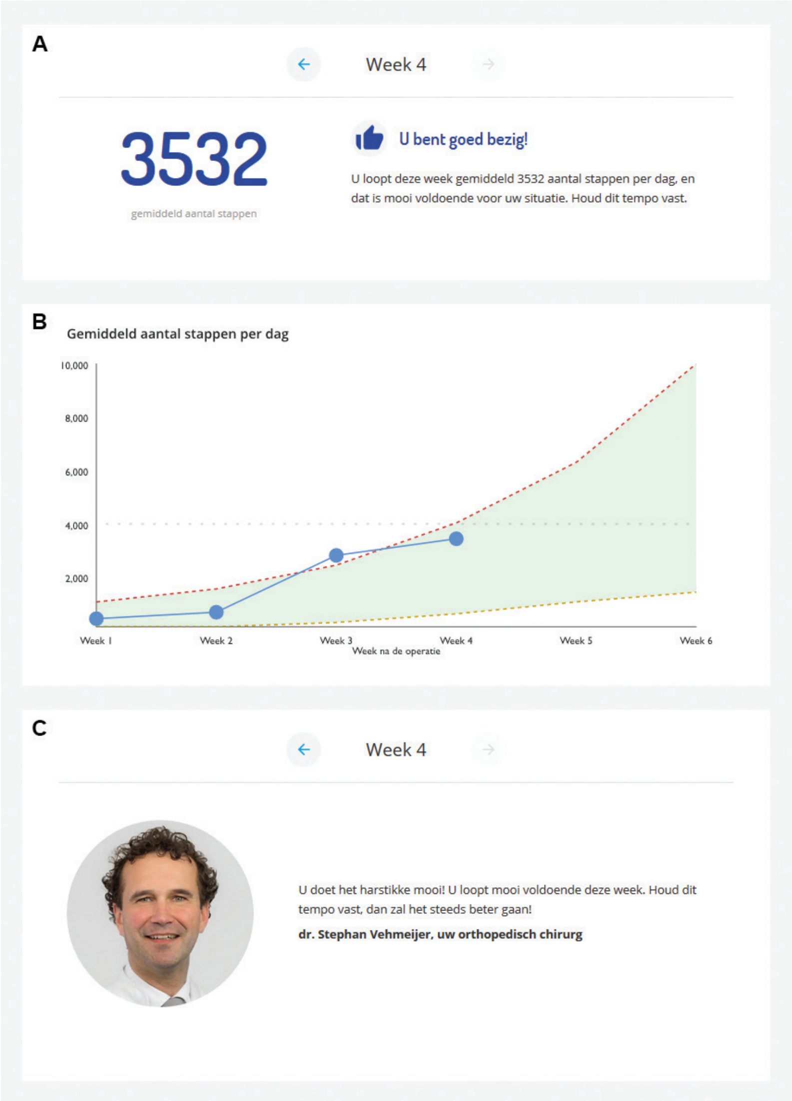

Figure 6.2. The feedback of the application is adapted to the profile to which the patient belongs: Patients in the optimistic profile receive a feedback message (A) on whether they are currently doing OK or not; patients in the managing profile can view a detailed graph (B) displaying the weekly average step counts as well as lower and upper thresholds; and patients in the modest profile receive a message (C) written as a quote from their orthopedic surgeon.

6

Data analysis

Web metrics

Descriptive statistics (means, standard deviations) were generated for the web application usage, separately for each profile. Confidence intervals were generated to estimate differences in usage between profiles.[25] (Sample sizes are too small for inferential statistics, but confidence intervals may be used to make such a preliminary assessment.) An intention-to-treat principle was adhered to in analysing usage data.

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6.3. Results

Between May and October 2019, 20 patients were involved in the study. Table 6.2 provides an overview of participating patients' background characteristics. Most notably, no patients from the optimistic profile were included. A technical verification confirmed that the profile assignment in the web application was working as intended, so this result suggests that the web application was less relevant to patients in this profile.

After consent, four participants dropped out of the study. One person suffered from complications after the study and felt that using the web application was too much of a burden. Three participants were unable to log in on the website, despite additional support from the researchers.

Table 6.2. Participanting patients' background characteristics.

Characteristic	n or MEAN ± SD (range)
Sex: Male	6 (30)
Age: Years	66 ± 10 (37-84)
Optimistic profile	0
Managing profile	10
Modest profile	8
No profile*	2

***These participants were unable to complete the questionnaire.**

Use (web metrics)

Usage data were gathered for 18 participants that completed the questionnaire and were matched to a profile. Table 6.3 provides an overview of usage metrics for both profiles that were included in this study. In this sample, the managing profile made 46,6 visits and undertook 262,5 actions (clicks, confirmations) on average, which is more than the modest profile (average of 28,8 visits and 194,3 actions). The total time spent with the application (from approximately 3 weeks before surgery until week 6 after surgery) was also longer in the managing profile (103,9 minutes) compared to the modest profile (88,4 minutes). However, on average each visit of the modest profile seemed more elaborate compared to the managing profile: The modest profile spent and average time per visit of 6,4 minutes compared to 4,7 minutes for the managing profile, and the modest profile undertook an average 8,6 actions per visit compared to 6,6 actions per visit in the managing profile. Statistical inferences were not drawn for the current study phase and sample sizes, but it is noticeable that the 95% confidence intervals between the two profiles overlap for all main metrics.

It is also noticeable in Table 6.3 that the variance in most measures is relatively large, with large ranges of confidence intervals in most cases. Further examination of weekly usage metrics for each profile indicates differences between participants within one profile, and overlaps between participants from different profiles. An example of this is given in Fig. 6.3, where the weekly number of visits are plotted throughout the use period for three participants of each profile. It is seen that the lines of different groups of participants overlap.

Table 6.3. Overview of application usage metrics for each profile. Descriptive statistics are provided as MEAN ± SD (CI).

Metric	Managing profile (n = 10)	Modest profile (n = 8)
Visits	46,6 ± 32,0 (26,8 – 66,4)	28,8 ± 27,7 (9,6 – 47,9)
Actions	262,5 ± 162,9 (161,5 – 363,5)	194,3 ± 152,1 (88,9 – 299,6)
Average actions per visit	6,6 ± 2,0 (5,3 – 7,8)	8,6 ± 3,7 (6,0 – 11,1)
Total time (minutes)	103,9 ± 50,4 (72,7 – 135,2)	88,4 ± 48,1 (55,0 – 121,7)
Average time per visit (minutes)	4,7 ± 6,1 (0,9 – 8,5)	6,4 ± 5,5 (2,6 – 10,2)

Abbreviations: CI = 95% confidence interval

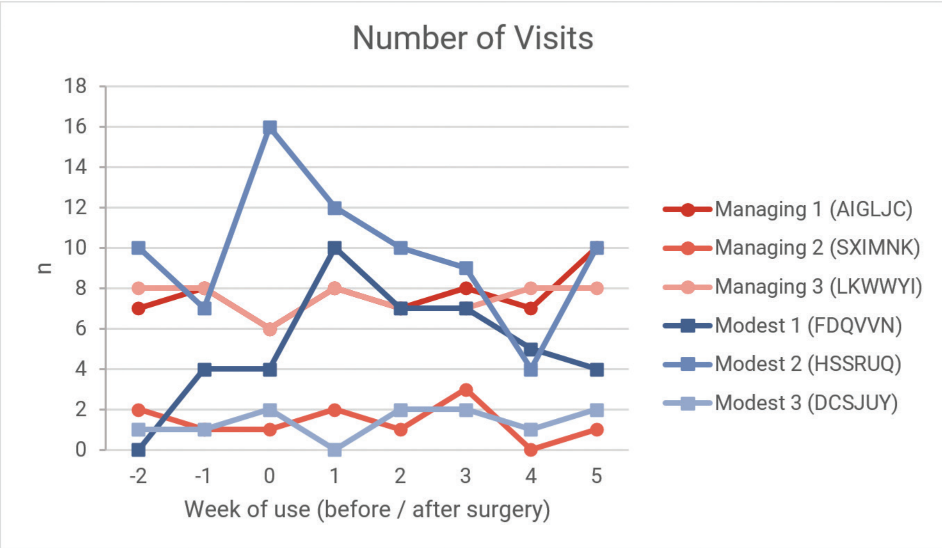

Figure 6.3. Graph of weekly number of visits throughout the use period for three participants of each profile. The managing profile is represented by orange lines, and the modest profile is plotted with purple lines. Week number are normalized for date of surgery. (Week 0 indicates the first week after surgery.) No patients from the optimistic profile were included, so data from this group is not yet available.

Evaluation (interviews)

All patients that used the web application gave feedback on its features and reflected on its perceived impact on their recovery. Table 6.4 provides an overview of patients' feedback. Summaries of the feedback from each profile are provided below.

Table 6.4. Summaries of patients' feedback on the application.

Feedback aspect			Managing profile (n = 10)	Modest profile (n = 6)
Application features		Survey	No specific suggestions	No specific suggestions
	Tracking daily step counts	Positive aspects	Step counter in itself also provided insight and stimulus to walk more (2)	Step counter in itself also gives insight and can influence behaviour (2) Entering data in application increases awareness (2)
		Issues / Suggestions	Address inaccuracies in step counter (5) Allow automatic storage of daily step counts (4) Include a diary or notes option for the step counts (3) Offer options to track different activities (e.g. cycling) and daily maximum steps in a single walk (2) Include a submit button at the top of the page for submitting step counts (1)	Address inaccuracy of step counter (e.g. registering too much steps, or too few) (2) Include a diary or notes option for the step counts (2) Provide options to track additional activities in between PT sessions (1) Place submit button for steps more clearly in the interface (1)

Managing profile (n = 10)

Some (2) participants in the managing profile valued the daily step count tracking as it gave them insight, but more often it was recommended to automate the process of storing step counts. In addition, participants recommended to allow for more activities (such as cycling) to be tracked, and to allow participants to add notes to their daily step counts e.g. to explain outliers. Several participants encountered technical or use issues while using the step counter: too many or too few steps were counted under specific circumstances.

Most (9) participants preferred the information variant that was assigned to them based on the questionnaire. They appreciated the overview and insight that the graph gave them, which was also reassuring in several cases. In about half of the cases, the graph provided either a stimulus to walk more, or an adequate inhibition for those that wanted to walk too much. On the other hand, most participants would have liked more explanation with the graph, either in the application or during post-surgery consultations. It was also suggested to

(Table 6.4 cont'd)

Feedback aspect			Managing profile (n = 10)	Modest profile (n = 6)
Application features (cont'd)	Weekly information after surgery	Information preference	9 of 10 prefer assigned information variant	4 of 6 prefer assigned information variant
		Positive aspects	Graph provides insight, overview, reassurance (8) Creates awareness about physical activity / stimulates to walk (enough) (5)	Nice or stimulating that 'physician is saying it' (4) Messages can be reassuring (4)
		Negative aspects / suggestions	Provide more explanation with graph / feedback about entered data (6) Graph can be frustrating/unsettling if walking goals can't be reached (3) Margins between safe limits are very large (2) Provide comparison to other patients (1) Provide explanation of graph during research meetings or post-surgery consultations (1) Let patients choose their own preferred information format (1) Include communication options with care providers based on data in application (1)	Contact patients that go outside safe walking limits directly, or provide contact options in this case (2) Message that patient needs to walk less can be confusing when this doesn't coincide with how patient feels (2) or is generally unsettling (1) Provide more insight (e.g. Graph for managing profile in combination with surgeon's message) (1)

let patients choose the information variant themselves, and to provide more contact options with care providers based on the graph.

Several (5) patients in the managing profile clearly experienced positive supportive effects of the application: It either stimulated them to walk more, or it prevented them from going too far. The step counter itself also provided insight and gave motivation to walk more. One participant actively referred to the application during the second post-surgery consultation. On the other hand, the graph was seen as irrelevant or even frustrating by patients that experienced complication during recovery, or where step counters were perceived as being highly inaccurate. As such, the application also often did not yet provide added

(Table 6.4 cont'd)

Feedback aspect		Managing profile (n = 10)	Modest profile (n = 6)
Perceived impact on the care process	Positive perceived impacts	Both stimulating and/or tempering effects of application on walking perceived (4) Step counter in itself also provided insight and stimulus to walk more (2) Graph actively discussed during consultation (1)	Surgeon's statement is added value (4) Surgeon's statement can give reassurance (3) and motivation to walk (1) Statement can inhibit walking behaviour (3) (Especially e.g. PT makes similar recommendation) Step counter in itself also gives insight and can influence behaviour (2) Entering data in application increases awareness (2)
	Limited, no, or negative perceived impacts	No or negative impact of graph when recovery is complicated, or when step counts seem very inaccurate (3) Own bodily sensations considered more important than graph (2) Graph only provided additional insight or reassurance, walking behaviour not influenced directly (2) Graph did not provide meaningful information (2)	Surgeon's statement that patient is walking too much can be confusing if it doesn't match with patient's bodily sensations (e.g. absence of pain, or muscle pain upon a subsequent reduction in walking) (2) Surgeon's statement can induce anxiety when it says that the patient is walking too much (1) Surgeons statement can lead to anxiety if other care providers are saying different things; own bodily sensation becomes leading (1) Surgeon's pre-set statements seen as 'impersonal' (1)
Other comments and remarks	Positive	Application and step counter were stable, easy to use, or required little effort (4) It was nice or interesting to use the application (2)	Application and step counter were easy to use or required little effort (4) Application was interesting to use (1)
	Suggestions / Negative	Make application usable on mobile browsers (4)	Several participants were unable log in (web browser issues, usability issues) (3)

value to the post-surgery rehabilitation.

Finally, although several participants had a generally positive experience with the application there were many other recommendations, the main one being to include more information (e.g. on weekly exercises) in the application.

Modest profile (n = 6)

Similarly to the participants in the managing profile, in the modest profile the insight provided by the step counts was valued but it was also recommended to include a diary or option to make notes with daily step counts. Likewise, a participant in the modest profile was also interested in recording more activities and exercises in-between consultations, or between sessions with the physical therapist. And similarly to the managing profile, participants in the modest profile also encountered accuracy issues with the step counter that needed to be resolved.

In terms of the weekly information, 4 (of 6) modest participants preferred this information format over other formats. Participants felt that it was 'nice' that the physician was making recommendations, and said that the messages can be reassuring. On the other hand, the warnings that a patient is walking too much can also be distressing, or confusing for participants that do not feel any pain in walking. As such, several participants in the modest profile recommended direct contact options with care providers for patients that were walking too much, and one participant would have liked to have more insight in the data (e.g. in the form of the graph for the managing profile.)

As the messages were experienced as both reassuring and stimulating, but also as confusing at times, there were variations in the perceived impact of the application on the care process in the modest profile. Several participants experienced the surgeon's statement either as a good stimulation or an adequate inhibitor, but it was also said that the statements are 'impersonal'. As in the managing profile, the use of the step counter in itself also proved to be a source of support and insight.

Finally, most patients in the modest profile found the application easy or interesting to use, similarly to the managing profile. But compared to the managing profile much more usability and technical issues were actually encountered by modest patients: Participants were unable to use the application on mobile browsers, or they were unable to log in and retrieve their passwords. This impeded or limited the use of the application in (at least) 3 cases.

6.4. Discussion

This study examined THA patients' use and perceptions of a web application that provided tailored information based on three patient profiles (optimistic, managing, and modest). 20 Patients (10 managing profile, 8 modest profile, 2 without profile assignment) were included in the study. In this sample, patients in the modest profile accessed the application less often than the managing profile and performed fewer actions, but the average duration of each visit and the number of actions per visit was lower for the managing profile compared to the modest profile. Variance within each metric was relatively large for each profile.

As for the feedback and perceptions of patients in both profiles, the results were more or less identical for both groups in relation to the use of a step counter and recording of daily steps: Both groups wanted more options for data input, and both groups encountered accuracy issues in the step counter. Feedback from both groups on weekly messages varied, in part because they received different information variants. Patients in the managing profile wanted more explanation and interpretation of the graph, while it was mentioned by a patient in the modest profile that she would like more insight into the data behind the surgeon's recommendation. Modest participants also wanted more contact options with care providers.

Half of the participant group perceived positive effects of the application: They indicated that the tool gave them reassurance, insight, stimulation to walk, and inhibition from walking too much. Finally, while patients in the managing profile made many additional remarks about what could be added to the application or how to could be improved, participants in the modest profile mainly encountered usability issues with the application. The final number of participants that were completely unable to use the application (5) is considerable.

Reflection on profile assignment and information variants

This study investigated whether the assignment of THA patients to one of three patient profiles could be used as a segmentation strategy in a tailored web application. In this study, most patients (n = 13, 81%) indicated that they preferred the information variant that they had been using over other variants that were shown to them in the exit interview. This finding sheds light on the assignment to profiles and the transition from profiles to design variants: It seems that in most cases the survey assigned the right profile to users based on their responses, and that the right adaptations were made in the design based on these profiles. However, it could be that a framing bias[27] played a role in this case: Participants had already been using the prototype variant, and were then asked to evaluate alternative design variants, so the stimulus differed between the information variants. (Two participants were unable to use the website after the survey, but these also preferred the information variant that was assigned to them based on their profile.)

Moreover, in some cases participants might have benefited more from other information variants. This was especially the case for participants in the managing profile, several of whom were inclined to ‘follow’ the upward trend of the green area with their own weekly averages. This was not possible for two participants, and it led to frustration for both of them. Instead, if they had received the information variant for the optimistic profile (Fig. 6.2a), these participants would have had the weekly message that they were doing fine. (Weekly averages for both patients were always within safe limits.) So although the participants said they would prefer the graph variant (Fig. 6.2b) for the insight it provided, a simpler information variant might have prevented any frustrations with the application.

During this study one managing patient complained that the questionnaire was awkward or steering, so this could be seen as a minor issue. In fact, the survey and profile assignment served as a filter: There were no patients in the optimistic profile that were included in this study, even though the profile assignment had been verified to work correctly with dummy data. This indicates that THA patients in the optimistic profile have no need for additional information tools or applications, as was previously expected by Dekkers.[22] As such, the profiles could be used to separate THA patients that benefit from extended information and support services from those who need no additional support.

However, within the managing and modest profiles there were mixed reactions to the application. Profile assignment alone is insufficient for these patients to determine whether they will experience a benefit from this application. Step counter issues and complications in the rehabilitation process can lead to inaccurate information in the application, and in these cases patients were unsatisfied with or did not see value in the information provided. A future version of the application could take this aspect into account, and make information adaptive to e.g. the recovery process (presence of complications).

