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Telemedicine support in total hip replacement: A randomized clinical trial testing a new multi-faceted intervention and an evaluation of the project's impact in a clinical setting.

The RRS project

PhD dissertation

Martin Svoldgaard Vesterby

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PREFACE

An innovator becomes a researcher and an innovation project becomes a quality control study. This Ph.D. thesis is carried out and written by a person with a strong profile for innovation and a less strong profile when it comes to execution of routines and detailed challenges. This innovation profile is developed over the years through various projects and co-operations, but as the tradition for documentation and evidence has grown strong in the healthcare sector and the incentives for raising money for innovative projects have followed, a change of focus was needed.

These facts were embraced early on in this PhD-thesis and ways to overcome personality challenges were found. First of all: This Ph.D. project continues to be an innovation project. However, it has an embedded clinical trial and description of development of methodologies and thereby at the same time qualifies in a more traditional way as a research project. Secondly, the only way I could have succeeded was by recognizing that I could not carry out the project all by myself. The results are not mine alone, but are a result of work performed by a group of fantastic people who stepped up whenever I failed or came short of solutions.

On this basis, I have become a researcher and interestingly this is a platform offering me a new and better understanding of what it is to be an innovator. Thirdly, I have learned to appreciate and recognize the gaps between innovation projects and validated scientific studies.

This is, therefore, a Ph.D. thesis based on an innovation project. It contributes with observations made during the process, key lessons learned, ideas and "brainchildren" conceived during the project that are not normally part of a Ph.D. at Health, Aarhus University. It also includes results from a randomized clinical study, data from a qualitative study conducted concurrently during my Ph.D. studies, as well as a novel method of innovation with ways to generate and apply evidence-based medicine in a highly specialized clinical setting.

All in all it has been a humbling but rewarding experience encompassing steep learning curves.

First and foremost, I would like to dedicate a very special heartfelt gratitude to all the staff at the Orthopaedic Department, Regional Hospital Silkeborg. Many of you have done much extra work, gone out of your way and have taken on tasks without getting nothing more than a "thank you" in return. I am in debt to all of you.
All the patients and relatives who took part in the innovation and the testing of the interventions; your contributions can never be repaid!
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It has been an honour to work with an inspiring interdisciplinary project group with the highest level of integrity and a never weakening commitment for trying to make the best decisions to the benefit of patients and the project; so thank you *Mette Farstad*, *Rikke Aarhus* and *Thomas Hohn* and last but not least, my connection to the ward, *Betina Gade*. All of you contributed to opening my eyes to different ways of

combining “know-how” with thinking, working, and researching, while retaining the highest level of respect for the individual patient’s needs. The many laughs we shared and off-topic discussions were important motivators.
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It has likewise been a great privilege to interact with all the gifted people at Innovation Center Denmark, Silicon Valley; Bio-X and BioDesign at Stanford University. In particular, to experience how you readily shared your network in my search for people with knowledge in the area of health innovation and interdisciplinary research.
When working in the area of science was tough and progress slow, the support, help and friendly advice from *Niels Ejskjær* and *Christer Swan Andreassen* has been priceless.
I would like to express my great gratitude to my initial supervisors Professor *Kjeld Søballe*, Associate Professor *Jens Rolighed Larsen*, *Malene Laursen*, Senior Consultant PhD. You entered uncharted territory guiding and leading an innovator into the field of clinical research; a difficult journey with me being reluctant, at times, to follow direct advice and due to a lack of insight into traditional ways of clinical research. The physical, and, sometimes the mental distance between Silkeborg and Aarhus have at times been too far. I thank you for your patience and my hope is that I am not the only one benefitting from working together.
Professor *Kjeld Møller Pedersen* I thank you for introducing me to a small part of the interesting field of health economics.
Lene Bastrup Jørgensen, when facing a crossroad where the easy choice seemed like the obvious solution, you empowered me and presented a better way. I sincerely thank you and Professor *Preben Ulrik Pedersen* for walking me the distance.
I was most privileged to work with Ph.D. *Kristian Larsen*. Kristian helped me to set up the project, and was a great inspiration always up for a sound discussion. Most sadly, Kristian passed away much too young. His work has not yet achieved the full potential impact on the healthcare sector that it deserves, and which he so passionately worked for. It will take many researchers to carry forward the work Kristian initiated.
Moreover, I would like to express my sincere gratitude and admiration to my superiors, *Søren Mikkelsen*, *Mette Fjord* and again *Lene Bastrup Jørgensen*; I believe, you run the most visionary and innovating hospital department in Denmark. I thank you for your invaluable support. Your willingness to take risks and your commitment to innovation for the benefit of patients and staff should be a guideline for many.
This is merely a Ph.D. thesis, however, in many ways; I have prioritised it above the most important part of my life. I owe gratitude beyond words to my beloved family: *Alfred*, *Klara*, *Naja* and my unconditionally supporting wife, *Tine*. I hope I will never take on a task like this again. Thank you for your love, patience and understanding. I wish for an innovative life - together!

Silkeborg, April 2014

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1. ABBREVIATIONS

ADSL	Asymmetric Digital Subscriber Line
CCBT	Computerized Cognitive Behavioural Therapy
CD	Compact Disc
CFIR	Consolidated Framework for Implementation Research
COPD	Chronic Obstructive Pulmonary Disease
DHR	Danish Hip Arthroplasty Register
EHR	Electronic Health Records
EQ-5D	EuroQol 5 Dimensions
FTHR	Fast-track Total Hip Replacement
GP	General Practitioner
HIT	Healthcare Information Technology
HBR	Harvard Business Review
HRQOL	Health-Related Quality Of Life
IQR	Inter Quartile Range
LSU	Lean Start-Up
LOS	Length Of Stay
MMR	Mixed Methods Research
NNT	Numbers Needed to Treat
OHS	Oxford Hip Score
QALY	Quality-Adjusted Life Year
RCT	Randomized Clinical Trial
RHS	Region Hospital Silkeborg
RM	Repeated Measurement

RRS	Remote Rehabilitation and Support
SCL-90-R	Symptom Check List 90 Reduced
SOP	Standard Operating Procedure
THR	Total Hip Replacement
TMS	TeleMedicine Support
TRD	Total Resource Demand
TRP	Total Resource Potential
TUG	Timed-Up-and-GO
VAS-A	Visual Analogue Scale Anxiety
WSA	Work Sequences Analysis

2. ORIGINAL MANUSCRIPTS

This thesis includes the following manuscripts:

Manuscript I	Vesterby M, Laursen M, Mikkelsen S, Søballe K, Larsen JR. Telemedicine-Support in Total Hip Replacement: Length-of-Stay Halved without Loss of Quality. A Randomized Clinical Trial
Manuscript II	Vesterby M, Aarhus R, Pedersen PU, Jørgensen LB. Length of Stay reduced with 75% for patients' receiving total hip replacement; understood through the theoretical frame of SCRUM. A case study based on the Remote Rehabilitation and Support project.

3. SUMMARY

ENGLISH SUMMARY

Background

The healthcare sector faces a wide range of economic challenges; lengthy admissions of patients, ageing population and challenges in discharging and readmissions that are all costly and demanding. The need for new ways of treating, supporting and rehabilitating patients are necessary in order to counter these challenges. Many initiatives using Health Information Technology, eHealth or telemedicine have been developed to support new ways to treat patients with chronic diseases. We found that no one had looked in to the possibilities of applying telemedicine in connection with orthopedics and elective surgery. Therefore, we investigated the efficacy of a multifaceted intervention, including telemedicine in perioperative care and rehabilitation for patients receiving total hip replacement. We then aimed to investigate whether effectiveness could be demonstrated based on implemented optimizations compared with current procedures. Finally, we documented the innovation process and method of implementation and the effect of the RSS Project to the organization.

Materials and Methods

The entire Remote Rehabilitation and Support Project may be regarded as a multiphase mixed methods design. The overall study design was a mixed methods design conducted in a partially mixed concurrent dominant status design. Development of all interventions were done inspired by the theories of agile development. The qualitative part of the study was given the least weight and was nested within a randomized clinical trial. The randomized clinical intervention trial with the embedded ethnographic study was used to investigate efficacy. A cost-minimization evaluation was conducted as a piggyback study to the efficacy study. 72 couples of patients and designated support persons (spouse, other relative or friend) were randomized to receive either the telemedicine-supported intervention or the existing intervention. In the efficacy study, the primary outcome was difference in length of stay including readmission. In the effectiveness study, we evaluated the difference in length of stay at discharge between the groups using a before-after design. Triangulations of analysed qualitative and quantitative results were conducted in order to give more insight to why the intervention worked. The interdisciplinarity of the project group and the use of different methods for innovation and design of interventions and study were documented.

Results

In the efficacy study, the median length of stay was significantly reduced from two days in the group receiving the existing intervention to one day in the group receiving the telemedicine-supported intervention. Close to 95% of the patients in the intervention group were discharged after one day. The cost-evaluation documented cost-minimization favouring the intervention. Patient safety and quality were preserved. In the effectiveness study, the reduction of length of stay was significant. From 2008 to 2012 length of stay was reduced by 75%. Triangulation of results indicated the importance of involving and

educating support persons and staff to embrace the innovation methods and culture in order to continuously optimizing the procedure.

Conclusions

A multimodal intervention including the use of telemedicine can be used to successfully bring forward the day of the patient's discharge after major surgery. The development of interventions, the RCT and the knowledge gained made it possible to accelerate the procedures and helped to achieve a (75%) reduction in the length of in day-to-day praxis. An interdisciplinary and agile development approach for innovation in the healthcare sector may be able to facilitate long-term changes in an organization's innovation culture.

DANISH SUMMARY

Baggrund

Sundhedssektoren står over for en lang række økonomiske udfordringer. Aldrende befolkning, langvarige indlæggelser af patienter og dyre og krævende udskrivninger og genindlæggelser. Behovet for nye måder at behandle, støtte og rehabilitere patienter er nødvendig for at imødegå disse udfordringer. Mange initiativer inddrager Sundheds Information Teknologi, eHealth eller telemedicin og er blevet udviklet til at støtte nye måder at behandle patienter med kroniske sygdomme. Vi fandt, at ingen havde set på mulighederne for at anvende telemedicin i forbindelse med ortopædi og elektiv kirurgi. Derfor undersøgte vi effekten af en mange-facetteret indsats, herunder telemedicin i perioperativ pleje og rehabilitering for patienter, der fik en total hoftealloplastik. Vi ville undersøge, om en påvirkning af effektiviteten kunne påvises på grundlag af gennemførte optimeringer sammenlignet med de nuværende procedurer. Endelig ville vi dokumentere innovationsprocessen og implementering samt effekten RRS Projektet havde på organisationen.