Differences and similarities between profiles (use and evaluation)

This study also aimed to explore differences and similarities in patients' use and evaluation of the tailored application, taking the patient profiles as the separating factor. While variances in use metrics were large, differences were observed in the use of the application: Patients in the modest profile spent less time with the application and paid fewer visits to the website. This could be because of user characteristics: Patients in the managing profile may have been more inclined to input step counts on a daily basis and view the latest updated version of their graph. In contrast, several participants in the modest profile reported that they noted their step counts on a piece of paper and enter the data once every few days. However, the nature of the information variants may also play a role: The blue line in the graph for managing patients (Fig. 6.2b) is updated for each step count entry, while the 'surgeon's message' for modest patients (Fig. 6.2c) may only be updated once per week. This may make it less interesting for patients in the modest profile to update their step counts daily.

Similarly, the differences in information variants lead to different comments from participants in both groups about this point. However, participants' comments suggest that for both profiles, the information variants of other profiles may be useful as well. For instance, the managing group preferred more explanation with the graph, similar to the information variants for the modest or optimistic profile (fig. 6.2a or 6.2c); and a participant in the modest profile wanted more insight into the surgeon's message, which could be realized with the graph (fig. 6.2b). There were similarities in participants' feedback regarding the application, especially regarding the daily step recording. There were also participants in both the managing and modest profile that perceived a reassuring effect of the information on their recovery. In all, the results indicate that overlaps exist between the profiles in their preferences and engagement with the application. An exception to this is that the participants in the managing profile made many suggestions for additional content and functions in the application, while the participants in the modest profile had few suggestions but ran into usability issues more often.

Comparison to existing tailored tools and support for THA patients

The application in this study applied the segmentation and customization mechanisms[8] to realize tailored support for THA patients. In the tailored guidebook of Fortina et al.[13] and the video recordings of Tappen et al.,[12] these mechanisms are not (explicitly) present. It is not yet clear whether the tailoring procedure in our application would lead to a greater improvement of post-surgery support, but in any case they allow for more automation in the process of tailored information provision. This gives the application an advantage over the guidebook[13] and video recordings,[12] as there is no need for direct involvement from hospital staff to produce the tailored content.

However, the tailoring in this application is limited in scope: Tailored information is only given about a patient's daily step counts after surgery. In comparison, the online tool by Saunders et al.[15] allows for adaptation of exercise regimes, and Jeong & Kim[14] provide tailored content about a wide variety of topics (e.g. THA and diabetes). As such, these tools provide more options for patients and care providers to shape the information or even the care path to a patient's preferences and capabilities. The tool in this study can be expanded to include more such tailored components, which was desirable for participants in the managing profile.

But even in its current form the tailored information tool was relevant for half of the study population. In this sense, the individualized feedback based on exercise guidelines of Blanch & Gabbett[23] expands the principle of Crizer et al.[28] to use daily step counts as outcome measure for THA. So even though the tool is limited in its current features, we hypothesize that it will post-surgery support for part of the patient population at least.

Strengths and limitations

This study has several strengths. First, the application was used by patients that actually received a THA and recovered from the procedure afterwards. It was possible to capture the interactions and evaluations of patients during this part of the patient journey, which meant lower risk of recall bias[27,29] In addition, the mixed-methods approach allowed to study both participants' use of the application, and their evaluation of its features and its impact on the care process. In addition, these data sources could be compared.

The study also has several limitations. First of all, samples sizes in this study were low. A rule-of-thumb for sample sizes in user studies was adhered to for the profiles,[30(p91)] but this only allows for preliminary conclusions regarding differences in use between the profiles as well as the expected contribution of the application to the rehabilitation of the general THA patient population. While a patient's perceived impact as gathered through interviewing provides an indication of the utility of the application, a control group (non-tailored application or care as usual) could be used to validate patient perceptions.[31] Furthermore, while patients were presented with the other information variants of the application during the final interview they did not use these information variants during their rehabilitation. As such, a framing bias[27] may have interfered with their indicated preferences.

Future research and development

The application in this study has potential to support the rehabilitation after THA in a tailored way. However, next to technical refinements and debugging several alterations and additions may be needed for this potential to be realized. First, additional modules could be added to the application for tracking alternative activities such as cycling. A log book could be added so that patients can record their experiences over time, or provide notes with deviating results.

In addition, orthopaedic surgeons that participated in this study responded positively to the application and saw its strategic value for hospitals. Differences in preferences between surgeons also emerged, as one liked the idea of discussing a patient's progress during a consultation while another preferred not to. This suggests that next to different patient preferences, the development of tailored information tools for THA could also take into account different preferences among care providers. For example, a separate consultation-oriented interface could be added as an optional feature. This could allow patients and care providers to discuss summaries of the information during post-surgery consultations, if the care providers wish to do so as well.

Next to this, the evaluation of the web application could be expanded by comparing the tailored variant to a non-tailored variant. Both applications should be evaluated by patients in a real-life setting in order to assess the impact of the tailoring components on patients and care providers. This effect could be measured in terms of general patient experience; a recent overview lists several patient experience measures that include the evaluation of information aspects.[32] Another alternative could be to assess the impact in terms of patient-centred care or communication as perceived by patients, in which case one of the patient-reported measures outlined by Hudon et al.[33] may be used. The impact of using the design could also be measured by evaluating the impact on the fulfilment of expectations, or knowledge expectations in particular.[5,34]

6.5. Conclusion

Using the mechanisms of segmentation and customization, the tailored information tool in this study gave THA patients reassurance, insight, and appropriate cues for walking after surgery. This way, we demonstrated that a segmentation of the THA patient population into three profiles can be applied in a web application to realize tailoring and improve post-surgery support. Patients from different profiles used the application in a different way, and provided different feedback to further improve its features. The profile segmentation may also be used to select patients that benefit from the application, but the information that a patient prefers may not necessarily be what he or she would benefit most from. Nevertheless, with further research and development the application has the potential to support THA patients post-surgery in a tailored way.

6.6. References

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7. General discussion

This thesis aimed to investigate how to integrate three patient profiles in the design of tailored information tools for THA patients. The profiles were used as a segmentation strategy, and complemented with customized features to realize tailoring (see also figure 1.1). A Research through Design (explained in Chapter 2) approach was used in this project, which resulted in a set of design guidelines and considerations for the creative industry and healthcare providers to tailor information and communication products and services for THA patients.

7.1. Summary of results

Chapter 3 aimed to assess individual differences in preferences regarding communication and information provision among THA and TKA patients. From generative sessions with 19 patients, it was concluded that an individual patient's *mind-set* (e.g. insecurity or anxiety regarding the surgery), and their *social support needs*, in combination with their *physical condition* and *medical history*, should guide the provision of tailored information and communication services. A storyboard evaluation presented in Chapter 4 created an *initial set of design guidelines* for each of the profiles defined by Dekkers.[1] The preferences indicated by participants aligned with the results from the survey study that was used to create the profiles. Chapter 5 *refined the guidelines* using paper-based prototypes, and explored the impact on patient-centered communication (PCC) during post-surgery consultations. As this impact was limited, defining a relevant set of functions for a THA patient information tool and simultaneously developing profile-specific variations of these functions was concluded to be challenging. Nevertheless, the updated guidelines were used in Chapter 6 to develop a *tailored web application* that informs THA patients about their activity levels after surgery. This final study explored the use and evaluation of the application by different profiles. It was concluded that the profiles are an adequate segmentation that, combined with customized features, can be used to designing tailored information tools in THA. However, to increase the relevance of the tailored information, it should align with the course of recovery (e.g. complications). Resolving generic technical and usability issues is also essential.

7.2. Reflections on using patient profiles: Patient perspective

Impact of tailored design on patient experience and PCC

The higher goal of designing tailored information tools using patient profiles was to positively impact the experience of the TJA patient journey, possibly through the promotion of patient-centred care and communication (PCC). As mentioned in Chapter 1 (paragraph 1.3) and Chapter 3, patient experience is defined as 'the sum of all interactions, shaped by an organization's culture, that influence patient perceptions across the continuum of care'.[2] It spans across the entire care process and is strongly linked to expectations and expectation management. The starting point for the project was that the information tools developed in this thesis could be useful for expectation management, especially after surgery, and that the tailoring process could be used to present the information in such a way that it is more relevant to individual patients. This coincides with PCC, in which the patient is seen and treated as a person with unique needs and characteristics.

Patient's responses to the design cases in Chapters 5 and 6 indicate that these effects were realized for at least part of the study populations. Participants perceived positive effects of using a given design: in the degree of support after rehabilitation, in the insights that it provided into a patient's progression, in the reassurance that a design provided in some cases, or in the way that it structured a patient's thoughts and questions before a consultation. However, as seen in Chapter 5 this did not translate to an effect on patient-centered communication (PCC) during post-surgery consultations. In addition, there were patients that experienced no or negative effects from using the design proposals.

This raises the question *how to select patients* that may benefit from an information tool such as the ones developed in this thesis. It was seen in Chapter 6 that there were no patients in the optimistic profile that wanted to use the web application, so this may be an indication that patients in this profile generally have no need for such an information tool. This is in line with conclusions from Dekkers about this profile, that care as usual may suffice for patients in this profile.[1] However, within the managing and modest profiles there were mixed reactions to the design cases as well, so it could be that the profile assignment alone is not enough to determine whether a patient will experience a benefit from added information services. In any case, it is recommended to emphasize to patients that the information tools can be used voluntarily.

The second question raised by the limited effect is one of outcome measures and *how to measure impact* of the information tools on patient experience or PCC. It is arguable that a patient's perceived impact as explained in an interview or survey provides an indication of the utility of the designs in this thesis, but a comparison to a control (e.g. care as usual) group would be needed to triangulate this data and validate patient perceptions.[3] However, the instrument used in Chapter 5 measuring healthcare providers' PCC behavior may be either too specific or too indirect for this purpose: For instance, differences in care providers' rates of open questions or verbal reassurances may not reflect any influence of the prototypes on how the patient experiences post-surgery support. Perhaps patient-reported measures of the patient experience are a better alternative to measure impact in future studies; Beattie et al.[4] provide an overview of instruments, several of which also include items to measure a patient's experience of information provided in the care process (e.g. doctor communication).

Finally, the limited impact and mixed reactions to the designs in this thesis may relate to the *specific design directions* chosen. As table 3.4 in Chapter 3 outlines, there were several unmet needs and differences in individual preferences that could have been addressed in the prototyping and development phases of this project. In hindsight, it might have been worthwhile to explore more holistic tailoring scenarios during the design process. For instance, the adaptation of the rehabilitation plan after THA to the personal wishes and needs of patients, as illustrated in Fig. 3.4 (Chapter 3), might have proven to be more impactful on the patient experience. This is in fact more closely aligned to well-established definitions and principles of patient-centered care, e.g. the sharing of power and responsibility between patients and care providers[5] or even involving patients and relatives in the design of health services.[6]

However, to offer services like these would probably also require a more intensive effort from healthcare providers, such as the physical therapist or physician assistant. In contrast, this project focused on design cases that could be used by patients alone as much as possible, without needing additional attention from healthcare providers. Looking back to the definition of patient experience (see also paragraph 1.3), it could be said that the designs in this thesis did not make many changes in 'the sum of all interactions' between people across the THA patient journey. Adding the designs to the existing procedures was relatively straightforward, but the impact on the patient experience could therefor also have been limited.

Successful matching of patients with design variants

Beside the aspired impact on the patient experience or PCC, the initial challenge of this project was to match individual patients with a profile, based on survey results, and then match the profile with an information variant in a design. This matching process was developed to a successful level, as a majority of the patients (n = 13, 81%) in the final study (Chapter 6) indicated that they preferred the information variant that they had been using over other variants that were shown to them in the exit interview. Although it requires further validation, this finding suggests that the right adaptations were made in the design based on these profiles (and that the right profiles were assigned to users based on their responses.)

Patients did not seem to have much trouble with being assigned to a profile, or they didn't even notice that this happened. For example, participants in the paper-based prototype study (Chapter 5) that commented about the profile assignment as explained in the prototype felt mostly positive about this explanation. In the web application (Chapter 6) it was even chosen to completely omit the profiles and be very implicit about what was done with the survey, but no patients expressed specific trouble with this aspect. However, some participants in both studies had negative associations with the survey and its types of questions, which were seen as "awkward" or "steering".

Are tailored services necessary to improve patient experience or PCC?

Summarizing the above, despite the current limitations the results of this thesis suggest that tailored information services may promote PCC or enhance the patient experience. But the results also show that these outcomes can be improved by simply promoting compassionate behavior of care providers. For example, patients (Chapter 3) generally seemed to value an *attentive attitude* and *kind treatment* by care providers. Patients also stressed the importance of *being taken seriously* or *being treated with respect*. Specifically, patients indicated that care providers should take physical complaints seriously. Finally, patients valued '*thinking along*' or a flexible attitude in care providers.

These themes connect to the literature describing compassionate care, which is associated with improved patient experience as well as outcomes for patients, and positive effects for care providers as well.[7,8] As Youngson [7] explains, improving compassion in care delivery can be as simple as being kind to patients, greeting them in a friendly manner, or providing physical contact (in an appropriate way, such as a hand on a shoulder to comfort or praise patients.) Care providers' behavioral aspects that participants in generative sessions mentioned are also very similar to generic components of compassionate care such as the virtuous response or attending to a patient's needs.[9] In addition, there is indication that (at least up to a few years ago) compassionate care was not sufficiently delivered for 47 percent of patients.[8]

7.3. Effect on healthcare providers

Another assumption in this study was that the design of tailored information tools for THA patients would impact care providers. For instance, by using the paper-based prototype (Chapter 5) patients should be more prepared to ask questions relevant to them during consultations. In this project, the actual impact on care providers was limited because the tools developed were mostly used by patients independently. They were free to use the tools offered (paper-based prototype or web application) during consultations, but this was hardly observed during the field studies. This also means that healthcare providers were not immediately involved in the assignment of patients to a profile, and so in most cases they were unaware of the profile that a patient belonged to, or they were only aware of the use of patient profiles on a generic level. In other words, healthcare providers' communication was not explicitly adapted to the patients based on their profiles. Dekkers et al.[10] did find that orthopedic surgeons intuitively adapt their communication during the consultation based on a patient's abilities, autonomy, and interpersonal behavior. To support healthcare providers in tailoring their communication, a more simplified profile assignment tool may be more useful.

Still, the design proposals have the potential to address some of the counselling-related issues perceived by healthcare providers in the fast-track TJA process.[11] For example, healthcare providers also point out that written materials are not yet personalized, and that patients are not ready to ask questions during consultations. The paper-based prototypes in Chapter 5 could address these issues. But next to differences between patients, there may also be differences in preferences between healthcare providers in how they want to interact with patient-generated data. For example, one surgeon involved in the project was interested to discuss a patient's progress during his consultation, whereas another preferred not to (Chapter 6). In general, healthcare providers may have difficulties in estimating the impact of information tools such as the ones in this thesis on their work process: As discussed in Chapter 5, orthopedic nurses worried that the paper-based prototypes might lead to many more phone-calls by patients, but this was not the case. This underlines the need for field evaluations with functional prototypes.

7.4. Effect of patient profiles on the design process of tailored information tools

Beyond the effect on patients and care providers of embedding patient profiles in the design of tailored information tools, the use of the profiles also influenced the design process itself.

Choosing the right design case: Pros and cons of limited functionality

Choosing the right design case was more of a dilemma than expected, because the starting point of the thesis was formed by relatively well-defined design cases (Kraak et al.[12], van den Berg[13]; see preface). The transition from these design cases to tailored information tools seemed straightforward. However, the basis for the design direction explored in this thesis was also influenced by the generative sessions (Chapter 3), which indicated that patients especially differ in their need for support after surgery, when they actually experience the rehabilitation with its uncertainties. This theme was connected to the original design cases, but slightly different in its focus. It was also backed up by existing needs of patients and observed problems within the TJA patient journey.[11,14]

Beyond the perceived need for certain design features as expressed by patients, there were several other considerations for the design cases: First, a set of design features was chosen for which it was possible to either turn it into a paper-based or a digital prototype that could be used and experienced by patients and care providers in the actual care process. Moreover, these prototypes had to be developed within the runtime of the PhD project. Second, there was a need to limit the functions and make systematic design variations for research purposes: Differences in patients experiences had to be clearly traceable to design features, so it could be more clearly determined which features or features variations lead to certain effects (as perceived by patients or observed by the researcher) on the patient experience. Thus, the design cases had to be specific enough to make systematic profile variations without greatly altering each design variant.

These above considerations are visualized in fig. 7.1. They set limits to the scope and types of features that could be worked out—especially for the web application (Chapter 6). That is, implementing the web-based questionnaire and profile assignment as well as the daily step log and information variants resulted in a minimal viable product. But it already took much design and software engineering effort to get to this point, even with the support of one of the design agencies involved in the project. This means that the customized content was also created in a relatively straightforward way, by using a diary in the paper-based prototype and off-the-shelf technology to record daily step counts in the web application. More advanced sensor tracking might also have been possible, but this was deemed undesirable for participants' convenience, usability issues, and technological development difficulties. However, there might have been more potential to capture user's experience in the web application and provide customized interactions with e.g. interaction and feedback from care providers. This would make the web application similar to online tele rehabilitation platform such as the one described by Paul et al.[15] In this platform, a patient and physical therapist make a rehabilitation plan together, and the therapist can monitor a patient's progress.

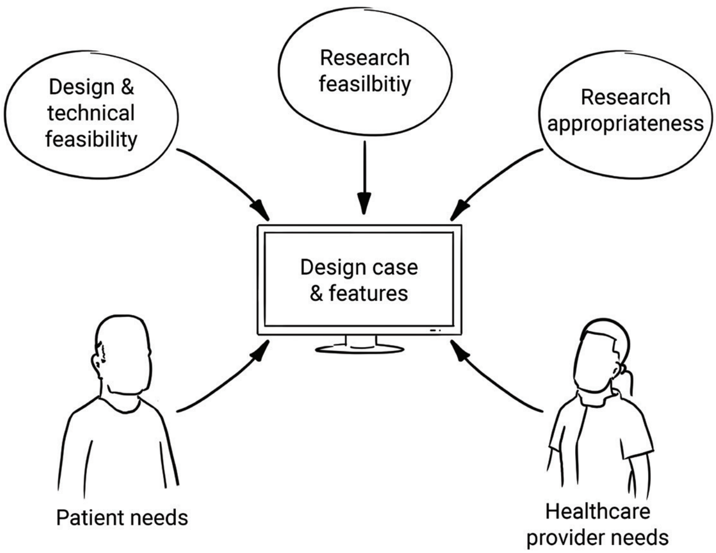

Figure 7.1. Considerations for the design cases in this thesis.

Summarizing this aspect of the design process, in design research projects that seek to implement theoretical knowledge into a prototype for use in context, careful consideration is needed to define and implement a relevant design case in the first place. In this project, the scope of features in the final design was limited due to time and budget constraints, as well as requirements for assessing the impact on patient experience within a scientific research context. Nevertheless, the final application provides a starting point with good potential to increase its relevance to patients, for instance by adding a diary feature or weekly information and recommendations.

'Translating' the profiles to design variants: Use, strengths, and limitations of guidelines and metaphors

The second challenge was to create design variants based on the differences between profiles. After the initial survey study (Thesis of Dekkers,[1] summarized in Chapter 2) and storyboard evaluations (Chapter 4), the sources used as a starting point were 1) profile-related data, such as differences in communication preferences and coping behavior, and 2) profile-specific patient feedback on generic design proposals (storyboards). For the design direction chosen, specific parts of each source were used.

The profile-related data was mainly used at the level of general descriptions and summaries of characteristics. For instance, for the optimistic profile it was assumed that patients would have less need for control and detailed information, because of their low anxiety and communication needs; the managing profile was assumed to need more detailed information and contact options, because this group employed more coping strategies and had higher communication competencies; and for the modest profile it was assumed that affective messages would be more suitable, because this group experienced higher anxiety. Beyond this, specific demographic data was used sporadically: One example includes the omission of information related to return to work for the modest profile (Chapter 5), because most people in this profile have already retired. However, these adaptations are risky because not all patients of the modest profile have actually retired.

The profile-specific patient feedback, summarized in the initial set of guidelines defined in Chapter 4, were partly used in the paper-based prototype (Chapter 5) and web application (Chapter 6). Not all guidelines were relevant to the functions defined in these designs, especially in the web application because it was limited in its features. However, it was experienced that the patient preferences that these guidelines were based on are elusive: For instance, during the evaluations of paper-based prototypes (Chapter 5) participants in the managing profile indicated that they preferred few or no open fill in fields, while in evaluating the web application (Chapter 6) several participants from the managing profile did actually suggest to include open fill-in fields to keep track of their experiences. Also, the guidelines were obtained from small numbers of participants so there was little validation of the initial guidelines. These limitations were also kept in mind during the design process, and the researcher took considerable care in translating initial patient feedback into design features. But it was argued that the preliminary feedback provided the best starting point for creating new designs and refining the guidelines, and sudden changes in patient preferences were expected.

Although the guidelines had their limitations, they provided general guidance in the design process. The general relevance of the guidelines as a whole was increased when they were summarized as design metaphors for each profile.[16(p78,79)] Figure 7.2 provides an illustration of the metaphors (adapted version). Beyond specific design guidelines, the metaphors were actually used as a main communication source between the researcher and the design team that was involved to develop the web application (Chapter 6).

Figure 7.2. Design metaphors for each profile, based on design guidelines defined in Chapters 4 and 5. Original metaphors were developed by van Dijk.[16(p79)] The metaphors depict interactions in the TJA patient journey as descriptions of actual travel modes. For the optimistic profile, the journey should generally feel as travelling with a travel book or using sign-posts, in discussion with the care provider; for the managing profile, the journey should be like using a map to plan each step specifically while being in the lead; and for the modest profile, the journey could be like following a guided tour, with the healthcare provider as the tour guide.

Finally, throughout the design process it was assumed that each profile would need its own design variant, but that the features and scope of an information tool could be similar for each profile. This was also the easiest way to initially translate profiles into design variants and compare the effect on patients from different profiles. But as was seen in Chapter 6 there were no patients in the optimistic profile that wanted to participate in the study. This suggests that different levels of functionality or support to each profile may be a more appropriate way to differentiate between the profiles in a design proposal.

Reflection on Research through design approach

This project used a Research through Design approach[17] to develop guidelines for the design of tailored information tools for THA patients. Several general reflections on this approach are noteworthy. As Chapter 2 outlined, the goal of this project was to create 'intermediate level knowledge', that would be applicable under specific conditions in other design projects.[18] With the guidelines created, this goal was reached. That is, the guidelines offer insights for the design of tailored information tools for TJA—they can be used to create new information tools. Their applicability for other patient groups has not yet been researched. Additional studies may increase the generalizability of these findings.

A major tension in this RtD project resided in the purpose of the prototypes and designs developed (Chapters 5 and 6). As mentioned by Stappers and Giaccardi,[17(p48,49)] prototypes can be created as objects for research but they can also be viewed as concepts for future products. This can be confusing to users, who view polished research objects as products or services that may soon be on the market. In this thesis, the objects created were manifestations of the tailoring theory (Chapter 2, figure 2.1) on one hand, and the aim was to study whether and how the theory was applicable in practice. On the other hand, the objects could also be seen as additions to the information and support services of Reinier de Graaf hospital, and several patients approached the designs as such. In all, for Research through Design projects that use prototypes for similar purposes it is recommended to clearly communicate this distinction to study participants and other stakeholders, and to clearly state whether the specific purpose of the prototype is to study a theory or to directly contribute to the context of study. The study design could also be adapted to better fit this prototype functionality (e.g. what outcomes are used, how data is gathered and analyzed, whether a control cohort or randomized design is used, etc.)

7.5. Design guidelines

An output goal of this project was to define design guidelines for creative industry. The guidelines were accumulated based on the studies in Chapters 4, 5, and 6. In collaboration with design agency Panton (Deventer, the Netherlands), these insights were incorporated in a suitable and accessible format for a broader audience. The guidelines can be found in table 7.1, and a complete overview is provided online (www.medisigntudelft.nl/research/patientprofiles). Considerations for the resulting set of guidelines are discussed below.

From research findings to guidelines: Flexibility, generalization, and examples

The guidelines defined in Chapters 4, 5 and 6 were taken as research findings. Several changes to these research findings were made to turn them into guidelines for design practitioners. First of all, users of the guidelines had to be able to easily explore them and select and adapt specific information required for a project rather than precisely following a protocol or method, which was deemed to be too rigid for design practice.[19] The format of the research findings (statements in tabular form) lent itself well for this, so this basic format was kept in creating the guidelines.

However, the research findings had to be made more generic: those defined in Chapters 4, 5 and 6 were specific to features of individual design cases (the storyboard, paper-based prototype, and web application, respectively). In discussion with designers from an agency involved in the consortium, it was decided to formulate the guidelines in a slightly more generic way. We reasoned that in this way, it would be easier for design practitioners to use the guidelines in other projects than e.g. an information booklet (Chapter 5) or website with step counter (Chapter 6). Three main categories emerged from this abstraction process: 1) How to design the information exchange, 2) what information patients want to receive, and 3) what information they want to give. Several sub categories were also defined to further structure the guidelines. A drawback of this categorization was that not every sub category contained guidelines for all profiles, but this was seen as a minor issue.

Second, illustrations were made for each guideline. The guidelines are formulated in a relatively abstract way, and some examples are given in text, but an image providing an impression of how each guideline may be incorporated into a design made the guidelines more comprehensive. These illustrations were made for a generic application (example in figure 7.3). It was also reasoned that examples could be made for healthcare providers in direct conversation with patients from specific profiles. As such, the guidelines were also illustrated with conversations between healthcare providers and patients (example in figure 7.4).

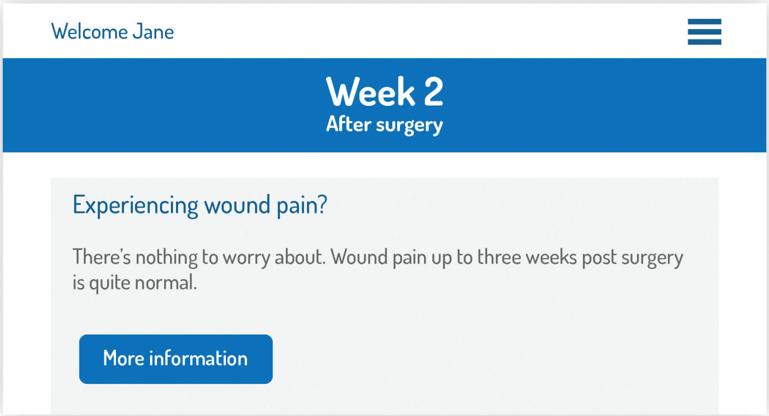

Figure 7.3. Illustration of the guideline 'Provide essential information only' in an application. In this illustration, short information about wound pain is given after surgery. The patient can click the button 'More information' if she wants additional details.

Figure 7.4. Illustration of the guideline 'Provide essential information only' in a conversation between healthcare provider and patient. In this illustration, a nurse only repeats the main guideline for physical activity to a patient after surgery.

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Finally, a notice of caution was added to the general introduction on the website. It was explained that the guidelines inform both designers and care providers, but they can only be used as a starting point for a design or for direct communication. Both designers and care providers should always obtain feedback from patients on their decisions.

7.6. Contributions and societal implications

This thesis has several contributions and societal implications. First, the project contributes to the theory of patient profiles in the context of computer-tailoring. It was found that the profiles can be an adequate way to segment the THA patient population, and that they provide a first step towards tailored information tools for patients. Several issues surrounding the use of patient profile and the design of tailored e-Health were also surfaced or clarified through the act of designing and evaluating information tools. For example, findings in this thesis suggest that 1) patients do not have much trouble with being assigned or 'labeled' to a subgroup or profile, 2) patients in the optimistic profile probably don't need additional support, while patients in the managing or modest profile may benefit from additional services, 3) at the very least, specific recovery trajectories (e.g. the presence of complications after surgery) need to be taken into account in tailored information tools as well, and 4) tailored information tools should also be adaptive to care provider preferences for information exchange or interaction preferences between both patient and care provider.

Second, there are contributions in the approach and learnings from the design process in this thesis. The project provides a novel example of a Research through Design project in a healthcare context. This approach was specified in particular detail in Chapter 2, and in several applications to a Medical Research Ethics Committee (MREC). The resulting knowledge on how to communicate this type of research to audiences outside the design research community can be supportive for future design research projects in healthcare.

Table 7.1. Final overview of design guidelines for TJA patient profiles. The table includes the categories and sub categories that were chosen as structure for a generic description of the guidelines. Blank cells indicate that there is no guideline (yet) for a given sub category and profile. Total numbers (n) of patients from each profile that were involved in the creation of the guidelines over all studies are included. An overview including examples is provided online (www.medisigntudelft.nl/research/patientprofiles)

Guideline category	Sub category	Managing profile (n = 23)	Optimistic profile (n = 7)	Modest profile (n = 12)
Information design	Tone of communication	Use upbeat, positive tone; emphasize positive stories Use reassuring tone	Indicate recommendations clearly / use positive, but strict tone (e.g. “walk outside with at least one crutch, or else…”)	Use positive feedback Emphasize affective dimension of care & patient experience
	Comprehensiveness	Provide interpretation or feedback of activity data (e.g. daily step counts)		Include simple, straightforward information Example: Frame information as stories of multiple patients, to show different recovery scenarios (e.g. ‘slow’ and ‘fast’ recovery)
	Structure	Provide information on (ab)normal complaints as a weekly (check)list, OR Provide information in a Q&A format	Provide essential information only	Include both generic and specific information (e.g., general statements about pain vs. specific information on pain in certain situations), perhaps in a hierarchy Provide ability to re-examine care provider advice
	Credibility	Emphasize that information is up-to-date	Recommendations should be made by someone with medical authority (e.g. surgeon, PT)	Show a face (of care provider) accompanying information

(Table 7.1 cont'd)

Guideline category	Sub category	Managing profile (n = 23)	Optimistic profile (n = 7)	Modest profile (n = 12)
What information to receive	Information on current symptoms	Emphasis on complaints / symptoms that are 'normal' or require contact with care providers		
	Rehabilitation expectations (e.g. duration)	Emphasize (more) that rehabilitation takes time	Include recovery scheme for comparison: 'Am I on track' OR create insight into progression	Give insight into progression
	Practical suggestions	Include information on pain killers / pain management	Provide specific weekly (practical) suggestions (e.g. putting pillow in-between legs when sleeping)	Give advice / heads-up about pain (prepare patients for pain experience)
	Activity Recom-mendations	Include PT recommendations Include specific recommended activity and exercise levels per week		

Third, the specific results in this thesis have societal implications and contributions. The profile-specific guidelines (table 7.1) that resulted from several studies can be used by both design practitioners and care providers to support tailored communication to patients. Even though the guidelines are formative and probably not complete yet, they clearly suggest that there are differences between the profiles in how they prefer to communicate. Finally, the design results in this thesis may have societal value. Whether it was in attending the generative sessions (Chapter 3), using the paper-based prototype (Chapter 5), or engaging with the web application (Chapter 6), there were patients perceiving positive effects of the process that they went through. The web application (Chapter 6) in particular provides a platform that is well-suited to be expanded and improved in the future. This way, its potential to support THA patients in a tailored way can be realized.

(Table 7.1 cont'd)

Guideline category	Sub category	Managing profile (n = 23)	Optimistic profile (n = 7)	Modest profile (n = 12)
What information patients can give (actions patients can undertake)	Types of questions	Emphasize that answering questions is optional (but possibly mention expected benefits of doing so, e.g. as testimonial from a patient)	Include weekly checklists only	Use short questions/ answers (e.g. more box-ticking or indications on scale) Provide sufficient room to write down experiences in addition to ticking boxes, e.g. a diary option Allow for tracking of different activities (e.g. cycling, exercises)
	Guidance with questions	Emphasize that answering questions is optional (but possibly mention expected benefits of doing so, e.g. as testimonial from a patient)		Emphasize that answering questions is optional
	What questions lead to (use of questions)	Facilitate that patient can see his/her progression over several weeks Facilitate contact with care providers when needed Facilitate comparison to other patients (e.g. in terms of physical activity) Care providers should discuss data during consultations	Facilitate that patient can see his/her progression over several weeks	Give insight into progression Actively contact patients that are not within safe activity limits (when digital information tool indicates this)

7.7. Strengths of this thesis

First, the mixed-methods design used in several chapters provided the researcher with complementary data and additional validation or expansion of insights.[3] For example, the qualitative data in Chapter 3 complemented the quantitative survey data from the PhD project of Dekkers, and provided insights on how to actually customize health information services for TJA patients. Additionally, the quantitative validation of care providers' patient-centered communication (PCC) during post-surgery consultations validated patients' perceptions of the paper-based prototypes (Chapter 5).

A second general strength of this study is that design proposals were evaluated with patients in a real-life setting as much as possible. The storyboard evaluations (Chapter 4) were an exception to this, but this step was seen as necessary and efficient to gather an initial set of profile-specific guidelines. Both the paper-based prototypes and the web application were tested with patients that actually received a THA and recovered from the procedure afterwards. It was possible to capture the evaluations of patients during this part of the patient journey, which meant lower risk of recall bias[20,21] compared to e.g. retrospective interviewing.

The third strength of this study is that there were multiple rounds of formative or explorative research, with insights from each study feeding into the next one. This way, knowledge gathered in individual studies could be accumulated and the design guidelines could be refined in each research step. The project succeeded in generating a single set of design recommendations (table 7.1).

7.8. Limitations

First, the tailored design proposals were not compared to non-tailored information tools with similar functionalities in this project. A comparison with a control cohort was done in the study with the paper-based prototypes (Chapter 5), but patients were not randomly assigned to control or intervention arm, and patients in the control arm did not receive any additional information resource other than the existing hospital information. This limits any claims that can be made about the effectivity of tailoring in the existing information resources: After all, even if patients had experienced a positive effect of the paper-based prototype, this could be due to the fact that information was simply made more accessible to them in this prototype.

Another limitation was that participating patients used a design (paper-based prototype or web application) that corresponded to the profile that they were matched to. This means that, save for a few exceptions, patients in one profile did not get to engage with a design variant for other profiles (Chapter 5), or that patients were not able to actively engage with a prototype variant from a different profile during their TJA patient journey (Chapter 6). Participants in the final study (Chapter 6) did get to see the other information variants in the exit interview and they could indicate which information variant they would have preferred during their rehabilitation, but a framing bias[20] (i.e. difference in presentation of stimuli between information variants) could have influenced their opinions.

Finally, although the studies in this project were mostly explorative in nature, sample sizes were low. The aim was to adhere to the rule-of-thumb for sample sizes in user research (as mentioned by Wiklund[22(p92)]) of at least 5 participants from each homogenous group. In this case each profile was seen as a homogenous group, so 5 participants from each profile ideally would have evaluated each design proposal. Even though this rule-of-thumb is also debated,[23] it occurred several times that this sample size requirement was not met, mostly due to logistic restrictions or the absence of patients in a specific profile that were willing to participate. For instance, in the final study there were no 'optimistic' participants, even though it was verified that the allocation of participants to profiles by the web application was technically operating correctly. The cumulative effect of several studies in which participants provided feedback on design proposals mitigates this limitation to some extent.

7.9. Directions for future research and design

Given the overall project results and the strengths and limitations of the project, there are several directions possible for future design research projects. This final section provides both suggestions for further research into the design guidelines, and further development of tailored design proposals. (Suggestions for further development of the tailored web-application were provided in Chapter 6.)

Expanding the current research: Cross-validation and different tools or populations

First, cross-validation may be used to expand the foundation of the guidelines. This means that participants complete the survey and are linked to a profile, but they may then be presented with any variant of a tailored information tool. In this way, patients can also evaluate design variants that are not matched with their profile. A study with a similar setup was conducted within the project of Dekkers[1]; this study evaluated information architecture variants with a larger population. Similar studies may be carried out for the evaluation of individual guidelines, or a reasonable combination of guidelines. A similar setup may also be used to compare the effects of using tailored and non-tailored information tool on the patient experience.

Beyond this, the guidelines can be implemented in other information tools for TJA patients, and perhaps in information tools for other patient populations as well. The latter would also require the validation of the patient profiles in other patient populations, but the relevant surveys to determine meaningful profiles in patient populations other than TJA patients may also be different. Therefore, within the reasonable scope of recommendations based on this research it is recommended to study information tools for TJA patients first.