Materialer og metoder

Hele RRS-projektet kan betragtes som en multifase blandet metoder design. Den samlede undersøgelse design var en blandet metode design udført i et delvist blandet sideløbende dominerende status design. Udviklingen af alle interventioner var inspireret af teorierne bag Agile. Den kvalitative del af undersøgelsen fik mindst vægt og er indlejret i et randomiseret klinisk forsøg. Det randomiserede kliniske forsøg med det integrerede kvalitative studie blev anvendt til at undersøge effekten. Evalueringen af en omkostningsminimering blev gennemført som en piggy-back undersøgelse til effektstudie. 72 af patienterne og udpegede støttepersoner (ægtefælle, anden slægtning eller ven) blev randomiseret til at modtage enten telemedicin-støttede intervention eller den eksisterende intervention. I undersøgelse af effekten var det primære resultat forskel i længden af ophold, herunder genindlæggelse. I effektiviteten studie evaluerede vi forskellen i længden af indlæggelse mellem grupperne ved hjælp af et før og efter design. Trianguleringer af analyserede kvalitative og kvantitative resultater blev udført. Tværfagligheden i projektgruppen og brugen af forskellige metoder til innovation og design af interventioner og studier blev dokumenteret.

Resultater

I undersøgelsen af effekten blev medianen af opholdets længde signifikant reduceret fra to dage i gruppen, som modtog den eksisterende indsats til en dag i den gruppe, der modtager en telemedicinsk intervention. Tæt på 95 % af patienterne i interventionsgruppen blev udskrevet efter en dag. Omkostningsevalueringen dokumenterer en udgiftsminimerende effekt af den telemedicinske intervention. Patientsikkerhed og kvalitet blev bevaret. I effektivitetsstudiet var reduktionen af længden af opholdet betydelig. Fra 2008 til 2012 blev opholdets længde reduceret med 75 %. Triangulation af resultater viste betydningen af at inddrage og uddanne støttepersoner og at gøre personale i stand til at tage imod de innovative metoder og kulturen og fortsætte med at innovere og optimere proceduren.

Konklusion

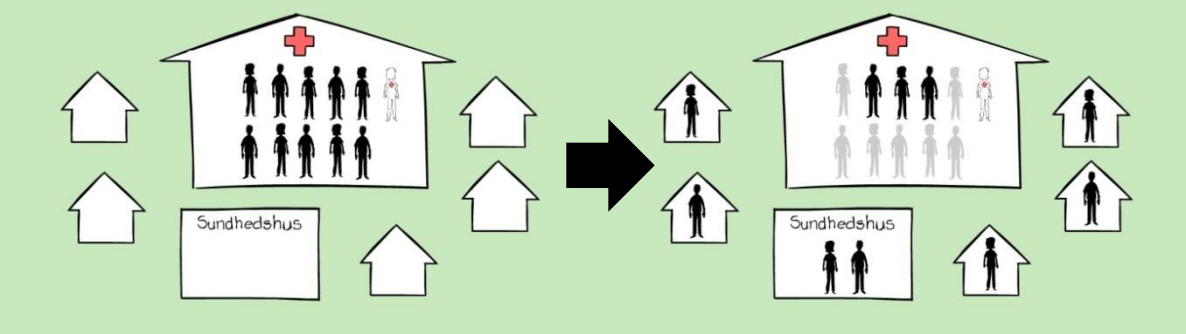
Et multimodalt intervention, herunder anvendelse af telemedicin, kan med succes fremrykke dagen for patientens udskrivelse efter en større operation. Udviklingen af interventioner, Interventionsundersøgelsen og den viden den frembragte hjalp til at fremskynde den peri-operative proces og hjalp med at opnå en (75 %) reduktion i længden af opholdet i en dagligdags klinisk praksis. En tværfaglig tilgang til innovation i sundhedssektoren kan være i stand til at lette langsigtede ændringer i en organisations innovationskultur.

4. BACKGROUND

THE EXPERIENCE THAT GAVE INSPIRATION TO THE PROJECT AND STUDY

Healthcare sectors around the world face a wide range of economic challenges, and spiralling expenses are one of the major challenges of our healthcare systems [1-3]. Lengthy patient admissions, and challenges regarding discharging and readmissions are all costly and demanding.

FIGURE 1 FEWER HOSPITALIZED PATIENTS ARE PREDICTED IN FUTURE HEALTHCARE SECTORS

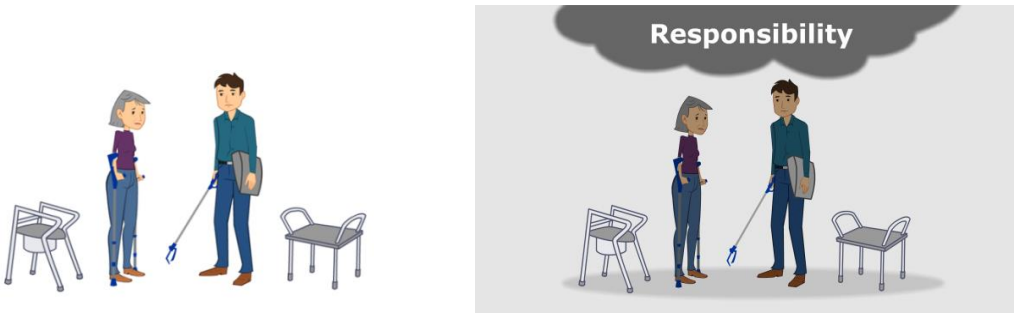


In Denmark, the hospitals of the future will be built based on calculations that predict fewer submitted patients, reduced length of stay and a higher number of out-clinic patients. ('Sundhedshus' = ' local healthcare center')

Leading up to the study presented in this thesis, clinicians at Region Hospital Silkeborg (RHS) in 2008 observed that most patients who had had a total hip replacement (THR) were in fact feeling quite well even on the same day of their surgery, and they then started to ask themselves why these patients should then be kept in the hospital. It was concluded that the average LOS of 4-5 days was not due to the operation, nor the risk of adverse effects or out of any ethical considerations. The hypothesis was that if the patients' feeling of security following their surgery was increased, they could be discharged sooner, for which reason it makes sense to focus on patient empowerment and patient-centred care.

When fast-track procedures are converted to same-day admissions, followed by a LOS, as short as one day, more tasks and responsibilities consequently need to be taken care of by the patients or their relatives and friends. These tasks and responsibilities that are then removed from the healthcare professionals create, however, an increasing need for more education and empowerment of the patients and improved social preparation. As a consequence of the fast-track procedures, the time available to prepare and empower patients for THR surgery is reduced, whereas, in our opinion, the patients actually required more resources to learn and to prepare themselves for surgery, discharge and rehabilitation.

FIGURE 2 PATIENTS FELT MORE RESPONSIBILITY WHEN LOS WAS SHORTENED



A visualisation based on the results from the formative research, which is now used when informing staff at RHS about the project. Here we can see that besides providing patients and relatives with physical aids when they are discharged from hospital, we also "provide" them with responsibility.

The hospital department already had experience with employing a Danish inspired telemedicine solution [4] for treating wounds. The first observations indicated that patients and staff felt safer when the mobile IT-solution was used. When searching for solutions to educate and support THR patients with regard to reduction of anxiety, no existing telemedicine solution was found.

Searching PubMed for relevant literature using the mesh terms Orthopaedic and Telemedicine only 21 hits came up at the start of the RRS project. Evaluated none were found relevant. The Cochrane library came up with a one relevant work when searched for telemedicine[5]. Hand searching references from the seven trails that were included in the work from Cochrane gave insight to a field of research that back in 2008 where without RCT's in connection to orthopaedics.

A project was launched in which a patient-involving innovation process would contribute to the development of a telemedicine solution in order to support patients and facilitate the organizational change. The hospital's goal was to make it possible to discharge THR patients one day after surgery. The quality could not be affected and costs were to be reduced. Any unclear and non-foreseeable effects of implementing a one-day fast-track THR procedure in the organization, such as logistic limitations and the possible adverse effects on the work environment, were to be minimized and documented together with the patients' experiences and the effects on the quantitative clinical endpoints.

5. INTRODUCTION TO KEY TOPICS FOR THIS THESES

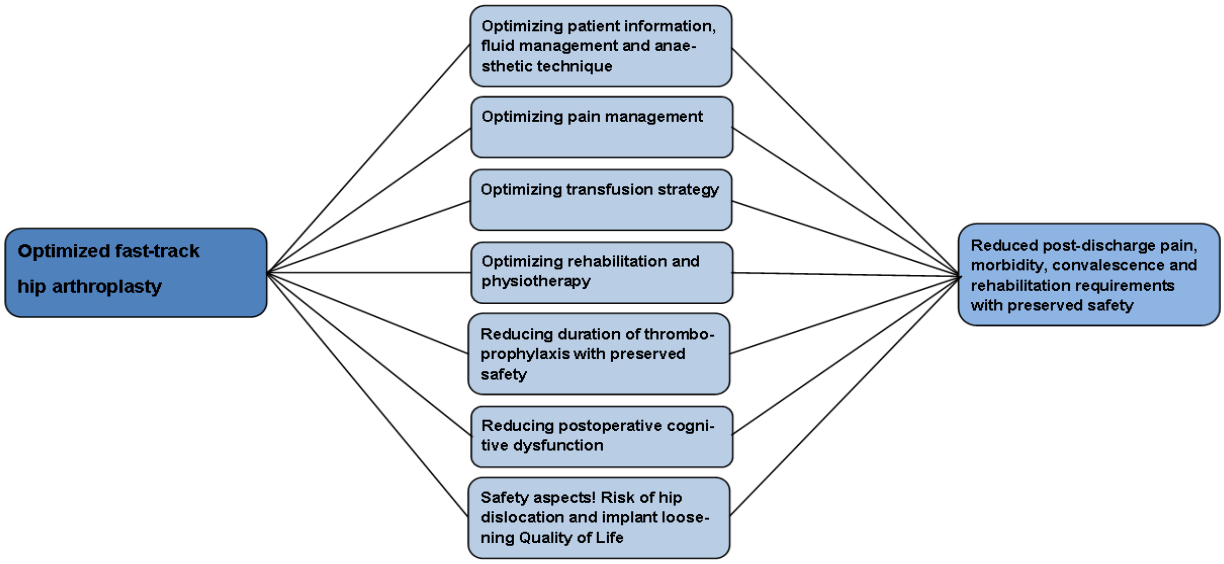
HEALTHCARE COSTS AND THE IRON TRIANGLE

The iron triangle of healthcare was introduced by William L. Kissick in 1994 in his book Medicine's Dilemmas [6]. The triangles elements of Cost, Access and Quality are used for augmenting for an "unachievable" goal of optimizing all three elements [7]. Aaron Carroll, one of the authors at news@JAMA, wrote "*We can make the system cheaper. We can make it more expansive. We can make it higher in quality. But we can't do all 3*" [8]. So the claim is, that cost, access and quality are in competition with one and another and the concept of trade-offs makes it difficult to have any change. For example, a reduction in cost in the healthcare sector cannot be accomplished without affecting access, quality or both. An increase in quality will most likely reduce access or increase cost. For some, this is universal law, the trinity that every politician, healthcare provider or innovator face. For others, it is an assumption that has to be challenged while trying to solve the problems of balancing quality and access to treatment versus the rising costs of healthcare. The leaders of the orthopaedic department challenged this assumption when setting up this project. They searched for a solution that, at minimum, would preserve quality, which THR patients and the organization could accept, therefore not reduce access, and yet significantly reduce cost. In other words, the fundamental principal of the Iron Triangle was disputed.