Future directions for research and design: Stepped care, factoring in recovery trajectories and healthcare provider preferences

Beyond the tools and guidelines investigated in this study, other design research directions may advance tailored care for THA patients as well. First, it could be considered to vary the intensity of guidance for patients in different profiles in general: Some patients may not need any additional support beyond the information already offered. The patient profiles could therefore be used in the context of stepped care, providing (part of) the guidance towards optimizing the amount of resources used per patient while still achieving good overall outcomes.[24,25] In addition to the patient profiles as a segmentation strategy, digital information tools should be adaptive to the individual patients' course of recovery (Chapter 5 and 6): Patients that recover well and with little pain may need less information, even if these patients are in the managing profile. The recovery trajectories of Porsius et al.[26] may be utilized for this purpose:

This study defines three distinctive recovery trajectories in the first six weeks after surgery, which especially differ in the first two weeks (fast, average, and slow). These trajectories can complement the set of profiles in this project: For instance, tailored services can be different for a slow-recovering managing patient compared to a fast-recovering managing patient. (There is not enough ground at this point to assume considerable overlap between these two sets of profiles.)

Finally, information tools could be developed that are adaptive to healthcare providers' personal communication preferences as well. As mentioned earlier and in Chapter 6, orthopedic surgeons in this project indicated different preferences for using information tools together with patients during the consultation. If this applies to more healthcare providers, then information tools for THA (and arguably and exchange between healthcare providers and recipients of healthcare) should be made flexible to 1) the patient, 2) the healthcare provider, and 3) the interaction between the two, as the matching of both parties' preferences will probably be a process of negotiation. Services could be developed that help navigate that process, preferably in a holistic way and throughout the patient journey rather than at specific points in time (see also paragraph 7.2). Fig. 7.5 provides a diagram of this design research direction.

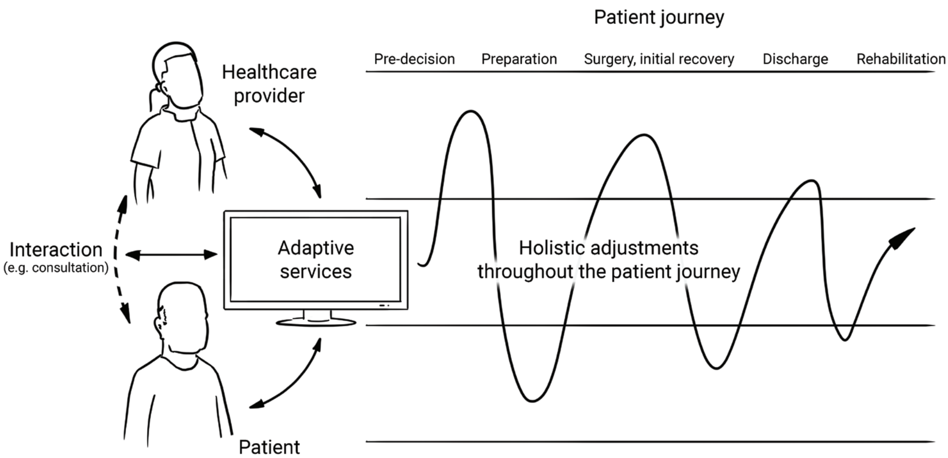

Figure 7.5. Diagram of services that are adaptive to patient, healthcare provider, and the interaction between the two, and allow for holistic adaptations throughout the patient journey.

7.10. Final thoughts

In all, there are many possibilities to use the patient profiles to improve THA care paths. The key to making tailored services successful in care practice lies in balancing the added value of a tool for patients with its feasibility for care providers. This requires design proposals that take the current care system into close consideration, but do try to bend the written and unwritten rules of the existing care process where possible and appropriate. Above all, to advance the process of care from a patient's point of view, future services can and should allow for active participation by patients when they want to, while promoting compassionate behavior by care providers. This is no straightforward task, but if it results in technology that makes healthcare more human, the effort is worthwhile.

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Het zal duidelijk zijn dat er op onze mooie faculteit in Delft heel veel fijne mensen rondlopen. Het zal wel even wennen zijn om dit achter me te laten bij mijn volgende stap. Toch heb ik daar ook heel veel zin in, en ben ik dankbaar dat ik bij Purpose een nieuwe sprong in het diepe kan maken.

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Curriculum vitae and publications

Bob Sander Groeneveld was born in Stad Delden, the Netherlands on November 5th 1988. He graduated at lyceum de Grundel (Hengelo OV, the Netherlands) in 2007 (subject clusters Science, Health and Technology). He obtained a Bachelor's degree in Industrial Design Engineering (cum laude, Delft University of Technology – 2010). During his Master's education in Integrated Product Design, he specialized in design for the healthcare sector (MSc. degree cum laude, including Medisign specialization, Delft University of Technology – 2013).

After his education, he participated in the high-intensity trainee program Teach First, which offered excellent young academics the opportunity to teach in secondary education and develop leadership in industry. As a freelance illustrator he occasionally does assignments and workshops on visual thinking. His PhD project was conducted at Delft University of Technology, faculty of Industrial Design Engineering (the Netherlands).

Publications

Groeneveld BS, Melles M, Vehmeijer SBW, Mathijssen NMC, Goossens RHM. Tailored Information Technology in Healthcare: Methodology of a Case Study Using a Web Application in Total Hip Arthroplasty. In: Cotrim TP, Serranheira F, Sousa P, Hignett S, Albolino S, Tartaglia R, editors. *Health and Social Care Systems of the Future: Demographic Changes, Digital Age and Human Factors Proceedings of the Healthcare Ergonomics and Patient Safety, HEPS, 3–5 July, 2019 Lisbon, Portugal.* Cham, Switzerland: Springer International Publishing AG; 2019. p. 334–41.

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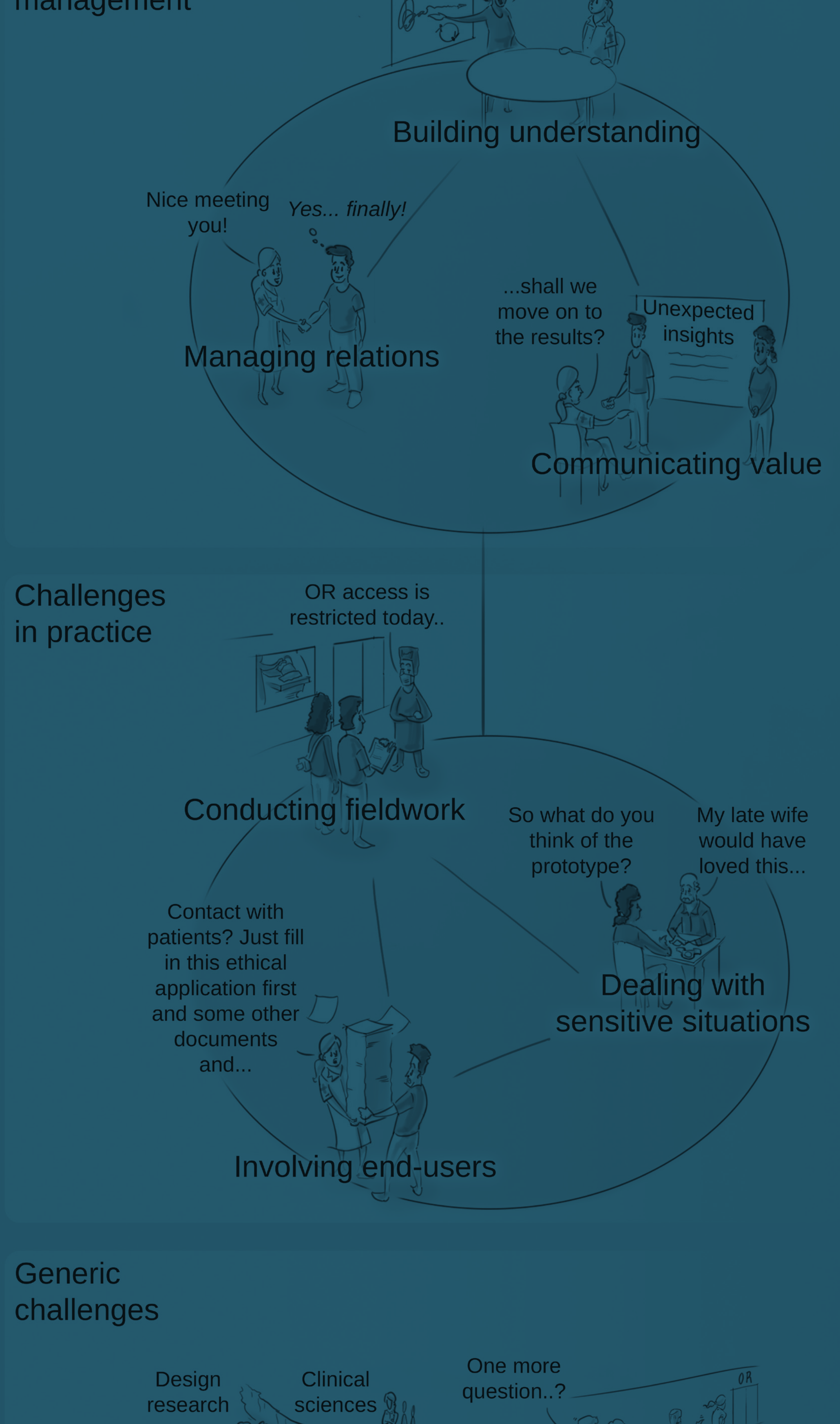
management
Building understanding
Nice meeting you!
Yes... finally!
Managing relations
...shall we move on to the results?
Unexpected insights
Communicating value
Challenges in practice
OR access is restricted today..
Conducting fieldwork
So what do you think of the prototype?
My late wife would have loved this...
Contact with patients? Just fill in this ethical application first and some other documents and...
Dealing with sensitive situations
Involving end-users
Generic challenges
Design research
Clinical sciences
One more question..?
OR

Appendix I: Overview of challenges for design researchers in healthcare

Appendix I provides a published overview of challenges for design researchers in healthcare that was published in parallel to this PhD project. This appendix is published as a research article.

Groeneveld BS, Dekkers T, Boon MJB, D'Olivo P. Challenges for Design Researchers in Healthcare. *Design 4 Health*. 2018; 2(2): 305-326.

All authors (Bob Groeneveld, Tessa Dekkers, Boudewijn Boon, and Patrizia D'Olivo) contributed equally to this publication.

Abstract

Design research in healthcare can be demanding. We report on eight challenges that designers and design researchers face when working on healthcare projects. We conducted four workshops with design researchers active in healthcare: six PhD candidates, a mixed group of thirteen design researchers, twelve design students, and eight design practitioners. Participants shared critical events from recent projects and reflected collaboratively to identify common challenges across different design approaches or disciplines. An analysis of the workshop ma-terials resulted in eight themes of challenges, divided into three clusters. The first cluster, challenges in practice, includes (1) *conducting fieldwork*, (2) *involving end users*, and (3) *dealing with sensitive situations*. The second cluster, managerial challenges, includes (4) *managing relations*, (5) *building understanding*, and (6) *communicating value*. Finally, in the third cluster, generic challenges, includes (7) *attuning to time and financial restrictions* and (8) *establishing rapport*. This overview can contribute to design education and practice by helping both novice and experienced designers recognize and anticipate potential hurdles when engaging with the complexities of the healthcare environment.

Keywords

Collaboration; design education; design management; interdisciplinary; narrative inquiry

8.1. Introduction

Going beyond its traditional role in the development of medical devices, design is now broadening its scope in shaping the future of healthcare practice.[1–3] Healthcare increasingly requires new ways of supporting patients, such as helping them understand the consequences of new treatments and extended lifespans,[4] promoting proactive decision-making to prevent illness and manage complex conditions,[5] and facilitating the use of tools to monitor their health on a daily basis.[6] Rather than being centred on the disease, these developments shift the focus of healthcare more towards the experiences, values, and quality of life of patients and their participation in care and treatment.[7,8] Similarly, health is increasingly no longer conceived merely as the absence of disease, but as the ability of patients to adapt and self-manage. This dramatically changes how professionals, patients, and the public engage with the topic of 'health'.[9]

We see similar developments in contemporary design research: people and experiences are taken as a starting point in experience design;[10] the potential for design to promote human values is studied in value sensitive design;[11] a positive impact on quality of life is a central goal in design for wellbeing;[12] and methods for people's involvement in the design process are developed in participatory design.[13] Given these parallels between contemporary healthcare and design research, it is no surprise that designers and design researchers increasingly contribute to shaping healthcare.

Designers and design researchers contribute to healthcare in a number of ways. As a discipline working at the interface between people and technology, design has long played an important role in the implementation of new technologies and medical devices in care domains. Furthermore, designers have applied information technology for health promotion through games,[14] wearables,[15] and other design interventions.[16,17] Participatory design has also gained traction in healthcare, empowering caregivers and recipients in shaping their future work and care.[18]

While design can play a valuable role in person-centred care, working as a designer in the context of healthcare can be demanding. In our work as design researchers, we experience a variety of challenges. For instance, healthcare researchers and practitioners are often unfamiliar with design in general, and with design research in particular. We note a number of differences in terms of research methodology. Design research often involves contextual inquiry, an emphasis on qualitative data, and user studies with small samples; in comparison, clinical research often takes the shape of randomized controlled trials with large samples and quantitative data. Similarly, it can be difficult for designers to get accustomed to healthcare procedures, standards, and culture. Finally, obtaining medical ethical clearance for design research studies can cause considerable delays. Through informal conversations with several design researchers, we noticed that many of the above challenges are not unique to our projects, but are actually commonly experienced.

Efforts have been made to identify these challenges. First, several one-off design inquiries report on healthcare-related challenges, such as healthcare professionals' unfamiliarity with the role of design in health,[3] the expectations of care professionals with regards to prototypes,[19] and managing multidisciplinary projects, such as the integration of different kinds of disciplinary expertise[20] and dealing with conflicting interests among collaborators.[21] While these contributions exemplify that healthcare is a challenging environment for designers to work in and provide actionable insights and suggestions, they do not originate from a collective reflection of designers and design researchers. As such, it cannot be assumed that the challenges also occur outside these specific projects.

An overview of challenges has also been created based on a collective reflection of Human-Computer Interaction (HCI) scholars on multiple projects carried out by different design teams.[22,23] Identified challenges concerned research ethics, lack of supportive policies, and the potential disruptive effect of technological interventions. However, HCI researchers often have different research goals and approaches than designers and design researchers. Moody[24] provides an overview of challenges applicable to design, but specifically focuses on user-centered design (UCD) in healthcare, discussing challenges of user involvement and effective communication of design thinking. Because of the specific focus on a single design approach, these findings do not necessarily reflect challenges shared among a broader range of approaches to design research in healthcare.

In summary, we argue that there is no clear overview of the challenges of design research in healthcare in the current literature. Specifically, previous work lacks generalizability and does not address challenges outside of the HCI or UCD disciplines. We suggest that mapping challenges, informed by a broad range of design practitioners and researchers can support future healthcare and design research collaborations. As such, this paper aims to provide a broad overview of the challenges design researchers encounter when working on projects in healthcare settings.

8.2. Methods

We ran a series of four workshops following a pilot-tested format. The main goal of the workshops was to identify key issues based on the participants' personal experiences. For this we took narrative inquiry as our main research approach,[25,26] investigating the ways in which design researchers experience challenges in their work as depicted through the stories they tell about particular critical events. These individual stories are then retold by the researchers and clustered into themes of challenges (see the Data collection and analysis section below).

Participants

A total of 39 participants attended the workshops, denoted as sessions (S) further in the text. We sought for diversity in our selection of participants, which is an appropriate sampling strategy for explorative studies.[27(p95)] The first session (S1) was conducted with six PhD candidates, of which one had a background as a general practitioner. They worked on various projects including redesign of electronic patient records and participatory service design in nursing. In the second session (S2) thirteen design researchers participated including: students working on their Master's degree; novice researchers with one or a few years' experience in healthcare design research; and more experienced (> 10 years) researchers. Examples of projects were the redesign of teamwork processes in the context of cardiology and the creation of a series of critical design artefacts exploring the shift towards home-based care. The third session (S3) was organized with 12 design students taking a master program specializing in design for healthcare at Delft University of Technology (the Netherlands). During the session, all students reflected on their experiences with a design project on operating theatres, as part of an elective course they followed. In the fourth session (S4), eight design professionals with an academic or applied sciences background took part. This group had several years' experience of working on projects such as patient journey mapping for chronic disease management and the redesign of a website for a paediatric hospital. Participants in the different sessions were affiliated with various institutions from the Netherlands as well as from Sweden, Australia, Germany, France, and the United Kingdom. Table 8.1 lists the numbers and background of participants for each session.

Table 8.1. Overview of numbers and background of participants for each session.

Session	Location, date	Setting	Participants	Participants' occupation	Background
S1	Brighton, UK, June 28th 2016	Workshop during Design Research Society (DRS) 2016 conference	6	PhD candidates (one former GP)	Various academic institutions: UK, France, Australia, Germany
S2	Amsterdam, NL, May 17th 2017	Workshop as part of the HospitAbLe exhibition of Lab4Living at Waag society	13	Design researchers (graduate level students, academic and non-academic researchers)	Various institutions: NL, Sweden, UK
S3	Delft, NL, June 14th 2017	Workshop as part of the master elective "Design of products for healthcare"	12	Design students (graduate level)	Academic institution: NL
S4	Delft, NL, June 16th 2017	Workshop as part of the Masterclass "Design for Healthcare"	8	Design professionals with an academic background	Various companies, NL

Abbreviations: NL = The Netherlands, UK = United Kingdom

Procedure

Informed consent was obtained before each session. All participants consented that the written, auditory, and visual information shared and generated during the workshop would be anonymized and thereafter could be used for publication.

During the 90-minute workshop, participants were guided through a 4-step procedure (see Figure 8.1). After a general introduction, participants interviewed each other about one memorable event they had experienced while doing design research in a healthcare setting (step 1). A memorable event was defined as *any personal event that the participants specifically remembered as a challenge that affected them, their work, or the context in which they were working*. In order to support the interview process, the participants were given a storytelling interview guide, a blank page for notes, and an *event card*. Participants formed groups of three and each subsequently took the role of interviewer, interviewee, or note-taker. When it was not possible to form groups of three, one person took on the role of interviewer and note-taker simultaneously. The storytelling interview guide was designed to facilitate the interviewer's narratives elicitation by exploring recent experiences of the interviewee.[26] The guide was divided into questions to help the interviewee in thinking of a specific event (i.e. *Can you think of a memorable event that occurred while you were working with design in healthcare?*) and to help the interviewer write down the event (i.e. *When and where did this event occur? Who was there when this event occurred?*).