FAST-TRACK METHODOLOGIES

There is an on-going revolution in the area of elective or planned surgery, a revolution has been going on. Fast-track methodologies, as described by its creators, "*focuses on enhancing recovery and reducing morbidity by implementing evidence in the fields of anaesthesia, analgesia, reduction of surgical stress, fluid management, minimal invasive surgery, nutrition, and ambulation*" [9]. Fast-track methodologies have reduced length of stay (LOS) significantly through an evidence-based approach, as seen when applied to total hip replacement (THR) [10-12]. Fast-track procedures for THR are known as accelerated intervention, joint recovery program, multi-disciplinary intervention, multi-modal intervention, and clinical pathway. The common theme here is that the procedures normally take place in the perioperative period, starting with the information meeting and continue throughout hospitalization to the day of discharge. The concept of fast-track treatment focuses on optimizing pre-operative education of patients, pre-operative optimization, attenuation of surgical stress response, optimizing pain relief, enforced mobilization, nutritional support, and up-to-date post-operative nursing care and rehabilitation [13,14].

FIGURE 3 ISSUES TO BE ADDRESSED TO OPTIMISE FAST-TRACK TREATMENT AS DESCRIBED BY THE LUNDBECK CENTRE FOR FAST-TRACK HIP AND KNEE SURGERY [15].



TOTAL HIP REPLACEMENT

Musculoskeletal disorders, such as chronic hip complaints, result in functional disabilities that have impact on healthcare costs and, ultimately, socio-economic consequences as well [16]. Osteoarthritis is a frequent reason for hip complaints and the most common indication for THR. Increasing life expectancy leads to an increased lifetime risk of THR [17]. The expenses in relation to THR can be divided into three categories. First, there is direct cost: the cost of surgery, hospital resources, caregiver time, pharmacological and non-pharmacological treatment, and the cost of side effects from treatments and research. Second, we have the indirect cost: loss of productivity, absenteeism, and premature mortality and disability payments/benefits. The third category is the intangible cost: pain and suffering, decreased quality of life, and potential depression/anxiety [18]. Cost could also include resources used by relatives and close societal networks supporting the patient. There are significant and costly differences in the ways the rehabilitation of THR patients are treated. Some are discharged to a comprehensive rehabilitation unit (as is often the case in the United States), [19] in contrast to those who go home with no home-care service, but relying on family and friends [13].

EMPOWERMENT

The definition used by The Danish Health and Medicines Authority is "*increasing patients and other citizens capacity, control and ownership in regard to decisions that affect their living conditions and health*" [20] (translated from Danish).

INFORMATION AND EDUCATIONS CONNECTION TO LOS

LOS is a validated end-point for cost-lowering effects in both public and private healthcare [21]. As part of the fast-track methodologies, education and information is included. However, little attention has been given to the evaluation of the effect of such initiatives and their possible influence on LOS. No evidence was found for pre-operative education with respect to pain, functioning and LOS in a Cochrane review [22], although the review reported that if "*tailored according to anxiety, or targeted at those most in need of support*" a modest beneficial effect on pre-operative anxiety was noted. Similar results have been found by others [23]. Studies on the use of video clips, as part of an educational tool, are inconclusive, varying from no effect to a positive effect on both physical and psychological parameters [24-28]. One study [29] evaluated the effect of a multimedia solution that included video, audio and printed nursing guides recorded on a compact disc (CD). The results showed a statistically better self-efficacy, better functional activities and shorter LOS. A general theme in the literature [30] is that information and education help the patient to manage, and contribute with regard to a reduced LOS and fast convalescence. A hypothesis that, to some extent, is supported by studies on the effect of increased patient empowerment and self-efficacy [31,32]. The associations between pre-operative variables, post-operative experiences, and LOS are many and difficult to account for. Pre-operative anxiety and depression have been found to correlate with post-operative pain, as observed by Rolfson et al. [33]. This study also observed a 55% higher cost per gained QALY for a group of patients with persistent anxiety. The risk of developing anxiety or depression in the immediate period following THR surgery should also be noted here [34]. In conclusion, education could have an effect on anxiety, and anxiety could influence post-operative health-related quality of life (HRQOL).

The Danish hospital department that took part in the present study already undertake pre-operative information/education meetings and hand out written information in the form of booklets, including information on intended LOS. Like most hospital departments in Denmark [13], the aim is to help the patients to better understand the (day of) surgery, hospitalization and recovery period, in order to optimize their chances for a positive outcome. At Region Hospital Silkeborg (RHS), patients are informed about the possibility of bringing a relative to the educational meeting, an option that is based on an observed need for strong social support of patients in order to be able to discharge them after a few days. We have found no validated guides on how to carry out the educational meetings or what teaching methodology that works best, although there are various guidelines [35-37] on how to structure the written information material. We also found a need to attend to health literacy [38], thus enabling the facilitation of information and patient empowerment to patients' with a low level of health literacy.

INNOVATION

There is no academically accepted definition on what innovation is, and as such it is not possible to find one word that describes all the innovative undertakings in this study, However, Steve Blank once made the following simple yet powerful statement: "*Innovation means to introduce something new*" [39]. When people think of innovation, or innovative products, they often think of products like a GPS or an iPhone. This type of innovation can be categorized as disruptive innovation. Clayton Christensen have coined the term disruptive innovation, "*it describes a process by which a product or service takes root initially in simple applications at the bottom of a market and then relentlessly moves up market, eventually displacing established competitors*" [40]. As this project progressed, it soon became apparent that certain key aspects

were required in order for the solution to be considered innovative. The project must create something new and different that serves a purpose - under the criteria previously listed - in the Danish healthcare "market." With these key elements in mind, we settled on the following definition: "*The development of a new and different solution that brakes into market*". Reasons for the importance of "*brakes into market"* is that it confirms that the solution solves a problem outside its "place of birth".

The deep economic crisis and fewer resources may stimulate motivation for innovation [41,42]. Another explanation for an increased focus in innovating for the healthcare sector could be that hard times bring people closer, thereby stimulating interaction, which leads to an increase in ideas [43]. So, this could be regarded as the time of possibilities for innovators, not only because people's minds are more likely to connect, but also because organizations, and therefore people, are forced to make changes regardless of how frightening or difficult the process might be. The "burning platform" metaphor is used to describe a situation where daring initiatives are executed, driven by the choice of probable closure over inevitable closure. Hospitals and hospital departments in Denmark find themselves in this situation. However, the need for innovation and testing new and perhaps disruptive procedures might collide with the need for evidence based practise and the use of standard operating procedures when treating patients at a clinical setting. The healthcare sector is, however, not the only sector that has experienced reductions and restructuring. Therefore, the question that begs answering is, could the healthcare sector learn from other sectors experience with innovation?

AGILE DEVELOPMENT

In 1986, SCRUM was introduced in an article, titled The New New Product Development Game [44], in Harvard Business Review (HBR) by professors Takeuchi and Nonake. They coined the term SCRUM inspired by how a team move in a rugby game being self-organizing and managing. The focus of a team as the main resource was new, "*the product development process emerges from the constant interaction of a hand-picked, multidisciplinary team whose members work together from start to finish. Rather than moving in defined, highly structured stages, the process is born out of the team members' interplay*". The authors listed six elements they described as "*a powerful new set of dynamics that will make a difference*".

SCRUM

1. Built-in instability
2. Self-organizing project teams
3. Overlapping development phases
4. "Multilearning"
5. Subtle control
6. Organizational transfer of learning

Jeff Sutherland and Ken Schwaber formalized the development of SCRUM in 1995 for use in programming. Many consider it the first and most important agile software development process. SCRUM influenced not only the development of software. It effected engineering process's in general and challenged the often-used project management style named "Waterfall" that used isolated sequential phases whereas SCRUM are overlapping phases of development.

SCRUM was the start of the agile movement and led to the Agile Manifesto created in 2001 [45] also signed by Jeff Sutherland

The Agile Manifesto

1. Individuals and interactions – Over processes and tools
2. Working software – Over comprehensive documentation
3. Customer collaboration – Over contact negotiation
4. Responding to change – Over following a plan

The agile movement has been spreading from software programming to other disciplines. It has inspired new manifestoes as the Pretotype Manifesto now used at Google and taught at Stanford University [46]. Participatory Design (PD) [47] have similarities with agile development. PD is used to sharpen focus on actively including staff, patients and their relatives in the design of a solution that meets the need of the users or participants [48]. Agile development have a strong foothold in engineering, software development and start-up communities. With this project, we use, as some of the first, agile development in the healthcare sector.

TELEMEDICINE AND HIT

Healthcare Information Technology (HIT) is regarded as one of the ways to reduce the escalating healthcare expenditures. Telemedicine holds a prominent position in the Patient Protection and Affordable Care Act [49], often referred to as 'Obamacare', and telemedicine is also part of the present Danish government's foundation [50] from October 2011.

Telemedicine is defined by the American Telemedicine Association as "*the use of medical information exchanged from one site to another via electronic communications to improve a patient's clinical health status*" [51]. The definition includes *tele-health, tele-care, tele-homecare, tele-rehabilitation* and *eHealth*, which all deliver clinical services by way of technology. Telemedicine is included in HIT, although HIT is commonly used as an umbrella term for information processing and services in the healthcare field [52].

Telemedicine is often used in connection with treating chronic conditions such as diabetes, heart failure and COPD [53,54]. Targeted patients have been selected to take part in projects that apply telemedicine, based on criteria such as which patients are expected to benefit the most and which patient groups receive the most expensive treatment now and in the future. The first results of these studies indicate that telemedicine has a place in the future treatment of patients with long-term conditions [53,55]. The American Telemedicine Association published in 2013 a list of publications addressing "Telemedicine's Impact on Healthcare Cost and Quality" [56]. Eight studies were included, all from the US and none was including the fields of orthopaedics or rehabilitation. A systematic review by Kairy et al. [57] evaluating outcomes, process, utilizations and cost associated with telerehabilitation included 28 articles. Two was evaluating effect of telerehabilitation after total knee replacement, published in 2003 and 2004. The review concludes, *"there is insufficient evidence to confirm that telerehabilitation is a cost-saving or cost-effective solution"*. The diversity of the telemedicine solutions creates a possibility for inspiration and learning across procedures. Therefore, the use of computers and the internet for computerized cognitive

behavioural therapy (CCBT) also opened up new ways of treatment for orthopaedic patients suffering from anxiety [58].

Efficacy (RCT) and Effectiveness (day-to-day practice)

The late Kristian Larsen, one of the initiators of this Ph.D.-project, focused on the need for documenting not only how an intervention work in a close test-environment (efficacy) but also to monitor the general development of a possible impact (effectiveness) in the hospital department where the intervention was tested.

During the study, we have experienced some having difficulties in understanding the fundamentals of efficacy and effectiveness in relation to clinical studies. For the sake of clarification, the definition of the two concepts by Encyclopedia of Medical Decision are: "*The terms efficacy and effectiveness refer to different concepts and are not interchangeable. In general, efficacy refers to whether an intervention works under ideal conditions for a specific outcome. Effectiveness refers to a broader view of the usefulness of an intervention in the routine care of patients in the day-to-day practice of medicine*".

Summary of evidence and the incentive for the project

In summary, an on-going economic crisis and increasing cost in the healthcare sector makes it the ideal time for innovation projects. The hospital department was prepared to take risks and make investments in order to reduce expenses; this provided an avenue to introduce new skills, technology and agile ways of innovation not normally used in the healthcare sector. Studies show that patients undergoing THR in a "fast-track setup" were capable of managing changes, with significant reductions in cost and without reducing quality or patient satisfaction. Thus, the possibility of using HIT in educating and supporting patients was positive but not tested with THR patients. Furthermore, HIT was a natural progression for a department already familiar with the use of telemedicine. The amount of evidence indicated that telemedicine could be a feasible way to achieve a further reduction in LOS and cost. The possibility of creating a solution with the potential of "go to marked" was also part of the overall goal. Brought in to the project by CareTech Innovation and Computer Science, Aarhus University.

In short, this project set off to reject the hypotheses inherent in the Iron Triangle. This project boldly aims to reach its stated goals without any trade-off.

6. AIM OF THE THESIS

The main purpose of this project is to dispute The Iron Triangle's claim of a given trade-off, between Quality, Accessibility and Cost, of care. This addressed in a RCT with a multi-faceted intervention that included a novel telemedicine solution, in order to improve the procedures included in the course of events for patients undergoing THR. Furthermore, to evaluated the effect of the RRS Project to the organisation.

The main purpose parts to the following aims:

I To develop an intervention - based on hospital and patient needs - using agile development methodologies to reduce cost, constrain or increase quality and accessibility. Thereby challenging the Iron Triangle.

II a To test the intervention applying telemedicine-support to accelerated perioperative care and rehabilitation to standard fast-track intervention for THR, in a RCT (efficacy).

II b To compare the expenses with a piggyback study to the RCT.

III To evaluate the development of LOS in day-to-day praxis with a before-after study (effectiveness).

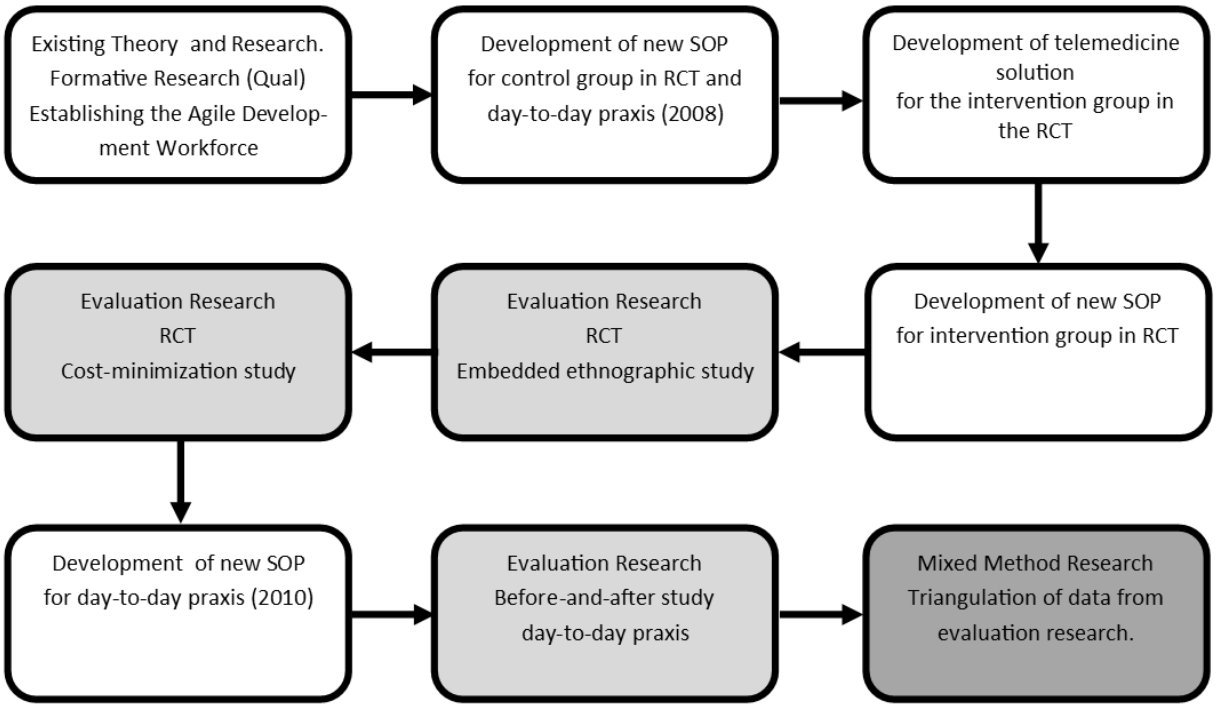
IV To assess with emergent MMR the effects of The RRS Project to the organisation, staff, patients and relatives.

7. STUDY DESIGN

THE OVERALL DESIGN OF THE RRS TRIAL

Creation of the intervention and the process of making new guidelines and standard operating procedures, develop for this project and the day-to-day praxis, will be descript simplified and schematic to give insight to an intermingled and complex process with many iterations. The process is depicted (see **FIGURE 4**) based on their dependency in a chronological way. The depicted phases are simplified and the distinctions across phases are artificial. Thus, for example, existing theory and research overlapped formative research as do evaluation research (RCT) and development of Standard Operating Procedure (SOP) for day-to-day praxis in 2010. Formative research conducted was evaluating current THR procedure, as part of the agile development process. Furthermore, the first four phases were not sequential, but occurred concurrently and with elements of iterations as expected when working with agile development. The selected mixed methods design emerged due to issues that developed during the first phases of the project

FIGURE 4 ILLUSTRATION OF THE RRS PROJECTS MULTIYEAR RESEARCH AND THE PHASES CHRONOLOGICAL DEPENDENCE

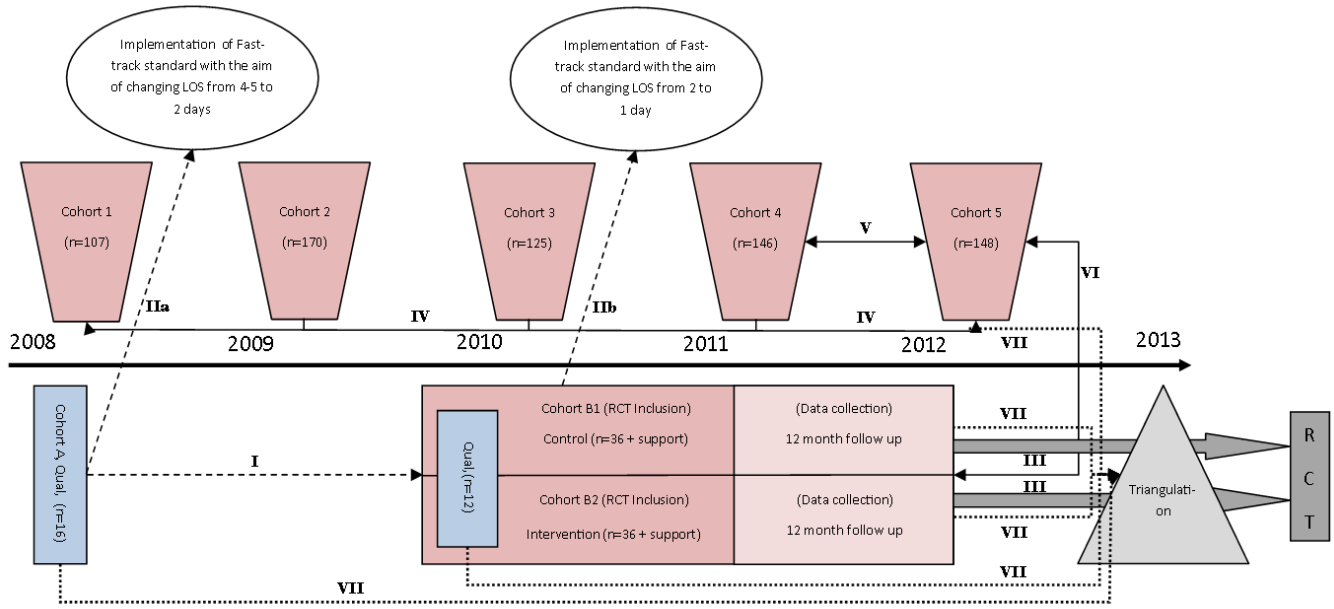


Inspired by the work on mixed-methods in intervention research by Nastasi et al [59].

The use of a novel interdisciplinary setup when designing the intervention resulted in many iterations, where aspects of the standard method currently used were evaluated, modified or altered to best fit the task before moving on. Still, the following considerations were taken into account when conducting the project: internal and external validity were to be as high as possible when taking place in a clinical

setting; and the study was to focus on a clinical problem of relevance to both patients and healthcare professionals. The formative research should allow for the inclusion of problems both known and unknown to patients and healthcare professionals. The mixed-method research design applied in the intervention studies was new to all participants in the project group. Much deliberation was given to the impact of an embedded qualitative (anthropological) study in an (quantitative) RCT.