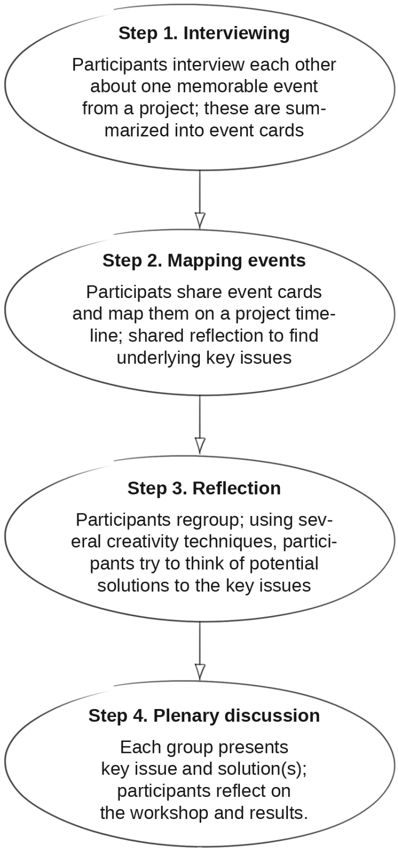

Figure 8.1. The workshop sessions were organized into four sequential steps.

The interviewer then asked questions to help the note taker write down a specific event on the blank page, resulting in a description of what, when, where, and with whom the event occurred. The event was summarized on an event card designed to contain self-explanatory short stories. Over three rounds, all three participants occupied each role, resulting in three filled-out event cards which were used in the successive step: *mapping events* (step 2). In this second step, participants were invited to reconfigure into groups of three to four people. Following an approach similar to contextmapping,[28] they were asked to share and complement each other's stories and map these on a project timeline (Figure 8.2, left). A 'timeline canvas' (divided into the phases of *project initiation, development, implementation, evaluation, and communication*) was provided. By reflecting together on event cards, participants drew and noted relations and underlying causes that connected the events. Using cardboard exclamation marks, they were instructed to identify 1 to 3 key issues or overlapping themes.

For the next *reflection phase* (step 3), participants rearranged into new groups of three to four. Each group was asked to select one exclamation mark (i.e. theme) and come up with a potential solution to the challenge described by the theme. This process was facilitated by creativity techniques, including formulating how-to statements, a brainstorm, and a brain writing exercise.[29(p119)] The brain writing exercise, in which participants wrote down as many ideas as possible in one minute before passing on the paper to their neighbour who builds on these ideas, was only carried out in session 1 due to time constraints. After the creativity techniques, participants were asked to select the one or two most promising ideas and note these on a solution canvas. The solution canvas consisted of who, what, where, why, how, and pitfall questions, and encouraged participants to elaborate and visualize their ideas.

The workshop concluded with a *plenary discussion* (step 4). Each group presented their challenge and solution(s) in a one-minute pitch. Together, participants reflected on the presented solutions. Furthermore, they were asked to share their main takeaway message from the workshop (Figure 8.2, right).

Data collection and analysis

Workshops were audiotaped and all written material generated during the workshop (including event-cards, timelines, solution canvasses) was collected. The written material was used as primary source of data. Figure 8.3 provides an example of the written material: a completed 'timeline canvas'. Auditory material was stored as a backup to clarify written statements by participants if required. All materials were anonymized.

Figure 8.2. During the sessions, participants mapped critical events and identified key issues (left). At the end of the session, participants presented a chosen key issue with potential solutions (right).

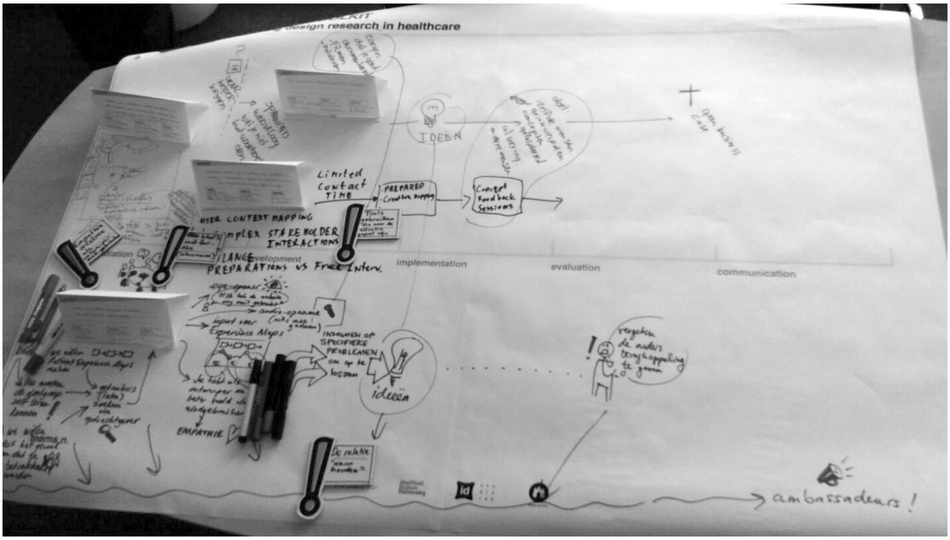

Figure 8.3. After placing event cards (the upright folded sheets) on a timeline canvas, participants made connections between them and identified key issues (the exclamation marks).

We used an inductive approach similar to qualitative content analysis[30] to identify the final themes and clusters. The qualitative analysis focused on the key challenges identified by groups of participants in step 2 of the workshops, as well as the specific experiences of individual participants linked to these challenges.

Data was analysed as follows: in a series of meetings, the authors summarized both verbatim key issues (e.g. ‘Use tools that are appropriate for the situation' - S4) in keywords (e.g. 'appropriate tools') and labelled these with the corresponding session and project phase(s) on sticky notes. The key issues were then sorted by session and by project phase to identify similar issues that could be merged into one theme (e.g. 'engagement' and 'eureka moment' in S2, both referring to key insights generated from the involvement of end users in the design process). Next, we considered the designers' individual experiences (as written on the event cards) and other notes taken during the workshop to identify similarities and differences between key issues that had not become apparent during the first sort of the data. From these analyses we derived eight higher-order themes that each described one or more key issues originally indicated by the participants. The relation between the original key issues and the final themes was discussed by all authors until consensus was reached on the categorization of the issues to each theme. Figure 8.4 visualizes this process of analysis; the final clustering of individual key issues into challenges is available on request from the corresponding author.

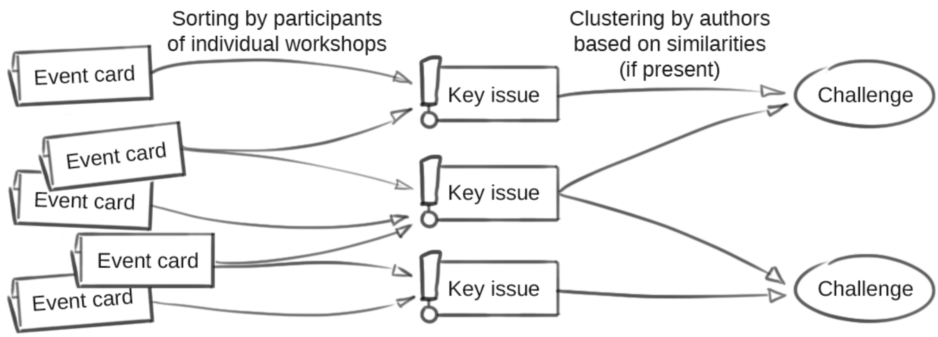

Figure 8.4. Event cards were clustered into key issues by participants from individual workshops. In the analysis, key issues were clustered by researchers based on apparent or implicit thematic similarities.

Since the scope of the work was to identify challenges of design researchers in healthcare, we did not regard solutions described by the participants as part of our interest. Rather, the solutions canvasses were used during the analysis only to better understand and more clearly define the challenges.

8.3. Results

Over all four workshops, participants formulated 20 key issues based on their experiences of design work in healthcare settings. These were clustered into eight themes, and subsequently divided into three broader clusters. The first cluster, practical challenges, includes (1) *conducting fieldwork*, (2) *involving end users*, and (3) *dealing with sensitive situations*. The second cluster, managerial challenges, includes (4) *managing relations*, (5) *building understanding*, and (6) *communicating value.* Finally, in the third cluster, generic challenges, includes (7) *attuning to time and financial restrictions* and (8) *establishing rapport*. These themes and clusters of challenges are presented in Table 8.2 and discussed in detail below.

Challenges in practice

The first set of challenges presented below relates to issues design researchers encountered when working in the field.

Conducting fieldwork

Several challenges arose when conducting fieldwork in clinical settings. At the start of fieldwork, especially the design students (S3) found it difficult to form *agreements* between involved parties. They expressed a general need to 'know the possibilities' for fieldwork within a given project, but had to 'balance between being polite and assertive' in gaining information or getting permission to be present during care procedures. This was further complicated by the fact that some care providers had no clear idea of what 'user research' entails. For example, students stated that the 'surgeon missed info [about the] research approach' that the students were taking, and that 'because of a lack of experience with user research, the whole procedure was confusing and difficult to perform'. The students indicated that they 'lacked knowledge of logistics/ context', concerning for example the 'availability of [the] surgeon'. Therefore, they saw this as challenge for both designer and provider; both parties 'lacked [...] knowledge on how the process would work'.

The design students mentioned that even after they reached agreement on fieldwork, they encountered challenges in *adapting to unexpected situations*. They stated that 'preparations do not always match reality'. More specifically,

Table 8.2. Main challenges experienced by design researchers in healthcare contexts.

Challenges levels	Theme	Description
Challenges within practice	Conducting fieldwork	Exchanging expectations and possibilities and reaching agreement prior to fieldwork. (Agreement)
		Adapting to restrictions and unexpected circumstances experienced during fieldwork. (Adaptation)
	Involving end-users	Involving care recipients, care providers, or both as end-users during the design project and using their input effectively. (Effective involvement)
	Dealing with sensitive situations	Approaching vulnerable end-users carefully and responsibly. (Vulnerability)
		Managing one's own reaction to confrontations with harm, violence, or death. (Self-protection)
Challenges in project management	Managing relations	Being able to gain the attention of, and build mutual interest and trust with, a healthcare organization or practitioner. (Initiating)
		Keeping the collaborators informed and engaged throughout the project. (Maintaining)
		Concluding the project and the developed relationships in an appropriate way. (Concluding)
	Building understanding	Recognizing differences in understanding between design researchers, care recipients, and care providers. (Recognising)
		Acting constructively upon the differences in understanding between design researchers, care recipients, and care providers. (Acting)
	Communicating value	Clarifying the added value of design work to the stakeholders involved in the project. (Clarifying)
		Aligning different expectations regarding the main value of the design work between design researcher and project stakeholders. (Aligning)

(Table 8.2. Cont'd)

Challenges levels	Theme	Description
Miscellaneous or generic challenges	Attuning to time and financial restrictions	Attuning the project tools and methods to fit time and financial constraints (including the limited medical specialists' availability)
	Establishing rapport	Creating a safe and open work context in which stakeholders can communicate easily and without prejudice.

students needed to adapt to restrictions: 'the environment is so controlled, it is difficult to improvise'. Others described how the 'surgeon was very strict and closed. That restricted research activities'. Students encountered a variety of unpredictable circumstances. For example: 'when I went to the hospital I had no guidance from the surgeon and felt lost'. In another case, a 'surgeon [told] her to wait and she appeared after two and a half hours'. This led us to conclude that challenges in fieldwork may arise at two points: first when establishing agreement about the possibilities and need for user research in healthcare settings, and second, in adapting to restrictions or unpredictable circumstances.

Involving end-users

Participants discussed the direct involvement of end users, for instance, in early prototype testing. When carrying out this work during healthcare design projects, participants encountered difficulties both in *involving* care recipients and/or care providers, and in *using their input effectively*.

User involvement was considered indispensable in producing valuable insights: 'insights into the needs of different users' (S4) and 'valid insights to inform and develop prototypes' (S2). However, it was experienced as challenging because care providers mediated the contact between care recipients and designers. This meant that contact with recipients could often not be arranged directly if the care providers were unavailable, despite availability of both other parties. For example, one participant had to postpone interviewing surgical patients due to unavailability of the surgeon: 'it took a while before [I] was connected to the orthopaedic surgeon. Communication took a long time' (S4). Strict protocols in clinical settings were mentioned as a potential cause; designers addressed this by substituting (possibly harmful or invasive) medical devices with simple prototypes that simulated the experience: '[it is] difficult to test in healthcare settings (rules, privacy, etc.) but much is possible [when] using prototypes or simulations' (S2).

New challenges of effective involvement emerged when participants had succeeded in contacting end-users. For one, it was noted that care providers and recipients were not accustomed to being involved in design and taking on a designer's role. Participants described 'the facilitation of helping people realize their ideas' (S2) as challenging, while it is relevant for 'allowing, enabling people to recognize they can help make and facilitate improvements and solutions' (S2). It required the 'designer's ability to be humble - not impose ideas' (S2). Together, these different aspects (e.g. arranging contacts, facilitation, and redistribution of roles) indicate a twofold difficulty in user involvement: not just to reach end-users, which was challenging specifically for care recipients, but also in involving all parties effectively.

Dealing with sensitive situations

A particular challenge of becoming immersed in the healthcare context and lives of vulnerable users relates to the sensitivity of this context. Sensitivity in healthcare contexts was described in two ways: taking the *vulnerability of care recipients* into account, and ensuring *self-protection* in sensitive situations. Vulnerability of stakeholders may surface unexpectedly, as noted by one participant: in a redesign project for a hospital website, parents of ill children talked with the design researcher about how they experienced their current situation and they suddenly became 'emotional.' (S4). Other participants consciously anticipated such situations; for example, one of the participants decided to take his time in making the care recipient feel more comfortable during the interview: 'so she trusted the designer and could share very intimate information' (S4).

Dealing with sensitive situations may also entail self-protection for the design researcher. An exceptional case was reported by a PhD candidate (S1) who witnessed direct and indirect evidence of harm inflicted on children when doing fieldwork for her project. She expressed that 'being confronted with violence exerted against children through observations or testimonials' was an intense experience. The same participant then rephrased her thought by asking the workshop audience 'How do we talk about death and violence?' (S1), suggesting that it is no easy task. This highlights two aspects that the designer and design researcher should take into account while dealing with sensitive situations; first, that some (unexpected) research situations are delicate for care recipients, and second that the design researcher may be confronted with situations that are emotionally charged and intricate.

Challenges in project management

Executing design work in the field is only one part of designers and design researchers' work. A large part of their job is related to project management: e.g. securing funding, tracking and communicating process, and engaging stakeholders. The set of themes below describes challenges related to managerial issues experienced in healthcare-design projects.

Managing relations

The participants described that care recipients and care providers were not only involved as end-users, but also as research collaborators. Effectively managing relations with and between these collaborators throughout the project was considered beneficial, yet challenging by participants at all levels of experience. Challenges in managing relations were described in three phases as *initiating*, *maintaining* and *concluding* relationships.

With respect to initiating a relationship, participants wondered 'How to motivate doctors to get actively involved in the development of a new product or service' (S4). One participant in particular shared that it took her 'two months before [getting] in contact with the orthopaedic surgeon.' (S4). In maintaining relationships, participants expressed difficulties in 'keeping the door open' (S1), keeping 'stakeholders motivated and enthusiastic' (S4), 'building trust' (S1), and finding ways to 'share the process and steps' (S4). Conclusion of relationships was discussed rarely and only in relation to care recipients. Nevertheless, it posed a challenge, as one participant expressed that the team 'forgot to give parents [of patients] feedback' about design results in the final stages of the project (S4).

Building understanding

One preliminary solution to effective relationship management posed by the participants included building empathy and understanding between collaborators and end users. Yet, building understanding was experienced as challenging in itself. Challenges regarding understanding manifested in two ways: *recognizing* the need for understanding and *acting* upon understanding.

In recognizing the need for understanding, design researchers referred to care recipients and the necessity to 'step into their shoes'. One participant described how a situation helped her to better understand elderly with dementia: 'during an interview with a couple with dementia, after 45 minutes the patient suddenly forgot that he was a patient.' (S2). A PhD candidate expressed that 'meetings can turn into tough moments' (S1), explaining that this happened in one of her projects due to misalignment and misunderstanding between various stakeholders.

When acting on these differences in understanding, participants shared that because they are 'being confronted with the fact that they had strong assumptions about a situation, there is a need for reflective tools to reframe the problem [...] and the means to address it.' (S1). Some participants already had strategies in place to reframe and be reflective. For instance, one participant considered rephrasing terms and language to be attentive towards the other parties: 'changing own words is being empathic' (S2). Other participants agreed that adopting specific techniques such as 'Appreciative Inquiry'[a] (S2) helped define the set-up of the investigation and could encourage everybody in the project to speak the same language.

Communicating the value of design

Related to building understanding was the challenge of communicating the value and contribution of design (research) to healthcare. All participants except the PhD researchers discussed how challenging it is to *clarify* this value and to align expectations on the design outcomes. The ability to argue for the value of design work was considered especially important during project initiation. For example, the designers felt they had to demonstrate 'what is in it for the interviewee' (S4) as their projects required initial time, energy, and monetary investments of stakeholders. When the added value was unclear, they felt it was difficult to justify these investments.

Design students in particular experienced difficulties in communicating value: '[it is] not clear what an industrial design student does and or can do' (S3). Yet, a more senior design researcher also described that 'I had a hard time bringing my expertise across when doing in-context research at the hospital' (S2). The breadth of design as a discipline, including 'fashion design, product

[a] Appreciative inquiry is "a research perspective intended for discovering, understanding, and fostering innovations in social-organizational arrangements and processes"[37(p124)]

design, graphic design, process design' (S2), further complicated discussions on the value of design as stakeholders (including the designer) had different notions of value. Other participants agreed, yet also considered this an opportunity for the design research field to frame its contribution to the healthcare sector: 'they know they need design, not why. For designers, this is an opportunity to see what design can be.' (S2). As one participant put it, 'what is "design" and what is "health"?' (S2).