FIGURE 5 PERIODS IN TIME FOR DATA COLLECTION, THERE DEPENDENCY AND PROCESS'S



The RRS Study visualized with phases of data collection and the process's (I-VII). Above the timeline are the day-to-day clinic. Below the timeline are the research set-up (RCT).
(Process I) Creating a telemedicine solution and the interventions for Cohort B1 and B2.
(Process IIa) Procedural change 1 (new SOP) optimizing the current fast-track procedure. A result from the first parts of the innovation process, including results from formative research (Cohort A) implemented between Cohort 1 and Cohort 2. The same procedure were applied in the control group (Cohort B1) in the RCT.
(Process IIb) Procedural change 2 (new new SOP), based on the telemedicine-supported intervention used for Cohort B2, implemented between Cohort 3 and 4 at a department for day-to-day praxis.
(Process III) A RCT including Cohort B1 and B2 to answer efficacy, with a nested (embedded) anthropological study that focused on experiences. A piggyback study, to the RCT was carry out as a cost-minimization study.
(Process IV) Comparing development of LOS at day-to-day praxis. From 2008 until 2012 with a before-after design.
(Process V) Evaluating further "spontaneous" effect on LOS after termination of the RRS-Study.
(Process VI) Comparison of effectiveness (Cohort 5) and efficacy (Cohort B2).
(Process VII) Triangulation was performed after interpretation of the results from Cohort A (Qual.), Cohort B1 and B2 (Qual. and Quan.) and Cohort 1 to 5 (Quan.).

The interdisciplinary pre-trial work and the interesting results gained from the formative deductive research inspired the inclusion of a qualitative study in the trial, and in this way the MMR design emerge, including data collection evaluating impact of THR on the support persons.

When formative research is included as data generating and contributing to the design of the RCT, the second anthropological study, the evaluation of day-to-day praxis the entire RRS project may be regarded

as a multiphase mixed methods design [60]. The overall design of the evaluation research was a mixed methods design conducted in a partially mixed concurrent dominant status design [61].

8. ETHICAL ISSUES

The RRS project took place at a public university-affiliated orthopaedic department in Denmark from November 2007 to February 2012. The first formative research took place in the beginning of 2008, whereas the efficacy study with an embedded qualitative study was carried out from August 2009 to February 2012. The study was performed in accordance with the CONSORT Statement [62] and followed standards for good clinical practice and applicable national regulations. All patients and close relatives, who met the inclusion criteria for the efficacy study, were given written and oral information about the study, and participants consented in writing. The regional ethics committee found that under Danish law, the quality-assurance study did not require prior approval. The study was registered with the Danish Data Protection Agency (j. no. 2009-41-3394) and at Clinicaltrial.gov (NCT00969020).

9. AIM I - DEVELOP THE INTERVENTION

METHODS, AIM I

In the creation of the interdisciplinary environment, many things had to be taken into account in designing the intervention (solution) and the evaluation research. Upholding respect and equality with regard to the various disciplines included in the project group was deemed important. We consider agile development as the term best describing the development phase.

THE PROCESS

Four individuals with four different professional backgrounds worked in co-operation, leading the project and participating in the decision-making with the common goal of creating a social movement and distancing the project from a programmatic approach. The interdisciplinary project group comprised a physiotherapist in charge of patient information material, guidelines and co-ordination of the surgical fast-track procedures in the RCT, an ethnographer, in charge of all qualitative studies, a computer scientist, in charge of the team designing the telemedicine solution and its software, and a medical doctor (Ph.D. Fellow), responsible for the quantitative studies and ethical considerations.

Most of the project took place in a working clinical setting. The intention was to enable staff to follow the progression and always know that they could contribute to the process. Furthermore, frequent presentations were made at the ward and at staff meetings and seminars held by the hospital. The concept enabling the staff to follow the progress, without the ability to interfere, was maintained throughout the entire project period, including the pilot test and the RCT. We named this the “greenhouse concept”; the concept of a shielded test environment, where the staff would be able to observe the progression of the project and share observations, challenges and ideas for improvement with the project group and in that way promoting knowledge sharing.

The innovation process carried out in an overlapping three-stage setup:

1. Defining needs and challenges.

2. Designing and prototyping.

3. Pilot testing and implementing.

DEFINING NEEDS AND CHALLENGES

The process in pertaining to defining needs and challenges was divided into three parts. Existing literature, existing patient experience and existing and logistics solution at Region Hospital Silkeborg.

A new literature search was performed in PubMed, Cochrane and CINAHL, focusing on challenges in existing practice for fast-track THR, education in relation to THR and supplemented with the results when searching for telemedicine in connection to orthopaedic surgery. Fifteen articles were considered relevant for the innovation process and presented for the project group, as what was considered stat of the art in the field. These included literature on pre-operative characteristics that potentially could affect the

outcome of THR, the effect of pre-operative instructions and education, health literacy, and evidence on the use of HIT [5,22,34,38,63-73].

A formative anthropological study was carried out to obtain knowledge of how patients, relatives and staff experienced a fast-track THR in order to contribute to the assessment of needs and identify possible challenges. The results from the anthropological study were used when designing the telemedicine solution and when planning the logistical setup used in the intervention, as well as, when designing the RCT.

The main findings from this study were that close relatives had a major possibility to influence the patients' perception of treatment and results, in both a negative or positive direction. This was considered a very imported finding and in accordance with other studies in relation to other types of treatment [74], and is, therefore, taken into account when we designed the intervention and the study. When designing the intervention, we also selected to focus on elements found by the anthropologist to either increase or decrease patients' anxiety [75] (Table 1).

TABLE 1 RESULTS FROM THE FORMATIVE ANTHROPOLOGY STUDY

Increase Anxiety	**Decrease Anxiety**
Knowledge	Focus forward
Complications	Support aids
Previous experience	Knowledge
Malfunction	Check-ups
Human Error	Experience
Staff	Home visits
Other patients	Video Interview
Waiting for OP-day	Phone calls
Experience with hip surgery	Location
Must have two hips replaced	Mentors
High demands for performance	Information
	Staff
	Good organization
	Information meeting

The table list same observations as both decreaser and increaser as they were found to have different effects on different patients.

DESIGNING AND PROTOTYPING.

The intervention for the RCT contained three main elements. A new logistic for the patient pathway. A telemedicine solution for the intervention group and new standard operating procedure supporting the procedural changes; including written informational material. All of this developed in interaction with staff and patients and their relatives.

The patients and their support persons, who participated in the workshops and the qualitative study, defined areas and topics, which they found relevant to address in the educational material used in the TMS. Several iterative tests were performed and much careful thought was given to the content and the way in which the material was to educate the patients (and their support persons). During the iterative involvement of the users, we looked for verification that we worked on solutions that the users believed could help empowering them.

The theories behind CCBT [58] were considered and in the best way possible included in the educational animations [76-78]. No member of the project group had experience with cognitive therapy. After evaluation of the findings obtained from the formative qualitative study and the observations made by the animators, we selected specific areas in the THR pathway subject to be animated. Due to lack of funding, we had to prioritize and therefore only a few topics were selected for animation. The selection process was not based on evidence, but on an evaluation of the possible of indirectly effect of the individual topic on the primary outcome (LOS) based on estimated possibility of minimizing anxiety. The spinal anaesthesia was one of the procedures that were not to be included as an animation, and this was although the qualitative study indicated that it was a frightening procedure to many. This decision was based primarily on an idea of the procedure being identical in both groups, and did not affect the time of discharge.

All video material on training procedures showed standard exercises as they were recommended from the department and the increase in intensity of the work-out after a predetermined period of time. The patients in the TMS group were able to start the more tedious workouts after seeing them via the TMS at a time of their choice. The control group would first learn the exercises at the outpatient clinic in connection with their control visit three weeks after surgery. We considered removing access to the videos of the specific tedious exercises till after three weeks, reducing the risk of differentiating the training in the groups, but did not find it feasible at the time.

The iterations and the agility selected when creating the solution did we have to run through cycles of inspiration in literature and formative research. Creating muck-ups and testing with users before going all over again. Based on the results from the workshops and the feedback from staff, patients and relatives using prototypes; the decision on what to move into the final solution, including the material on the TMS, were decided by the project group.

The TMS ended up including the following:

- Personal information from the EHR
- Personal X-ray's
- Personal medication with pictures and descriptions of the pills
- Animated films of the operating procedure
- Animated films of parts of the treatment
- Written information with added speak
- Videos on how to use supplied aids
- Videos on how to walk crutches
- Videos on how to cope with everyday tasks

- Videos on how to do all recommended rehabilitation exercises
- Integrated video-conference system
- Q&A function for problem solving issues with the TMS or internet connection

The logistic of the patient pathway

In order to define the existing logistic clinical THR pathway, we held a workshop, based on a lean-light inspired method [79] . An interdisciplinary group consisting of 28 individuals selected from the staff participated in the workshop. As part of the workshop, the patient's journey from start to finish was illustrated with a track-and-trace visualization, where the patient was represented as a "package". The first workshop resulted in defining 194 specific interactions between patients and staff during one THR.

FIGURE 6 FROM THE WORKSHOP IN 2008 DEFINING THE CURRENT PATIENT' PATHWAY

The second workshop - with the same 28 participants from the initial workshop - was inspired by the concept of agile software development and its manifesto [45]. The goal was to create a new procedure with only one day of admission. The result was a new logistical pathway for THR patients with one day of admission and a white-paper that became the mandate for the innovation project in the department.

Design of telemedicine hardware and software

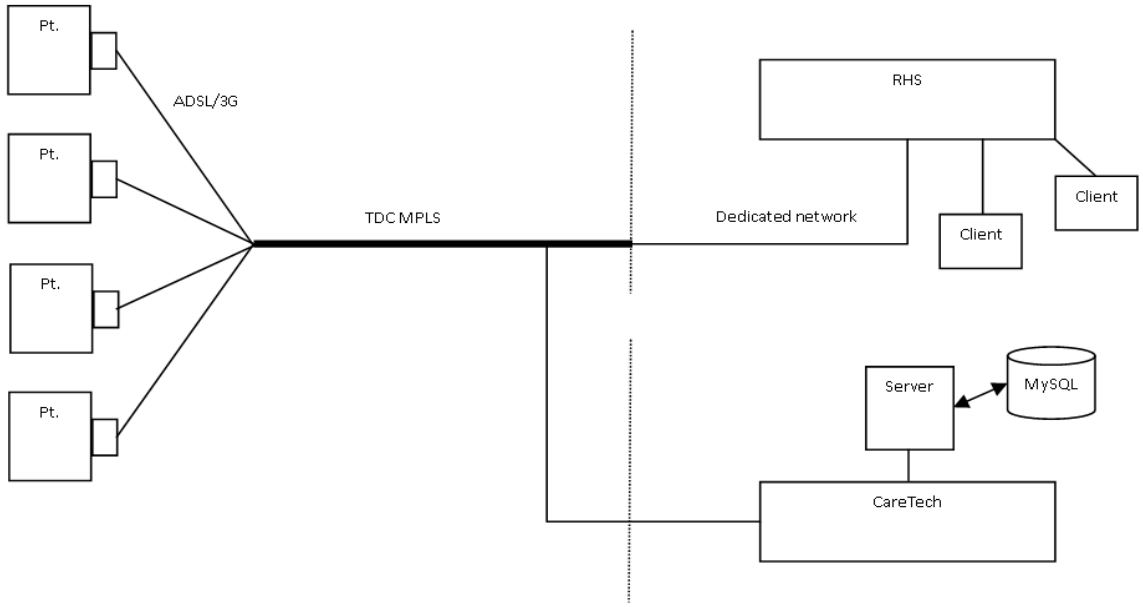
A computer scientist who was a trained SCRUM master led the design group. A total of three design workshops were held in the work environment of the orthopaedic ward in October 2008, January 2009 and March 2009 respectively. The documentation was by means of notes, through video and photographs.

FIGURE 7 FROM WORKSHOPS TESTING USER INTERFACE AND PROTOTYPES

The final telemedicine solution (TMS) that was used for a clinical test was a TV set-top box with material displayed on the patient's own TV. The video-conference solution was constructed in such a way as to allow a conference to be initiated by either the patient or the hospital staff. The camera was mobile and could, therefore, be used for close-ups, for instance, of a surgical wound. Navigation and use of the solution was undertaken with a simple remote control.

The idea of a TV set-top box was devised, inspired by patients and based on the qualitative data. The application was developed in Python 2.5 with embedded Skype4Py, Mozilla web-browser and Flash player 10. A CherryPy webserver was chosen, as was as a MySQL database. The hardware was an Intel® Atom™ computer with a flash memory and connected to an external WI-FI antenna. A Logitech® webcam was connected via USB. An IR-remote controls the set-top box. The box use a 220V power adaptor and connects to the TV with a 21-pin SCART connector. The cabinet was made of plywood and MDF. For a description of the network (see Figure 8)

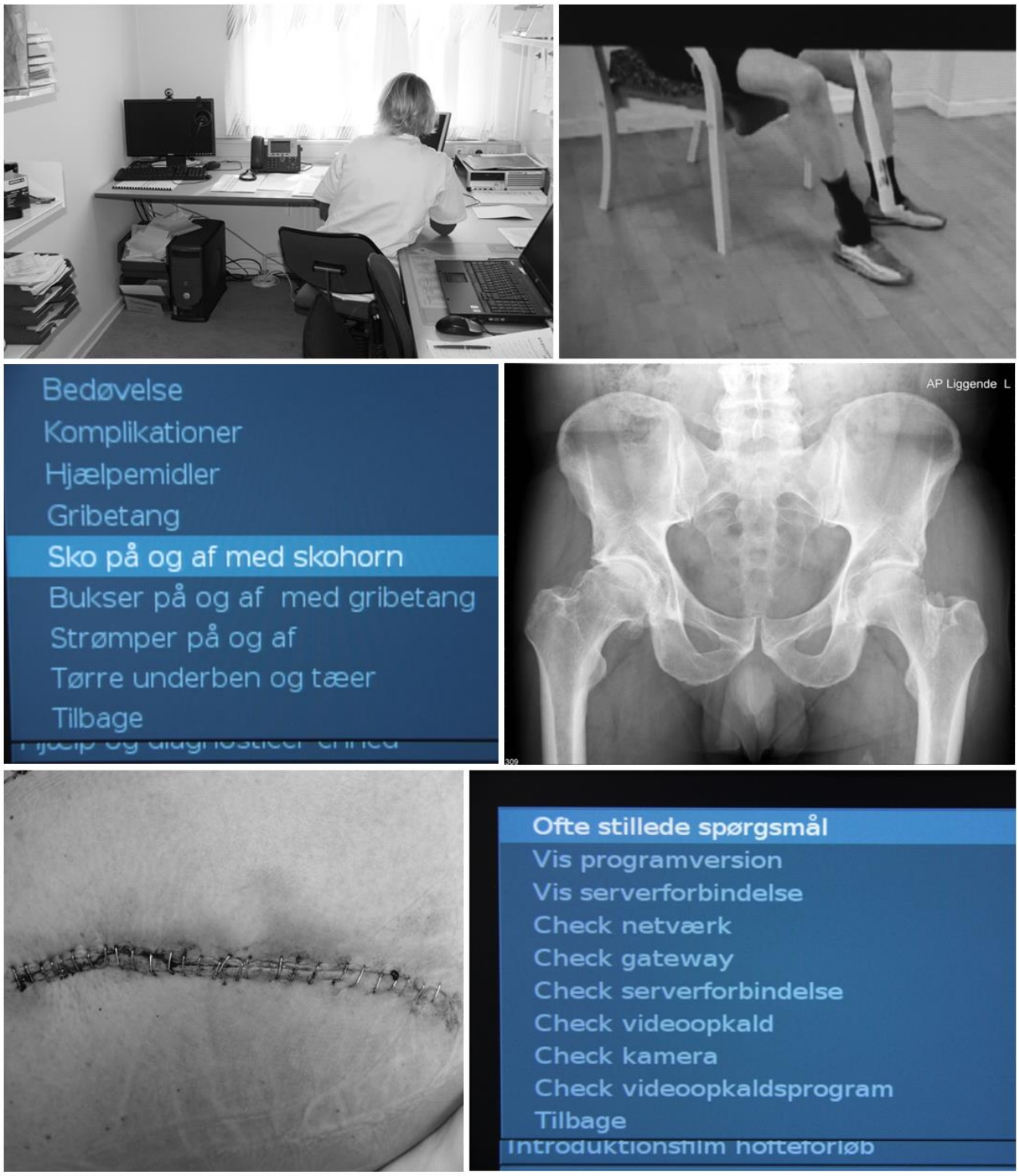
FIGURE 8 THE NETWORK USED IN THE RRS INTERVENTION TRIAL



A dedicated network from RHS was connected to a multi-protocol label switching network (MPLS). The server, located at CareTech, used the same MPLS and the connection to each patient's home was handled by an ADSL connection. In-house, we span a Wi-Fi network using a Check Point™ Wi-Fi router dedicated to the set-top box.

FIGURE 9 TV SET-TOP BOX AND VIDEO CAMERA IN A PATIENT'S HOME. HOSPITAL WORKSTATION AND SET-TOP BOXES

FIGURE10 THE HOSPITAL PART OF SOLUTION IN USE AND EXAMPLES OF THE MATERIAL PRESENTED TO PATIENTS



Design of the information material, animation and videos for the TMS

Our primary goal with the information and educational material was to address as many of the patients' and their relatives' needs as possible. The videos contained information acquired from current written material, including all the exercises used in the rehabilitation program, as well as information about, and examples of, how to perform everyday tasks in the first period after the operation, such as getting in and out of a car and up and down from the floor. Furthermore, patients could see their own X-rays and access an interactive overview of prescribed medicine controlled by the hospital. Animations were created for selected topics instead of videos, which might have had a counterproductive effect due to the content being too explicit, which thus, would not be suitable for presenting the information in a comprehensive way. Animators followed patients and participated in information meetings, watched operations, spent time on the ward, and participated in follow-up visits at the hospital to learn everything that the patients experienced. The project group defined the necessary material, which included descriptions, visualizations and information about the background for primary hip arthritis, the anatomy of the hip, the surgical procedure and the importance of rehabilitation, as well as risks and limitations in the immediate post-operative period. The material was reviewed; by staff, patients and relatives during the process, and the anxiety-reducing effect was tested in a small-scale study before the implementation using a visual analogue anxiety scale.

Design of new SOP for the RCT

The coordinator responsible for the new guidelines for THR-procedures had access to all information obtained through the previous work by the RRS project. A ward nurse, responsible for handling the patient care in the intervention study, consecutively evaluated and contributed to the compilation of the written guidelines, which attempted to take all the new initiatives and existing evidence into account. The results from the literature search and the formative research, as well as results from the workshops and the guidelines from the Unit of Perioperative Nursing [80] , and local logistic preferences, had to be considered when designing the guidelines. Goals regarding treatment of blood loss, pain relief, nausea control, nutrition, and mobilization and discharge criteria were the same for both the new intervention and the procedural changes. The guidelines were also evaluated by surgeons and nurses working with fast-track THR and ultimately, approved by the hospital management.

Discharge criteria for both arms in the RCT:

- Dry wound, otherwise subject to assessment by doctor
- Independent concerning bath and dressing
- Sufficient pain management
- No dizziness
- Discharge summaries reviewed with the patient
- Instructed in exercise program and principles of training
- Walk safely with crutches
- Familiar with restrictions of movement

Design of new SOP for day-to-day Praxis

When the RRS project group had created the white paper for a shorter LOS, known as "One-Day Hips", the department decided to optimize the current procedure. The new guidelines and procedural changes were

based on the work from the RRS project. The aim was a full-scale implementation of the multi-disciplinary organization and the multi-modal intervention in a new department with new staff. The aim was a two-day LOS (see Process IIa, Figure 5). A second optimization was completed while the study was underway in 2010; with the same goal, LOS of one day, as in the intervention group of the RCT (see process IIb, Figure 5). The optimization was completed in a more programmatic way, although it applied the knowhow based on preliminary results from the study and methods inspired by the RRS project. Although no HIT was implemented in day-to-day praxis. The changes was logistic, organisational optimisations and the use of new ways to inform and educate patients and post-surgery phone calls.

Pilot test and implementation of the intervention in the RCT

As part of the implementation process, we performed a pilot test to prepare for the study. Nine patients agreed to test the new hospital setup used in the intervention. This was done to ensure that the patients would be able to complete all the elements of the procedure. Based on the response from these patients, their relatives, and the evaluation by the staff, it was confirmed that we could continue to the next step and test the dimension regarding patient discharge. Three patients were invited to be discharged with telemedicine support on the day after surgery. Each of the participants received the set-top box a few days before the operation. The set-up with the telecommunication company supplying the internet connection was tested. The patients and the relatives were observed while setting up the solution to the TV-set and connecting it to the Internet. The speed of the Internet connection was checked. Tests were conducted to assess the functionality of video-conferencing, and picture and sound quality were checked. One patient decided not to participate as planned and left the test. The conclusion was that the solution was ready for the clinical trial.