Value was also discussed in terms of *aligning* expectations regarding the outcomes of a design project. Participants expressed that some clinical stakeholders expected a specific end product (e.g. a device, a website) while they regarded the design process itself also as valuable. 'Care people want to jump to results' (S2) one design researcher wrote in response to an event shared by a junior designer, who had finished a project about training residents in the operating theatre. 'The surgeon asked right away, "what will you do?" They are focused on results. That is the way they are taught.' (S2). Becoming aware of these different expectations and aligning them between stakeholders was viewed as a complex challenge.

Generic challenges

In addition to the practical and managerial challenges discussed above, other miscellaneous topics were highlighted by the participants. These more overarching or generic challenges concern difficulties that can aggravate other challenges, thereby slumping or limiting research efforts. These comprised challenges with attuning to time and financial restrictions, and in establishing rapport with stakeholders.

Attuning to time and financial restrictions

Financial and time restrictions can have a major impact on a project's development and success. Due to budget limitations, participants experienced that it was sometimes hard to reach professionals or keep in touch with them (see also 'managing relations'). One designer commented that once a connection was established 'communication has [had] large lags' (S4). Only afterwards did he discover that this was a consequence of monetary concerns, as the specialist could not be reimbursed for the effort in the design project. Time restrictions turned into a challenge when the aim was to '[...] arrange contact moments with users and get feedback within very limited time' (S4).

Establishing rapport

Many of the previously described challenges were considered to result from the different, even contrasting, nature of the domains involved: health (research) following structure and strict protocols, and design (research) processes based on flexibility, ambiguity, and creativity. Participants discussed a general necessity to 'understand how other dialects express themselves' (S2) in reference to the two knowledge domains (e.g. health and design). Creating a safe and open work context in which all stakeholders could communicate easily and without prejudice was considered a substantial challenge, as well as the main bridge capable of linking the two different fields.

8.4. Discussion

The aim of this paper was to understand and make explicit what challenges designers and design researchers face when conducting design work in healthcare contexts. We identified eight overarching challenges and divided these into three clusters: challenges occurring in practice, challenges in project management, and generic challenges that may aggravate other challenges. Although these challenges were described separately in the results, they are interrelated in various ways.

In Figure 8.5 we present a tentative overview of interrelations among the different themes and clusters of challenges. What we can see from the diagram is that challenges concerning project management and practice mutually influence one another. For example, a lack of understanding might result in unexpected restrictions and delays during fieldwork. This in turn complicates relations with stakeholders. Across the entire 'landscape' of challenges, *building understanding* plays a pivotal role due to its effects on managing relations and communicating value. We expect that building a good understanding among stakeholders can help avoiding many obstacles related to the other themes. Finally, the two miscellaneous challenges at the bottom of the diagram retain a more structural role in projects in healthcare. They underlie many of the other challenges. For example, attuning to time and financial restrictions plays a role in managing relations as well as conducting fieldwork.

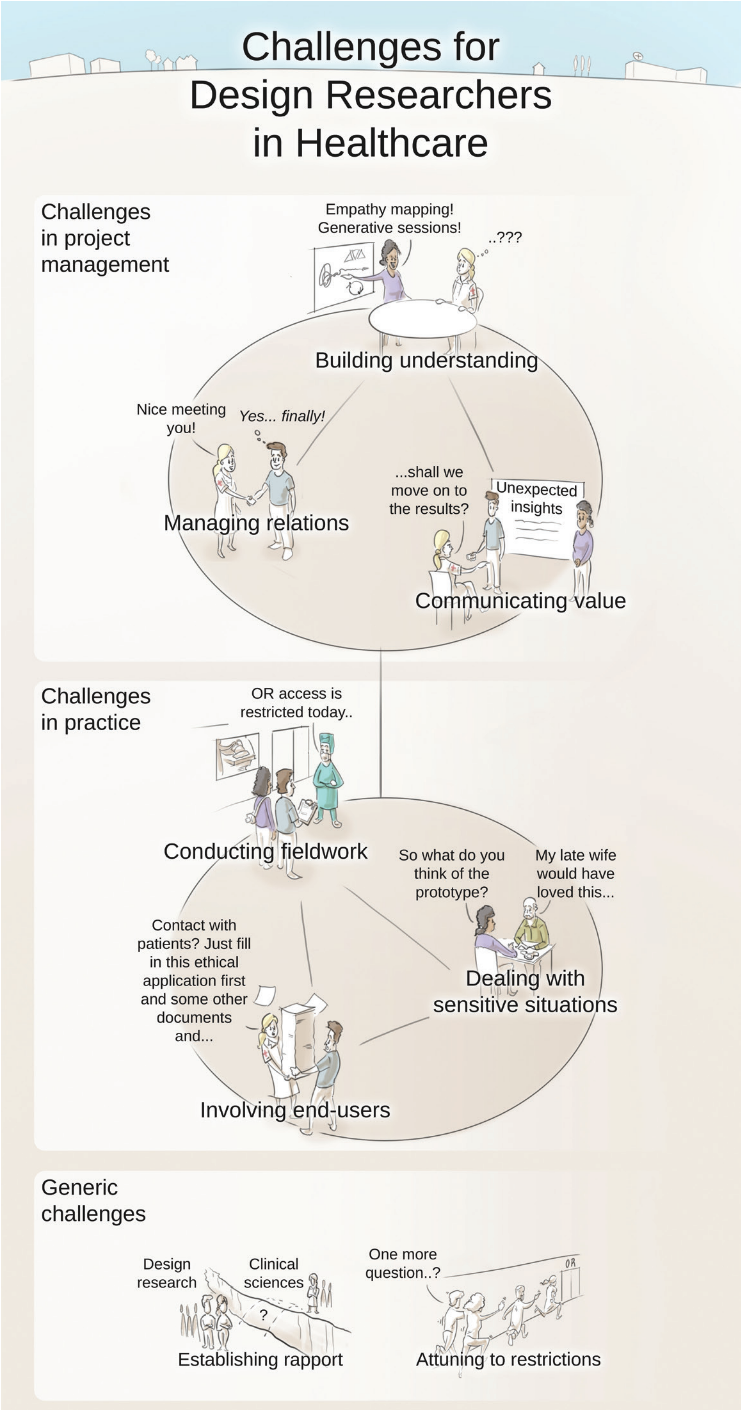

Figure 8.5. We identified eight themes of challenges that design researchers encounter in their work in healthcare contexts. These challenges relate to one another in various ways.

Due to the interrelations between challenges, addressing one challenge may contribute to solving other challenges. For example, participants envisioned that the care providers they collaborated with should become design research ambassadors to improve relationship management. Potentially, if clinical researchers would advocate design research to other colleagues, this could also communicate design's value. Despite this overlap, we feel that all themes do provide a specific set of challenges to focus on. Our experience is that discussing the various separate themes naturally results in making sense of their interconnections.

We do not assume that the challenges identified in this paper are necessarily unique to the healthcare context. They may be encountered more generally in interdisciplinary or participatory projects, or studies that involve extensive fieldwork. However, we do expect that many challenges are more prevalent, recurrent, or demanding in healthcare. For example, involving end-users can prove to be more difficult, since contact with care recipients generally occurs via care providers and involves additional medical ethical considerations.[31] In many other contexts, end-users can be approached directly, and this often requires fewer ethical considerations.

The challenges identified in this study are similar to those found in qualitative health research. For example, the perceived value of clinical qualitative research is often questioned.[32] With respect to vulnerability and sensitive situations, social researchers in healthcare have made a strong effort to provide guidance and support under the label of 'sensitive research'.[33] These extensive and elaborate contributions in the social sciences can serve as a valuable resource for design researchers as well, as their work is often qualitative and occurs in close contact with care recipients.

Our paper contributes to previous work in several ways. First, the challenges are grounded in the experiences of a variety of design researchers working in various contexts. In this way, it represents a broader design community than previously considered.[3,19,22,24] Second, this broader scope has resulted in a more complete set of challenges. In particular, the challenge of communicating the value of design was not reported in existing overviews. As we do not expect collaborations between the design disciplines and healthcare to decrease, the current broad overview can equip project managers, designers, and policy makers with timely knowledge to ensure success in future collaborations in healthcare.

Our findings have several implications. We specifically want to emphasize the educational value that our findings have for design students and researchers, and how both the design field and the healthcare field can learn from this content and anticipate hurdles during collaborations. There is a growing interest among design students in design for healthcare and wellbeing.[34] However, the design methods currently taught to design students do not sufficiently prepare students for the complex nature of healthcare contexts.[35] Others have highlighted the need for designers to cultivate skills and competences in order to perform patient-centered and evidence-based design in healthcare.[31] The challenges identified in this paper can serve as focal areas for developing and selecting the educational methods, skills and competencies to address in educational programs. Furthermore, the overview of challenges and their interrelations in itself may provide a valuable framework for design students to make sense of the complexities of working in healthcare and to contribute to what Aspinwall and Taylor[36] call 'proactive coping' – i.e. the process of anticipating problems and taking steps to prevent or modify them. Aspinwall and Taylor note that successful proactive coping requires problem owners to actively engage with these challenges, as opposed to trying to avoid them. Finally, we suggest that the abovementioned implications do not only apply to students, but extend to design practitioners and researchers who deal with managerial and fieldwork-related challenges on a regular basis.

This study also has several limitations. First, as in any qualitative work that involves interpretation, our personal experiences may have influenced the final selection of themes. Second, the overview of challenges is based on events that happened in the European, British, and Australian healthcare context. While we tried to include a wide range of possible professionals in the study, the cultural characteristics of these specific countries may have resulted in an overview that is not exhaustively representative for non-Western practice. Third, the workshop took place in an active group setting and mostly relied on written participants' statements. This resulted in less detail compared to qualitative interviews. Still, the variety of quotes allowed us to provide rich and informative descriptions of the challenges. Fourth, the intention of this paper to provide a generic overview of challenges may have led to the disregard of specific challenges related to a particular domain of care. Whether these specific challenges still fall within the themes identified in this paper, only future work can tell. Fifth, the identified challenges of 'user involvement', which emerged mostly during workshop 4, may be partially influenced by a master class in Patient Journey Mapping participants attended directly prior to the workshop. This method promotes user involvement and may have made the topic more salient to participants. A final limitation is that more than half of the participants could be described as novice design researchers; this could mean that several challenges may simply be overcome through experience. Future work can perhaps better distinguish between challenges of novices from those challenges that are more tenacious and independent of the level of experience or expertise.

Several future research directions can explore aspects not fully addressed in this paper. First, it would be valuable to know whether these challenges only occur in healthcare settings. As previously mentioned, we suspect that challenges are likely not unique to healthcare contexts; but rather more substantial there. For design education, it is especially important to gain a clear understanding of unique challenges, as these may point to specific strategies or skills to be addressed in curricula. A second direction for future research is to explore the prevalence, frequency, and impact of specific challenges. This should also include gaining a better understanding of how these challenges develop over time, for example, throughout the course of a project or collaboration. Together, the suggested research directions can create a more nuanced understanding of healthcare-related challenges and their dynamics. This can serve as a solid basis for devising new strategies and methods for design research in healthcare.

8.5. Conclusion

As healthcare is moving from a disease-oriented model towards care that aims to support and empower patients in various ways, exciting opportunities are emerging for design to contribute to the wellbeing and positive experience of both care recipients and care providers. However, conducting design research in healthcare settings is not an easy task and poses challenges for both novice and experienced design researchers. In this paper, we identified eight themes of challenges, ranging from dealing with sensitive situations to managing relationships with stakeholders and communicating the value that design can bring. The overview of challenges is a unique contribution as it is based on real-life experiences from a variety of design researchers with diverse disciplinary backgrounds. We suggest future work should explore under what conditions these challenges occur, what effects these challenges have on the design work as it emerges over time, and above all, which strategies are suitable to deal them. We trust that our overview of challenges will serve as a set of focal areas for design educators, design researchers, and project managers to formulate strategies that help them work more successfully in the complex environment of healthcare.

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Appendix II: HREC application and technical specifications of web application

Appendix II provides a more detailed technical description of the web application, which was submitted to a Medical Research Ethics Committee (MREC) as part of the final study (Chapter 6).

List of abbreviations and definitions

ABR	General Assessment and Registration form (ABR form), the application form that is required for submission to the accredited Ethics Committee; in Dutch: Algemeen Beoordelings- en Registratieformulier (ABR-formulier)
AE	Adverse Event
CCMO	Central Committee on Research Involving Human Subjects; in Dutch: Centrale Commissie Mensgebonden Onderzoek
CV	Curriculum Vitae
EU	European Union
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation; in Dutch: Algemene Verordening Gegevensbescherming (AVG)
IB	Investigator's Brochure
IC	Informed Consent
METC	Medical research ethics committee (MREC); in Dutch: medisch-ethische toetsingscommissie (METC)
(S)AE	(Serious) Adverse Event
SPC	Summary of Product Characteristics; in Dutch: officiële productinformatie IB1-tekst
Sponsor	The sponsor is the party that commissions the organisation or performance of the research, for example a pharmaceutical company, academic hospital, scientific organisation or investigator. A party that provides funding for a study but does not commission it is not regarded as the sponsor, but referred to as a subsidising party.
UAVG	Dutch Act on Implementation of the General Data Protection Regulation; in Dutch: Uitvoeringswet AVG
WMO	Medical Research Involving Human Subjects Act; in Dutch: Wet Medisch-wetenschappelijk Onderzoek met Mensen

Summary

Rationale: After a Total Hip Arthroplasty (THA), post-discharge contact moments with care providers may be scarce. Online resources may offer support, but these are based on the average patient and to optimize their supportive value they need to be tailored to patients' varying post-surgery information needs and capacities. In previous research, three subgroups were identified that are similar in these characteristics. It is hypothesized that these subgroups can be used to tailor online information resources for THA patients.

Objective: To evaluate tailoring components in a web application for THA patients and to refine guidelines for tailored web applications for patients.

Study design: Qualitative observational study: Evaluation of a tailored web application for THA patients.

Study population: 20 patients (adults) receiving THA within one month; 3 care providers.

Intervention: A tailored web application for THA patients. The web application informs THA patients about recommended activity levels in the first months after surgery using individualized thresholds based on daily step counts. The feedback given by the application is designed in three variants that match characteristics from three different THA patient subgroups defined in previous research.

Main study parameters/endpoints: Use and evaluation of the application by patients and care providers. After each consultation, patients will be interviewed about their experiences with the prototype. Participating care providers will also be interviewed at least once about their general experience with the prototype during consultations. In addition, web metrics will be recorded for each patient to assess usage over time. Parameter: The patient subgroups are used as parameter. Secondary endpoint: experiences of participating patients will be qualitatively compared to those of a control sample (data from earlier qualitative studies.)

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participating patients receive a wrist-worn step counter, and are given the option to monitor their step counts from three weeks before surgery until six week post-surgery. Participants can also use the web application, which includes completing a questionnaire and filling in daily step counts. Both tasks are not compulsory. Patients also partake in short interviews adjacent to post-surgery hospital visits; no additional site visits are required and patients are free to decline answering questions. The website may indicate that the patient can do more than what feels safe to him or her; in this unlikely event, patients are repeatedly instructed only to follow their own feeling. Patients may benefit from the information from the application, and have additional opportunities to share their experiences. The study can only be done with THA patients because they go through the process of recovery after THA.

9.1. Introduction and rationale

The elective procedure of a Total Hip Arthroplasty (THA) is increasingly followed by fast discharge to home. Historically, patients used to stay for up to seven days after surgery or even longer, whereas today patients are more often discharged from hospital after few days in the hospital or even on the same day.[1,2] This trend is driven in part by a clinically proven benefit: Most patients are able to recover safely or even more efficiently in fast-track THA trajectories.[2,3] However, it is also a way of increasing patient throughput, which is relevant in the context of financial pressure faced by many hospitals today.[1]

After discharge from the hospital, patients are mostly self-responsible for their recovery. For example, the surgery wound is checked after two weeks by a nurse instead of the surgeon, and an X-ray and consultation with the surgeon may occur in the sixth week. In-between these consultations, patients work on recovery themselves, perhaps supported by a physiotherapist, informal caregivers, or products and services such as educational booklets provided by the hospital. This post-operative protocol sets an average that works for most patients and is still feasible: that is, intensive and frequent contact with each and every patient after surgery cannot be realized, and is also probably unnecessary for most patients. Still, no two patients are identical. Orthopedic surgeons seem to account for differences between patients intuitively during the consultation, considering a patient's abilities, autonomy, and interpersonal behavior, and they also intuitively tailor their communication accordingly.[4] While this intuitive approach may have its deficiencies, indirect communication (such as information on web sites, and in flyers or booklets) usually has a one-size-fits-all format and does not take into account any differences between patients at all. So THA with fast discharge and few post-surgery consultations may be successful from a clinical perspective, but a challenge remains to meet individual patients' varying perioperative information and support needs.[3,5] This is especially the case because fulfilment of expectations is an important determinant for patient satisfaction after THA.[6]

Within this context, a user-centered design process can address this challenge, and we expect that it will result in tailored information resources. Tailored communication is originally described as "intended to reach one specific person, based on characteristics that are unique to that person, related to the outcome of interest, and derived from an individual assessment".[7] In this definition, tailoring is a way to optimally embed human factors principles in the design of online or print materials, given the variance in patients' needs and characteristics. Tailored communication has been conceptualized as a specific adjustment to the individual, rather than targeted communication which is adapted to groups of people.[7] Hawkins et al.[8] argue that it is more useful to view tailoring as a process of segmentation (dividing a generic target population into subgroups) and customization (making person-specific adaptations within each subgroup). The more communication is adapted in this way to recipient characteristics, the more it can be seen as tailored.[8]

Various reviews and meta-analyses exist of tailored interventions for general physical health behavior and education, providing insights and considerations for designing tailored services for lifestyle adjustment.[9–11] However, these lifestyle interventions are designed to prevent health decline. In contrast, THA is an elective procedure followed by a relatively well-defined period of physical rehabilitation. Thus, the goals of information provision are also very different in the THA context, and insights from health behavior change interventions offer little guidance in this case.