The results from the preparation project and the testing of the telemedicine solution were shared with the staff at the department in order to facilitate the implementation of the final intervention, including the study protocol. The implementation took place at the ward treating all the patients included in the study. Computers with an internet connection, telemedicine software, a video camera and a headset were installed at the ward, and in the room used by the co-ordinator. A server was located at the Institute of Computer Science, at the Aarhus University, Denmark. None of the computers was connected to the Electronic Health Record (EHR) and the connection to the server and the telemedicine solutions at the patient's home was made via a secure multiprotocol label-switching network (Figure 8).

10. AIM II A AND B - THE RCT AND COST-STUDY

DESIGN OF THE RCT

The randomized clinical trial took place from October 5, 2009 to February 2, 2012. (Cohorts B1 and B2, Figure 5). The criteria for enrolment in the RCT were as listed:

Inclusion criteria:

Patients referred for evaluation for THR at RHS, outpatient clinic.

Exclusion criteria:

Distance to hospital > 60 km
Prior hip surgery of any kind
Mental disability
Inability to communicate in Danish
No support person
Inadequate internet connection
No possibilities of setting up an adequate internet connection

Sample size calculation was performed by an external statistician, who also carried out a simulation of LOS. The estimated distribution of submitted patients, five days post-operatively, was made after evaluation of the standard procedure for more than 40 patients and the test procedure for nine pilot patients. Alpha was set at 0.05. Based on a conservative, though realistic, simulation including 37 patients in the control group and 37 patients in the intervention group, the study showed a power of more than 99% for a difference in LOS. The simulation was based on a distribution of patients, as shown in Table 2 and max LOS was set at 5 days. A sample size of 74 was chosen based on these calculations.

A cost-minimization analysis was chosen as the health-related outcome measures TUG, OHS and HRQOL were not statistically significant when comparing the groups in the RCT. However, in the present case, the primary outcome, LOS, pointed directly towards an economic evaluation. It was done as a piggyback to the RCT. A distinction between societal costs and financial hospital costs was evaluated based on available data.

TABLE 2 DISTRIBUTION USED IN THE SIMULATION

Group \ Day	1 day	2 days	3 days	4 days	5 +
Cont. (n=37)	0.5%	67.5%	21%	8%	3%
Intv. (n=37)	57%	29%	9%	4.5%	0.5%

A total of 654 patients were screened. Eligible patients were randomized to either the control group or the intervention group approximately 14 days before surgery. Written informed consent was obtained from both patients and support persons prior to randomization.

CONTROL AND INTERVENTION GROUP

The control arm followed the standard fast-track hip replacement (FTHR) plan, whereas the intervention arm (TMS) followed the new intervention plan, developed for this study. The ward selected for the study designated a four-bed unit used by both arms. The ward nurse, participating in the development of the intervention, also served as the person responsible for the intervention, and ensured that procedures were following the protocol. The patients were all received individually and given information by a surgeon, an anaesthetist and a nurse at the outpatient clinic. All patients and their support person were invited, and all participated in a two-hour long group information meeting, on average two weeks before surgery. Subsequently, they were informed about the outcome of the randomization. The study protocol for data collection and its application was introduced to all the patients and their support person. All patients were hospitalized on the day of surgery and placed in the same ward. The skin in the incision area was checked and the patients received their hospital clothes. They met the surgeon at the ward before the surgery, and the side of the hip to be replaced was marked with a permanent marker. All 72 patients in both groups were operated on by the same surgeon and subjected to identical operational procedures from leaving the ward for operation until they were back on the ward. The operational procedures followed Danish guidelines [81]. Spinal anaesthesia was used and local wound infiltration anaesthetic was administered in the final stage of the operation. The support person was asked to join the patient in the ward after the surgery and take part in the post-operative education and training. If at all possible, the patients wore their own clothes. Medication for pain relief was identical in the two groups. There was no intentional difference in the treatment of blood loss, pain relief, nausea control and nutrition. Discharge criteria were identical for the groups. Before the discharge, a discharge checklist was followed and contact information for the department was handed out to the patient, if it had not already been done. The patients themselves took care of organizing their own transport to their respective homes. It was possible, for the patients in the interventions group, to access the educational material on the telemedicine solution before day of surgery.

TABLE 3 PROCEDURE FOR TMS ARM AND FTHR ARM

	TMS (Intervention)	**FTHR (Control)**
Day -14	Information meeting	Information meeting
Day -9 (-13 - -6)	Access to the telemedicine solution	
Day 0	Surgery and mobilization	Surgery and mobilization
Day 1	Discharge to home	Training and rehabilitation
Day 2	Video-conference	Discharge to home
Day 3	Home-visit by physiotherapist	
Day 6	Video-conference	
Day 21	Visit to outpatient clinic	Visit to outpatient clinic
Day 90	Visit to outpatient clinic	Visit to outpatient clinic

CONTROL GROUP

If the physiotherapist found the patients up to it they were mobilized for the first time on the day of surgery by a physiotherapist and a nurse. The following day, mobilization time and exercise volume were increased in order to reach the discharge criteria at day two. Patients were evaluated with regard to discharge criteria and acceptance of discharge one day before the planned discharge. On day two, mobilization time and exercise volume were further increased, now focusing on at-home exercises and performing personal needs, including changing bandages. Care was given in response to the patient's actual needs, and rehabilitation was adjusted according to the patient's immediate state.

INTERVENTION GROUP

After the information meeting (see Table 3), the intervention group was introduced to the telemedicine set-top box and its features. They were instructed on how to set up the solution themselves. They were also informed about the primary goal of one day of hospitalization. They were also insured that no one would be discharged against their will or if found unfit for discharge by the clinicians. The use of the set-top box was entirely voluntary, but it was pointed out that some of the videos and material would be relevant to watch and become familiar with before surgery. The physiotherapist involved in the study and a nurse mobilized the patient on the day of surgery. An exercise programme focusing on the patients' individual home needs started the day after surgery. Patients were evaluated in regard to discharge criteria and acceptance of discharge on day one. Videoconference and home-visit times by the physiotherapist for the following days' were also scheduled. The day after discharge, the first videoconference was held. The patients' needs and a checklist determined the course of action. The patients were questioned about pain treatment, oedema, sleep, elimination, nutrition and fluid consumption, mobility and the surgical wound. During the home visit, the physiotherapist continued the exercise programme initiated at the hospital, focusing on the patient's needs and individual way of live. The bandage was also changed during the visit. The last videoconference was held six days after the surgery, using the same approach as in the first conference.

EVALUATION OF COST-MINIMIZATION IN THE RCT

The number of services used, e.g. home visits, was compiled alongside the trial, while unit cost, e.g. the costs related to home visits or unscheduled visits were calculated based on an analysis of the relevant work processes, e.g. the time used by the staff and the equipment used. Resource consumption with regard to the video-conferences, home visits and introductions to the TMS was based on a minimum of 14 work sequence analysis's (WSA), telephone calls on 16 WSA's and documentation from the EHR. The WSA's were all done in the first four months of the study. Time spent on transportation was based on estimates from an online navigation solution from Google, calculated for each patient in daytime traffic. The cost of the TV set-top box, the setting up and the cost of the Internet were supplied by CareTech Innovation and the telephone company (TDC). The cost of hospitalization and the unscheduled visits were supplied by the hospital administration, based on normal and usual monitoring registration at RHS. We did not include work sequences or interventions that were identical for the two groups, e.g. pre-planned and pre-scheduled post-surgical contacts with healthcare providers at the outpatient clinic, time spent at group information meetings, introduction to study-folders and the costs of any surgical implants and medication.

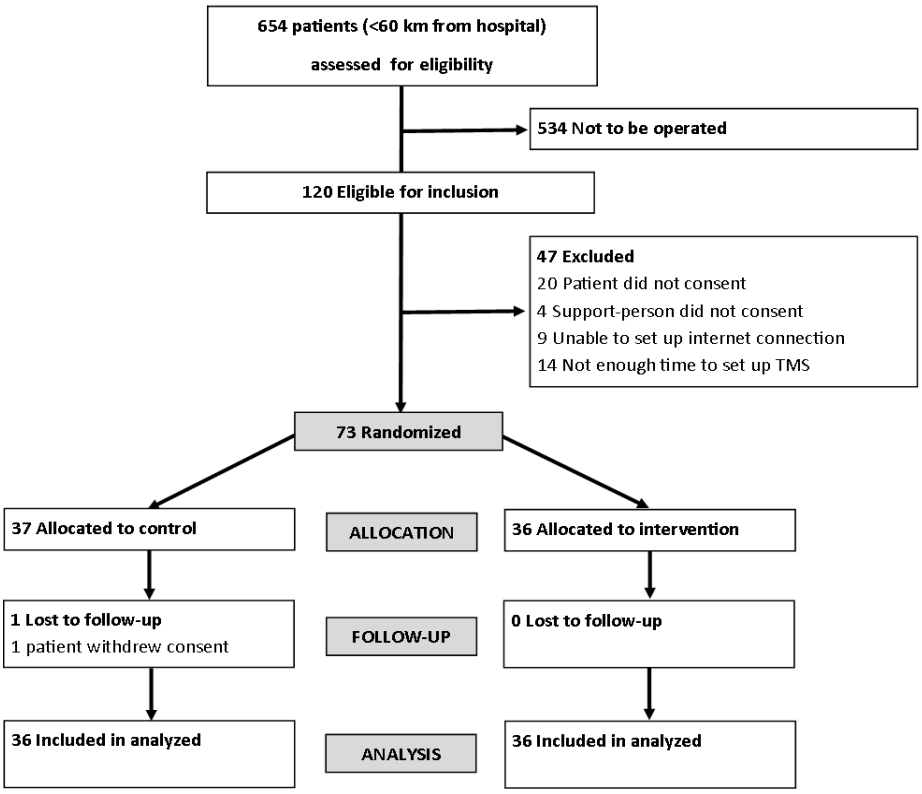
UNIT COST

The WSA resulted in an estimated time to handle the TMS procedures, including the introduction to the TMS (avg. 17 minutes), video conferencing (avg. 50 minutes) and transportation and visits (avg. 150 minutes). The salaries used in the cost assessment were based on Danish wages from March 2011 and collected from a public national registry [82].

TRIAL PARTICIPANTS

Seventy-two patients and their support-persons were included in the RCT (efficacy study), and of those, twelve pairs also participated in the embedded anthropological study (Figure 5). Seventy-three patients were randomized, but one withdrew consent just before study-start.