However, literature describing tailored information provision and support in THA through printed or online channels is very limited. Tappen et al.[12] describe the recording of patients' own exercise videos for review at home, leading to short-term benefit in physical functioning; Fortina et al.[13] discuss a guidebook with tailored exercise, with which patients seem highly satisfied; Jeong and Kim[14] outline an adaptive information website based on patient input of e.g. BMI, and Saunders et al.[15] also describe a protocol to evaluate a web application with tailored exercise recommendations. In addition to the limited body of research, authors are unaware of the contemporary terminology used to describe tailored communication interventions[8,16] and none of the resources explicitly apply the segmentation and customization mechanisms described above to realize tailoring.

To address the knowledge gap, we aim to investigate whether and how segmentation and customization as described by Hawkins et al.[8] can be applied in a web application for patients. This is done to realize a tailored web application that improves post-surgery support. We take THA as a case study. In order to realize a tailored web application that will add value for THA patients, it is necessary to evaluate at least one working prototype (intermediate version) with the target audience in context.

Objectives

Primary Objective

1. To describe the use and evaluation by patients and, if relevant, care providers, of a tailored web application prototype that aims to support THA postsurgery rehabilitation.

Secondary Objectives

1. To assess how and how often THA patients use a tailored web application prototype (use)
2. To assess the experiences of patients with the prototype, and their experienced impact on THA rehabilitation until week 6 post-surgery (evaluation)
3. To assess what differences exist in the abovementioned aspects, between patients from three different subgroups (that are similar in their communication preferences, experienced health, and coping).

9.2. Study design

A small-scale observational study design is used. Participants (THA patients) will be given the option to use a prototype of a web application, which they may use from three weeks before surgery to six weeks post-surgery. Patients are interviewed about their experiences after two post-surgery consultations. The study will be conducted at the Orthopedics department of Reinier de Graaf hospital (Delft); duration per participant will be 9 weeks, and the overall study is expected to last four months.

9.3. Study population

Population (base)

Patients of the outpatient department of orthopaedics and rheumatology of the Reinier de Graaf hospital (RdGG) will be recruited. Patients with a clinical diagnosis of hip OA and planned THA will be asked to participate in the study. A total of around 20 patients who meet all inclusion and exclusion criteria will be included.

An inclusion frequency of two patients per week is aimed for. Given that participating surgeons perform around 8 elective THAs per week on average, the total duration of the inclusion period is expected to be 2 to 3 months.

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

1. Planned THA within three to eight weeks
2. Age ≥18
3. Signed informed consent
4. Regular use of internet and e-mail.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

1. Insufficient knowledge of the Dutch language
2. Mental disability

Sample size calculation

Qualitative feedback forms the primary source of data in this study, so a sample size calculation is not possible but the estimated sample size is 20. Two considerations were used to estimate the sample size. This first is theoretical saturation: that is, the point at which additional data does not result in new themes or categories after analysis.[17] It is up to the researcher to assess whether saturation is reached;[18(p102)] we intend to use a 'stopping criterion' (number of cases that do not result in new insights) of two participants as a starting point. Second, we considered practical guidelines for usability testing in medical device development, which this study bears resemblance to. It is considered good practice in user evaluations to include at least five participants from each homogenous group in formative testing (i.e., testing with unfinished designs in order to improve the design).[19(p92)] Previous research has resulted in three subgroups of THA patients that are similar in their clinical, psychological, and communication characteristics (see also "Summary of findings from non-clinical studies" in paragraph 9.5), so a sample of at least 15 participants in necessary. Given that the subgroup to which each participant belongs will be determined during the study, we expect that some additional participants are necessary. We estimate that 20 patients will suffice; we also estimate that at this point the stopping criterion of two participants will be reached.

9.4. Treatment of subjects

Investigational product/treatment

This study evaluates a prototype of a tailored web application for THA patients. Patients will voluntarily use a prototype of the web application from approximately one month before surgery to the sixth week post-surgery. Participants are free to discontinue using the application; this information can also be used to improve the application. The web application informs THA patients about recommended activity levels in the first six weeks after surgery using daily step count thresholds that are individualized for each patient. The feedback given by the application is designed in three variants that match characteristics from three THA patient subgroups from previous research (see also "Summary of findings from non-clinical studies" in paragraph 9.5). The development process and application characteristics are further explained below.

9.5. Investigational product

Name and description of investigational product(s)

The intervention is a prototype of a web application Mijn Heupherstel (www.mijnheupherstel.nl). The application was developed in collaboration with Delft University of Technology. The application informs THA patients about recommended activity levels in the first six weeks after surgery using daily step count thresholds that are individualized for each patient. The feedback given by the application is designed in three variants that match characteristics from three THA patient subgroups from previous research (see also “Summary of findings from non-clinical studies” in paragraph 9.5).

The web application starts with a digital questionnaire to determine the subgroup that is the best match to the patient; this is a shortened version of the questionnaire used in previous research (see also “Summary of findings from non-clinical studies” in paragraph 9.5). An algorithm is used to assign a subgroup based on the responses, and the web application is adapted accordingly. For instance, patients in group A receive more detailed and neutral information, whereas patients in group C are provided with simple, affective messages (see also “Summary of findings from non-clinical studies” in paragraph 9.5 for more information on the subgroups).

After completing the survey, the patient can keep track of daily step counts before and after surgery. Patients use a step tracker (Fitbit, Inc., San Francisco CA) to record daily step counts. To determine the average pre-surgery physical activity level, daily step count tracking is started approximately one month before surgery. After surgery, patients receive weekly feedback on their weekly average step counts. The feedback mechanism was established in consultation with an orthopedic surgeon and guidelines from literature 20 (see also “Summary of findings from clinical studies” in paragraph 9.5). In short, a gradual increase in physical activity is recommended. When a patient wants to intensify his or her walking too quickly, the application will recommend to lower the weekly average, and if the patient is walking too little compared to his or her own pre-surgery average, the application will respond oppositely. The exact thresholds for high or low activity are determined each week for each individual patient, and are based on the weekly averages of daily step counts as they develop over time. This can be seen as a customization strategy.[8]

In addition, the feedback of the application is adapted to the subgroup to which the patient belongs. To this end, insights from earlier studies are translated to three variants of the application, corresponding to characteristics and wishes of the three subgroups. The adaptation in feedback mode is done in order to increase the personal relevance for the patient using the application, thereby enhancing the likelihood of elaboration on the message by the patient.[21] Fig. 9.1 shows the difference between feedback for the three subgroups. Patients in group A view a graph displaying the weekly average step counts as well as lower and upper thresholds; patients in group B receive a feedback message on whether they are currently doing OK or not; and patients from group C receive a message written as a quote from their orthopedic surgeon. This quote (accompanied by a picture of their surgeon) contains the same information as for group B, but is framed in a more personal and affective way.

Summary of findings from non-clinical studies

Fig. 9.2 provides an impression of the pre-clinical development process of the web application, which is described in more detail elsewhere.[22] (See also Chapter 2.) The segmentation and customization mechanisms applied in the web application are defined based on several studies. First, 191 patients who had recently undergone total lower limb arthroplasty completed a questionnaire consisting of a set of validated instruments to measure patients' communication preferences and psychological and clinical characteristics. Hip and knee surgery patients are similar in their communication needs,[23] and were pooled together to increase sample size. In the survey, we assessed patients' clinical, psychological, and communication characteristics using a series of validated questionnaires measuring quality of life,[24] self-perceived health status,[24] pain,[25] anxiety,[26,27] tendency to catastrophise pain,[28] coping style,[29] communication skills,[30] communication preferences,[31] and self-efficacy for health information .[32] We used the resulting data set to identify clusters of patients in a series of unsupervised and supervised machine learning methods, including cluster analysis[33,34] and recursive partitioning.[35,36]

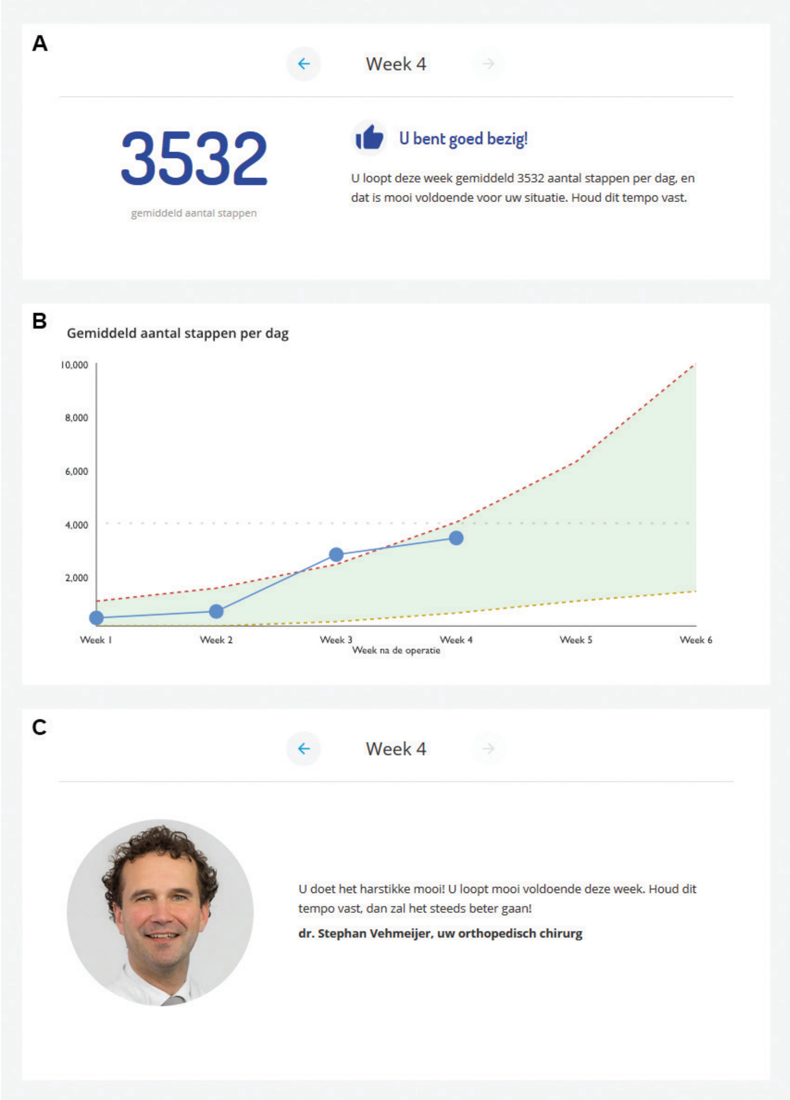

Figure 9.1. The feedback of the application is adapted to the subgroup to which the patient belongs: Patients in group A can view a graph displaying the weekly average step counts as well as lower and upper thresholds; patients in group B receive a feedback message on whether they are currently doing OK or not; and patients from group C receive a message written as a quote from their orthopedic surgeon.

Figure 9.2. Development process of a tailored web application in THA. More details on this development process are described in Chapter 2.[22]

This resulted in the identification of three subgroups. Subgroup A (44% of the study population) consisted of individuals with poor preoperative clinical status, who reported a diverse set of coping styles (e.g. active coping, planning, seeking support in others, self-distraction) and strong preferences towards communication, particularly discussing personal circumstances. Subgroup B (33%) had a good preoperative clinical status and quality of life, reported limited strategies for coping and found patient-provider communication of lesser importance, with the exception of a need for open information. Subgroup C (24%) was significantly older and more anxious. They reported coping behaviour that was distinct from other patients (e.g. coping through religion) and were less skilled and self-efficacious in communication about health.

A subset of these patients (n = 19) took part in generative sessions[37] to explore their experiences from the past and ideals for the future. Based on in-depth qualitative insights from this study, storyboards of design proposals for supportive products and services were created and evaluated with another subset of patients (n = 12).[38] This was followed by the creation of paper-based prototypes that were evaluated by a new sample of patients (n = 15) within the care process.[22] All studies were used to create and refine subgroup-specific guidelines for tailored web applications in THA (Fig. 9.2).

Summary of findings from clinical studies

The web application uses guidelines for increasing walking after a total hip arthroplasty. To determine maximum and minimum walking activity thresholds, pooled results from several studies into the acute : chronic workload (AC) ratio of Blanch and Gabbett[20] is used. The AC ratio is defined as the ratio between the workload of a given week (acute workload) and the average workload over the past four weeks (chronic workload). The ratio can be driven up by a large numerator (large acute workload) or small denominator (low chronic workload). Based pooled data from several sports a fitted polynomial (R^2 = 0,53) was established that provides the estimated risk of subsequent injury as a function of the AC ratio. In other words, the AC ratio should remain between certain boundaries for the risk of subsequent injury to be small.

In discussion with the orthopaedic surgeon participating in the project, it is reasoned that is the principle of physical activity in sports may correspond to walking activity in THA, and that THA bears similarity to a sports injury. As such, the principle of AC ratios is applied in the web app. Based on the previous study,[20] an AC ratio of 1,746 is taken as the upper limit to increase walking activity (10% estimated risk of subsequent injury), and an AC ratio of 0,5 is taken as the lower limit (estimated risk of injury increases to 5 percent; an AC ratio of 0,923 is associated with the lowest risk of subsequent injury).

Summary of known and potential risks and benefits

After performance of risk identification and analysis, it can be concluded that the potential risks are minimal, especially after mitigation. Refer to paragraph 9.11 for the report.

Patients may benefit from the information from the application, which allows them to track their progress over time after THA. In earlier studies (see also "Summary of findings from non-clinical studies" in paragraph 9.5) patients indicated that they would find it highly valuable to have an indication on whether they are 'on track' with their rehabilitation.

9.6. Methods

Study parameters/endpoints

Main study parameter/endpoint

Main study endpoints are insights into the use and evaluation of the prototype by THA patients from different subgroups. As such, results will be based on qualitative feedback from patients and care providers, as well as metrics describing participants' use of the application. The patient subgroups will be taken as a parameter.

Secondary study parameters/endpoints (if applicable)

Feedback from care providers will form the secondary endpoint of this study.

Study procedures

Eligible patients are screened in consultation with the care providers involved, using the planned date of surgery as a starting point. Eligible subjects are called around one month before planned THA date. If a patient indicates that he or she is interested in participation, a mail containing the patient information for the study will be sent to him or her. These patients will be contacted after 3 to 4 days; in case of non-respondence, another phone call will be made one day later. During the first appointment to the hospital after informal consent, patients provide informed consent. During this meeting, participants are lend a Fitbit Alta HR™ (Fitbit, Inc., San Fransisco CA) for use during the study. They will also register on the web application during this meeting, with the help of the researcher if necessary. If the first hospital visit of a participant is further into the future than two weeks, the informed consent form and/or device will be sent to participants over mail, or a researcher will visit the participant at home to explain the device and answer any questions about the web application.

Participants will then use the prototype of the web application from approximately one month before surgery to the sixth week post-surgery. After consultations in week 2 and 6 post-surgery, patients will be interviewed about their experiences with the prototype and their perceived impact of the prototype on their rehabilitation. Patients will be asked about their general experience and impressions at first ("How did you experience using the prototype so far?") Subsequently, specific questions will be asked regarding the different features of the prototype ("What do you think are strong or weak aspects of this feature? What points for improvement can you think of for this feature?"). Follow-up questions will be asked based on answers given by participants ("Can you elaborate on the answer you just gave regarding [general experience with prototype/a specific prototype function or feature]?") Patients will also be asked to estimate the impact of using the prototype on their communication with the healthcare provider during the consultation ("To what extent do you think the prototype did or did not influence the conversation in your post-surgery consultations? What makes you think this?").

Participating care providers will also be interviewed at least once about their general experience with the prototype during consultations. Specifically, they will be asked to evaluate the use of the prototype and the overall interaction across all cases, and they will be asked to shortly explain this evaluation through similar questions as those described above.

In addition, one post-surgery consultation will be observed (in week 6, with surgeon) to observe any impact of prototype use on the consultations (e.g. subjects discussed, specific details mentioned by patients regarding daily step counts, etc.). Web metrics will be recorded for each patient to assess how many times he or she has logged in over time, and which pages of the prototype were regularly visited upon log-in.

The prototype will be embedded in the THA care pathway at Reinier de Graaf hospital as unobtrusively as possible. The prototype will impose no restrictions to optimal or usual care. This also means that patients and care providers are free to use, or discontinue using, the prototype during consultations or at home. Participants are however requested to report discontinued or altered use to the researchers. Reasons for discontinued, incomplete or altered prototype use will be taken into account in iterating and improving the design.

To stimulate intervention adherence (i.e. the use of the prototype), a researcher will shortly explain the use of prototype to participants, and will also be present in meetings where the prototype is used.

Withdrawal of individual subjects

Subjects can leave the study at any time for any reason if they wish to do so without any consequences. The investigator can decide to withdraw a subject from the study for urgent medical reasons.

Specific criteria for withdrawal (if applicable)

If participating patients feel uncomfortable with the information given by the application, they are first urged to contact the researchers or care providers at Reinier de Graaf hospital and they are also urged to view their own sense of safety as leading. If this does not take away the discomfort in using the application, the participant will be withdrawn.

Replacement of individual subjects after withdrawal

Subjects will not be replaced. As described in the sub section “Study procedures” (current paragraph), reasons for discontinued, incomplete or altered prototype use will be taken into account in iterating and improving the design.

Follow-up of subjects withdrawn from treatment

Subjects withdrawn from treatment will receive an exit interview about their experiences, as described in the sub section “Study procedures” (current paragraph), specifically focused on learnings to prevent discomfort with the information given by the application in the future.

Premature termination of the study

The study will be terminated prematurely if the estimated sample size for patients cannot be met within the time available for inclusion (3 months; this limit was set due to limited total project runtime). In this case, analyses will be done based on the subjects that were included in the study. Participating care providers will be informed about the study termination.

9.7. Safety reporting

Temporary halt for reasons of subject safety

In accordance to section 10, subsection 4, of the WMO, the sponsor will suspend the study if there is sufficient ground that continuation of the study will jeopardise subject health or safety. The sponsor will notify the accredited METC without undue delay of a temporary halt including the reason for such an action. The study will be suspended pending a further positive decision by the accredited METC. The investigator will take care that all subjects are kept informed.

AEs, SAEs and SUSARs

Adverse events (AEs)

Adverse events are defined as any undesirable experience occurring to a subject during the study, whether or not considered related to use of the prototype of the web application. All adverse events reported spontaneously by the subject or observed by the investiga¬tor or his staff will be recorded.

Serious adverse events (SAEs)

A serious adverse event is any untoward medical occurrence or effect that

1. results in death;
2. is life threatening (at the time of the event);
3. requires hospitalisation or prolongation of existing inpatients' hospitalisation;
4. results in persistent or significant disability or incapacity;
5. is a congenital anomaly or birth defect; or
6. any other important medical event that did not result in any of the outcomes listed above due to medical or surgical intervention but could have been based upon appropriate judgement by the investigator.

An elective hospital admission will not be considered as a serious adverse event.

The investigator will report all SAEs to the sponsor (research coordinator and head of department) without undue delay after obtaining knowledge of the events. The investigator will also instruct involved care providers to immediately inform the investigator and/or the sponsor if they observe any of the SAEs described above.

The sponsor will report the SAEs through the web portal ToetsingOnline to the accredited METC that approved the protocol, within 7 days of first knowledge for SAEs that result in death or are life threatening followed by a period of maximum of 8 days to complete the initial preliminary report. All other SAEs will be reported within a period of maximum 15 days after the sponsor has first knowledge of the serious adverse events.

Follow-up of adverse events

All AEs will be followed until they have abated, or until a stable situation has been reached. Depending on the event, follow up may require additional tests or medical procedures as indicated, and/or referral to the general physician or a medical specialist.

SAEs need to be reported till end of study within the Netherlands, as defined in the protocol.

9.8. Statistical analysis

Feedback from patients and care providers will be qualitatively analysed. Metrics describing participants' use of the application will be presented through descriptive statistics, confidence intervals, and data visualizations (graphs). The THA patient subgroups will be taken as a study parameter where possible: Results will be described separately for each subgroup.

Primary study parameter(s)

Feedback (interview responses) from patients and care providers will be analysed and presented qualitatively. Specifically, interview data will be analysed inductively, in accordance with the guidelines of qualitative content analysis.[39] Each transcript is segmented into 'meaning units', containing words, sentences or paragraphs that are related in terms of their content and context. To summarise the content, all meaning units are condensed and interpreted. These condensed meaning units are grouped into categories, which are then grouped into themes. Themes will be generated inductively, and may for instance concern prototype features, the interaction between the patient and the care provider, and patient or care provider experience of their interactions in general. Structures and themes will be identified for each subgroup of patients. The perceived impact on the consultation (from interview data) will be analysed separately as well.

The analysis will be considered satisfactory when rich qualitative insights can be described for each subgroup regarding the web application prototype. These insights should be actionable in the sense that they can guide further development of the application. In addition, it should be possible to indicate differences and similarities between the subgroups for patients' evaluations of the prototype. Finally, the criterion of theoretical saturation is used for the sample as a whole: Qualitative data from the last participant should not add new categories or themes to the overall analysis. (See also "Sample size calculation" in paragraph 9.3.)

Descriptive statistics (means, ranges, standard deviations) will be generated for the web application usage, and the results will be presented for each sub group separately. Confidence intervals will be generated to estimate differences in usage between subgroups.[40] This data will be presented visually: Line graphs or histograms will be used to illustrate the number of logins over time for individual participants (anonymously) or for patient subgroups, and flow diagrams will illustrate which pages were visited for each login. An intention-to-treat principle will be adhered to in analysing usage data.

Quantitative data analysis will be satisfactory when usage data (as gathered through web metrics) are known for all participants, and a preliminary assessment can be made whether usage patterns are similar or different for each of the subgroups. Sample sizes are too small for inferential statistics, but confidence intervals may be used to make such a preliminary assessment.[40]

Secondary study parameter(s)

The determination of the subgroup that best matches to each participant is the main secondary parameter of this study. Based on previous research (see also "Summary of findings from non-clinical studies" in paragraph 9.5) non-discriminating variables were eliminated from the original survey, and patients only fill out a shortened survey in the web application. For the shortened survey, the subset of variables includes age, anxiety,[26,27] pain catastrophizing,[28] coping style,[29] skill in active-disease related communication,[30] and preference for open communication.[31] Eliminating non-discriminating variables reduced the survey length from 40 to 10 minutes. For the determination of the subgroup to which a patient belongs, a classification algorithm is used: A series of decision trees is applied to the data, and the outcomes of each individual decision tree is pooled in order to find the subgroup that best matches with the participant. A web-based version of the software R (the R project for statistical computing, www.r-project.org) is used to carry out the classification algorithm. The accuracy of this approach is estimated at around 80 percent.

9.9. Ethical considerations

Regulation statement

The study will be conducted according to the principles of the Declaration of Helsinki (version 10, October 2013) and in accordance with the Medical Research Involving Human Subjects Act (WMO).

Recruitment and consent

See also "Study procedures" in paragraph 9.6. Eligible patients are screened in consultation with the care providers (orthopaedic surgeons) involved, using the planned date of surgery as a starting point. Eligible subjects are called around one month before planned THA date. If a patient indicates that he or she is interested in participation, a mail containing the patient information for the study will be sent to him or her. These patients will be contacted after 3 to 4 days; in case of non-respondence, another phonecall will be made one day later. During the first appointment to the hospital after informal consent, patients provide informed consent. If the first hospital visit of a participant is further into the future than two weeks, the informed consent form will be sent to participants over mail, or a researcher will visit the participant at home.

Patients from the reference sample were included in previous research that fell outside the scope of WMO; therefore there will be no formal inclusion of the reference sample within this study.

Benefits and risks assessment, group relatedness

After performance of risk identification and analysis, it can be concluded that the potential risks are minimal, especially after mitigation. Refer to paragraph 9.11 for the report.

Patients may benefit from the information from the application, which allows them to track their progress over time after THA. In earlier studies (see also "Summary of findings from non-clinical studies" in paragraph 9.5) patients indicated that they would find it highly valuable to have an indication on whether they are 'on track' with their rehabilitation.

Compensation for injury

The sponsor has a liability insurance which is in accordance with article 7 of the WMO.

The sponsor has obtained dispensation from the local MREC (METC Zuidwest Holland) for the insurance cover for damage to research subjects through injury or death caused by the study (Article 7 WMO). Given the nature and design of the application and the safety procedures within the study (see paragraph 9.11, this risk is deemed sufficiently low.

Incentives (if applicable)

Participating patients will receive a 40 euro gift voucher for their efforts.

9.10. Administrative aspects, monitoring and publication

Handling and storage of data and documents

Data are handled encoded. All subjects participating in the pilot study will be linked to a subject identification code; this code is generated when the subject receives the first message to register on the web application. The code is used to encrypt personal data on the web application. The key of the code (and link to personal data) is safeguarded by the principal and coordinating investigator.

Usage data will be exported from the web application analysis portal using this code.

Participant feedback data (summaries) are recorded in Excel 2016 for Windows, using the same codes as the web application. This file is password-protected. Audio recordings of interviews are also anonymized using the subject codes from the web application. Analysis of patient input will be done in collaboration with Delft University of Technology. As such, files related to (qualitative) patient input are stored in a password-protected server at Delft University of Technology (SURFdrive cloud storage service for Dutch education and research) for the duration of the analysis; afterwards, all data are exported in a zipfile and stored for 15 years at Reinier de Graaf hospital. The attending physician, the researchers and, where appropriate, monitors and staff of the IGJ have access to source documents. The handling of personal data will be comply with the AVG.

Monitoring and Quality Assurance

All studies are monitored annually by an independent physician of Reinier de Graaf hospital, who is not involved in this study.

Amendments

Amendments are changes made to the research after a favourable opinion by the accredited METC has been given. All amendments will be notified to the METC that gave a favourable opinion.

Annual progress report

The sponsor/investigator will submit a summary of the progress of the trial to the accredited METC once a year. Information will be provided on the date of inclusion of the first subject, numbers of subjects included and numbers of subjects that have completed the trial, serious adverse events/ serious adverse reactions, other problems, and amendments.

Temporary halt and (prematurely) end of study report

The investigator/sponsor will notify the accredited METC of the end of the study within a period of 8 weeks. The end of the study is defined as the last patient's last visit.

The sponsor will notify the METC immediately of a temporary halt of the study, including the reason of such an action.

In case the study is ended prematurely, the sponsor will notify the accredited METC within 15 days, including the reasons for the premature termination.

Within one year after the end of the study, the investigator/sponsor will submit a final study report with the results of the study, including any publications/abstracts of the study, to the accredited METC.

Public disclosure and publication policy

This study will be registered on www.trialregister.nl to receive an NTR-code. The researchers aim to publish the results of this study in an orthopaedic journal or conference. Every effort will be made to realize timely publication of the results, both positive and negative.

9.11 structured risk analysis

Risks / Failure modes

● R1	Biocompatibility	Allergic reaction to wearable device
● R2	Biocompatibility	Irritancy while using wearable device
● R3	Usability	Patients do not understand application or instructions
● R4	Biomechanical	Patient ignores bodily signals and over exercises
● R5	Psychological	Patient experiences distress from information in application
● R6	Privacy	Data is leaked/passwords stolen

Risk Analysis

Summary

An executive summary of the risk categories after mitigation is stated below in table 9.1.

Table 9.1. Quasi-quantitative risk matrix after mitigation.

	Negligible	Minor	serious	critical
Frequent				
Probable				
Occasional		R3		
Remote		R1, R2, R5, R6	R4	

Failure Mode and Effect Analysis (FMEA)

Risk evaluation was performed by giving every severity level a rating (S) and every probability level a rating (P).

The risk score, R, of the various risks / failure modes is determined as follows:

$$R = S \times P \qquad (1)$$

Tables 9.2 and 9.3 list descriptions and severity/probability levels to determine the ratings and score for every risk.

Table 9.2. Qualitative severity levels.

Severity levels	Description	Rating (S)
Critical	Serious discomfort and/or pain for the patient.	4
Serious	Moderate discomfort and/or pain for the patient.	3
Minor	Minor discomfort and/or pain for the patient.	2
Negligible	Inconvenience or temporary discomfort.	1

Table 9.3. Qualitative probability levels.

Probability levels	Description	Rating (P)
Frequent	Likely to happen during the duration of trial.	4
Probable	Can happen, more frequently during the duration of trial.	3
Occasional	Can happen, but not frequently during the duration of trial.	2
Remote	Unlikely to happen during the duration of trial.	1

In table 9.4, risk scores for every risk / failure mode can be seen before and after mitigation.

Risk evaluation

The risk scores for every risk / failure mode have been plotted against their corresponding severities (S) and probabilities (P) before mitigation in table 9.5. The same has been done after mitigation in table 9.6. We stated that a risk score of 4 or higher is unacceptable and therefore requires mitigation. Risks R3, R4, R5 and R6 had a risk score of four or higher before mitigation. As can be seen, after mitigation, all risk numbers except R3 are lower than four. As the usability of the application is still under development, we consider the risk score of R3 to be acceptable for the duration of the trial. Insights from the trial will be used to reduce the probability of R3 in future versions of the application.

Table 9.5. Quasi-quantitative risk matrix before mitigation.

	Negligible	Minor	serious	critical
Frequent				
Probable		R3, R5		
Occasional		R6	R4	
Remote		R1, R2		

Table 9.6. Quasi-quantitative risk matrix after mitigation.

	Negligible	Minor	serious	critical
Frequent				
Probable				
Occasional		R3		
Remote		R1, R2, R5, R6	R4	

Table 9.4. Failure Mode and Effect Analysis (FMEA)

Category	Risk number	Description	Severity (S)	Probability (P)	Risk score	Why dangerous	Mitigation	Implementation date	S	P	New risk score
Bio-compatibility	R1	Allergenic reaction to wearable device	Minor (2)	Remote (1)	2	Patient may develop painful or uncomfortable rashes	Use certified device; communicate manufacturer's safety instructions to participants; Discuss with patient if alternative means of step tracking (e.g. phone-based) is possible	21-01-2019	2	1	2
	R2	Irritancy while using wearable device	Minor (2)	Remote (1)	2	Patient may develop painful or uncomfortable rashes		21-01-2019	2	1	2
Usability	R3	Patients do not understand application or instructions	Minor (2)	Probable (3)	6	Patient cannot correctly use application	Usability test with five people from target audience to isolate any usability issues	17-01-2019	2	2 (Occasional)	4 (acceptable for formative nature of evaluation)

(Table 9.4. Cont'd)

Category	Risk number	Description	Severity (S)	Probability (P)	Risk score	Why dangerous	Mitigation	Implementation date	S	P	New risk score
Biomechanical	R4	Patient ignores bodily signals and over exercises based on application information	Serious (3)	Occasional (2)	6	Patient may be injured because he/she starts walking too much too soon	Provide several prompt in application that patients should always ignore application information if it conflicts with their own feeling of safety or bodily signals; two additional phone calls in week 1 and 4 after surgery to check possible over exercise/distress	17-01-2019	3	1	3
Psychological	R5	Patient experiences distress from information in application	Minor (2)	Probable (3)	6	Patient may experience severe stress and uncertainty from using application		17-01-2019	2	1	2
Privacy	R6	Data is leaked/ passwords stolen	Minor (2)	Occasional (2)	4	Personal data may be leaked	Generate unique master password for application monitoring; host application on secure server and encrypt data following latest conventions; do not store sensitive information or hospital data on site beyond date of surgery	2-10-2018	2	1	2

Risk control

Where risk reduction is required, risk control activities were performed. The risk control activities for every failure mode are stated below:

a. Inherent safety by design
b. Protective measures in the application itself or in the development process
c. Information for safety
d. Alternative instruments

Table 9.7 summarizes risk mitigation measures for each failure mode.

Table 9.7. Risk control activities for each failure mode and their respective mitigation measures

Failure mode	Risk control	Description
Allergic reaction to wearable device (R1); Irritancy while using wearable device (R2)	a	Use CE-certified step tracker (Fitbit, Inc., San Francisco CA)
	c	Communicate manufacturer safety instructions to participants
	d	Discuss with patient if alternative means of step tracking (e.g. phone-based) is possible
Patients do not understand application or instructions (R3)	b	Usability test with five people from target audience to isolate any usability issues
Patient ignores bolidy signals and overexercises based on application information (R4); Patient experiences distress from information in application (R5)	b	Provide several prompts in application that patients should always ignore application information if it conflicts with their own bodily signals
	c	Two additional phone calls by consulting nurses/ investigator in week 1 and 4 after surgery to check for possible over exercise/distress
Data is leaked/ passwords stolen (R6)	a, b	Generate unique master password for application monitoring; host application on secure server and Secure online access with SSL/TLS certificates; do not store sensitive information or hospital data on site beyond date of surgery

A comprehensive explanation of the measures taken to mitigate the failure modes listed in table 9.6 is given below for each risk control activity.

a. Safety by design

Allergic reaction and Irritancy (R1, R2)

To decrease the chances of the step tracker causing an allergic reaction or irritancy, a CE-certified device (Fitbit Alta HR™, Fitbit, Inc., San Fransisco CA) is used during the study.

Data leaks / privacy breaches (R6)

Participant data is kept safe by a computer-generated user code that is used as a unique key to anonymize the data. Participants also generate their own password for using the application when they first register. For sending a registration email to the patients we make use of the Mailjet API, which is GDPR and ISO27001 compliant.[a]

The application is designed in such a wat that no sensitive or personal information or hospital data is stored in the application, except for date of surgery, name, and mail address. The participant number for the web application also cannot be linked to other databases such as medical records.

b. Protective measures in the application itself or in the development process

Issues in usability/understanding (R3)

To mitigate this issue, a usability test was carried out with five persons from the target audience 2 male, 3 female, mean age 63) using a paper version of the application.[19(p91)] Screenshots of the application (draft from November 2018) were shown to the participants, and questions about functionalities, descriptions or explanations were asked to assess their understanding of the application in its current form. Several minor issues were resolved based on user comments, for instance in placement and size of buttons and explanatory texts.

[a] Mailjet (2019). Security and privacy. Accessed 1-2-2019 at https://www.mailjet.com/security-privacy/

Over exercising (R4) or distress (R5)

To prevent misuse or negative psychological effects from using the application, it is repeatedly mentioned in the application that patients should always ignore information from the application if it conflicts with their own feeling of safety or bodily signals. This message is shown every time that patients receive feedback about the step progress, after each time they enter or adapt daily step counts.

Data leaks / privacy breaches (R6)

A unique master password is generated for the administrator environment to monitor application usage and patient data. This password is known only by the investigator. Logging in is done with SSH key based authentication.

The application is hosted on a Virtual Private Server(VPS) at Digital Ocean, at a data center in Amsterdam.[a] The specific Amsterdam data center (AMS3) is ISO/IEC 27001:2013 compliant.[b] All serverside (application back end, databases, analytics back end) all are run on the same VPS. All web access will be secured with SSL/TLS certificates.

Research data from participants that is not generated by using the web application are stored in a password-protected server at Delft University of Technology (SURFdrive cloud storage service for Dutch education and research) for the duration of the analysis; afterwards, all data are exported in a zipfile and stored for 15 years at Reinier de Graaf hospital.

c. Information for safety

Allergic reaction and Irritancy (R1, R2)

The following safety instructions from the step tracker manufacturer will be communicated to participants:

“Prolonged contact may contribute to skin irritation or allergies in some users. To reduce irritation, follow four simple wear and care tips: (1) keep it clean; (2) keep it dry; (3) don’t wear it too tight, and (4) give your wrist a rest by removing the band for an hour after extended wear.”[c]

[a] DigitalOcean (2019). Data security; GDPR; Data Porcessing Agreement. Accessed 1-2-2019 at (respectively) https://www.digitalocean.com/legal/data-security/; https://www.digitalocean.com/legal/gdpr/; https://www.digitalocean.com/legal/data-processing-agreement

[b] DigitalOcean (2019). Compliance. Accessed 1-2-2019 at https://www.digitalocean.com/legal/compliance/

Over exercising (R4) or distress (R5)

To prevent misuse or negative psychological effects from using the application, it is also explained at the start of the trial to participants that they should always ignore information from the application if it conflicts with their own feeling of safety or bodily signals.

Also, two additional phone calls by consulting nurses and/or investigator will be made in week 1 and 4 after surgery to check for possible over exercise and distress.

d. Treatment alternatives

Allergic reaction and Irritancy (R1, R2)

If the other measures described above are inadequate, it will be discussed with participants if alternative means of step tracking are possible. For instance, many smartphones also have a step tracking functionality, so if a participant is in possession of such a phone this may be an alternative. (This is not preferred, to keep data gathering as consistent as possible.)

9.12. References

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[c] Fitbit, Inc (2019) Important safety and product information. Accessed 22-1-2019 at https://www.fitbit.com/legal/safety-instructions

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