FIGURE 11 FLOWCHART OF ENROLMENT



METHODOLOGICAL CONSIDERATIONS, AIM II A & B

SELECTION OF STUDY DESIGN IN THE EFFICACY STUDY

When the benefit of an intervention is that the measured parameter is reduced (in this case a shortening of LOS to as close to one day as possible) and neither participant nor researcher can be blinded, it might be appropriate to consider other study designs than the normal first choice of a RCT. However, despite the limitations of the RCT, we preferred the simplicity and the robustness of a superiority trial (RCT).

ATTEMPTS TO REDUCE BIAS IN THE RCT

The randomization process was handled by a secretary, who was not otherwise in contact with the patients, and was performed by drawing sealed, opaque envelopes from a box containing the seventy-eight envelopes. When conducting a RCT, the total effects can be explained by the sum of spontaneous improvement, non-specific responses, and the treatment. As the treatment consists of removing the hip believed to be responsible for the patient's problems, the role of the natural history is considered to be negligible. The Hawthorne effect may have occurred in both arms of the trial, as can be the case for the placebo effect. The size of the Hawthorne effect and the placebo effect may differ, and could be affected by the way the intervention was introduced and applied. Study awareness and a potential Hawthorne effect could occur for both the healthcare staff and the patients. No attempts were made to try to determine the size of a potential Hawthorne effect. When performing an embedded observational study, the risk of study awareness affecting the outcome might increase. By selecting the patients randomly for both intervention arms in the observational study, we sought to ensure that the groups did not differ with regard to study awareness and placebo.

MASKING AND MINIMIZING CONTAMINATION

It was not possible to mask patients or staff in the RCT. One exception to this was with regard to the physical test (TUG), where those conducting the tests were masked. Contamination was reduced by making a small dedicated group responsible for the intervention and rehabilitation. This group also comprised of the only staff that were trained in using the telemedicine solution. The control group, which was treated in the same facilities, was given the current standard treatment by random staff at work. However, we could not totally exclude that staff cared for patients in both groups and thereby might reduce LOS in the control group and minimizing the effect of the intervention. The healthcare staffs were evaluated with regard to differences in rehabilitation and care burdens between the two arms, but they were not aware that they were evaluated. The evaluation was part of the work sequence analysis (WSA), which was included in the cost-minimization analysis.

ATTEMPTS TO REDUCE FUNDING BIAS AND OBSERVER BIAS

By performing a qualitative study prior to the intervention study, and applying the information gained when designing the intervention study, we hoped both to minimize funding bias, and be able to apply the knowledge in order to select the best possible outcomes, test samples, and test procedures. The staffs, working with the patients, were also evaluating when the discharge criteria were fulfilled. Although we did attempt, we were not able to design a study with inclusion of external evaluation of discharge criteria, as it was too logistically challenging. Except for data on TUG, we obtained all patient-related data and self-perceived cost/benefit from registers and questionnaires. All data were collected in an individual study folder and anonymized before data entry.

REPRESENTATIVENESS

We used descriptive studies to evaluate representativeness of our study sample in the RCT (Cohort B1 and B2) (see Figure 5).

Cost Minimization evaluation

The number of services used, i.e., home visits, visits to general practitioners or private physiotherapists, was recorded alongside the trial for cohorts B1 and B2, while unit costs, i.e., the cost of a home visit or unscheduled visits, were calculated based on an analysis of the relevant work processes.

Outcomes, Aim II a & b

The primary outcome in the efficacy study was LOS at discharge defined as day including nigh spent at the hospital. LOS was recorded using the study protocol and validated by means of data from the EHR. Among the supplementary outcomes were patient gains in health-related quality of life (HRQOL), [83,84] assessed with EQ-5D-3L. The Oxford Hip Score (OHS) was applied to assess hip-related function and pain, [85,86] recorded from baseline (two weeks pre-operatively) to the twelve-month follow-up visit. Furthermore Timed-Up-and-Go (TUG) [87] and VAS-anxiety measured in millimetre [71], were recorded from baseline to the follow-up visit three month later. For support persons, data on HRQOL and VAS-anxiety, were likewise recorded from baseline to the follow-up visit three month later. To evaluate a range of psychological problems and symptoms of psychopathology that theoretically could affect the outcome, we used the validated Symptom Check List 90 R (SCL-90-R).[88] . SCL-90-R formed part of the baseline parameters for both patients and support persons. Data were collected in a study folder that was returned at the three-month stage. Data from the six-month and twelve-month stages were obtained by mail from the patients. Mortality, readmissions, complication types and frequency rates were validated, within twelve months of the operation, by means of the Danish e-Health Portal, [89] accessible through the local EHR.

For conducting the piggyback cost evaluation, we followed all patients and logged their contacts with the hospital. Phone calls to the hospital, made by the patient or the support person, were monitored, as were unscheduled visits and readmissions in Denmark. Events not involving the hospital were obtained for the first twelve weeks after surgery by the use of a post-operative diary. Data on patient-related work performed by the support persons were also obtained in this way. The patients' perception of the cost-benefit of the procedure in relation to society as a whole, to the patients themselves and to the support persons was assessed at the twelve–month stage by means of three multiple-choice questions with three choices. This questionnaire was designed specifically for this study and face validated before use.

Statistics, Aim II

EpiData, V. 3.1 (EpiData Association, Odense, Denmark) was used for data entry when it was not possible to import directly to STATA. The statistical analysis was performed using STATA software V. 10.0 (SPSS Inc., Chicago, IL).

The primary outcome (LOS) was non-normally distributed, for which reason a more robust non-parametric test (Mann-Whitney) was applied. There were no adjustments to the data. Secondary outcome measures (HRQOL, VAS-anxiety) from patients and support persons were assessed for equal development of mean over time by Repeated Measurement (RM) analysis and presented as Wilks' lambda p-value. The same methods were chosen for OHS and TUG. Non-parametric outcomes, presented as a median (range) or as proportions (percentage) were compared by a two-sample Mann-Whitney test. Differences in baseline data were analysed by means of Fisher's exact test for categorical variables and the student *t-test*

for continuous variables when normally distributed, and the results were presented as a mean with 95% Confidence Intervals (CI). Incidents of post-discharge events were tested by means of the Mann-Whitney test when n≥5 or Fisher's exact test when n<5. Numbers Needed to Treat (NNT) was calculated based on LOS for evaluated patients needing to be treated to benefit compared with the control group. Incidents used in the cost-minimization analysis were tested by means of a Mann-Whitney test, except for one, where n=2 which was tested by means of Fisher's exact test.

STUDY OUTCOMES, AIM II A & B

Supplementary results for the RCT is reported in the individual paper.

The protocol for the RCT was violated regarding sample size. Due to a prolonged inclusion period, it was decided to terminate the study when 73 patients had been included.

PATIENT CHARACTERISTICS

A total of 654 patients, referred to the orthopaedic outpatient clinic with hip-related issues and living less than 60 kilometres away from the hospital, were assessed for eligibility. Of these, 534 patients were not due to be operated on. A total of 120 couples - patients and their support persons - were eligible for inclusion. Of these 47 couples were not included: 20 patients and four support persons did not consent. It was not possible to set up adequate Internet connection in nine cases. 14 couples opted to have THR surgery within the first two weeks after the day of the introduction to the study, which did not leave enough time to set up the intervention. As a consequence these 14 couples could not be included. This left us 73 patients for randomization, 37 of whom were allocated to the control arm of the study and 36 patients to the intervention arm. One patient in the control group withdrew consent before surgery, leaving 36 couples in each study arm (Figure 11). The patients and their support persons in the two groups were comparable at baseline. With regard to the post-operative data, six patients did not complete the entire post-operative diary, or all outcomes, in the twelve-month follow-up period.

TABLE 4 DEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF THE FTHR AND TMS GROUPS

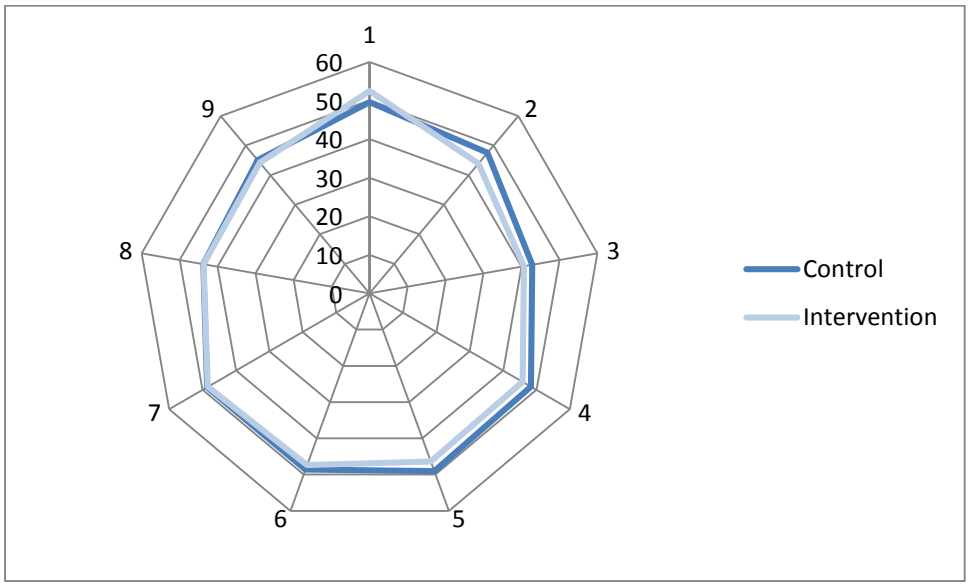
	FTHR	TMS	Not eligible
Female / Male (n)	17 / 19	17 / 19	271 / 287
Age, years	63.5 (45-84)	62.5 (43-80)	66.0 (27-92)
Dist. (Km) from Hospital	40.45 (1.8-56.8)	33.10 (0.4-56.7)	
Implant type (n=72)			**Fisher's exact test**
Corail/BHR*	29/7 (40%/10%)	31/5 (43%/7%)	P=.75
Social status (66 responded)			
Alone/With partner	5/27 (8%/41%)	2/32 (3%/48%)	P=.25
Employment status (66 responded)			
Working	11 (17%)	19 (29%)	
Sick leave	0 (0%)	2 (3%)	P=.051
Retired	20 (30%)	13 (20%)	
Other	1 (2%)	0 (0%)	
Support-person (66 responded)			
Partner	26 (40%)	32 (48%)	
Friend	2 (3%)	2 (3%)	P=.26
Son / Daughter	2 (3%)	0 (0%)	
Other	2 (3%)	0 (0%)	
SCL-90-R (70 responded)			**t-test**
GSI†	46.97 (41.68-49.52)	43.22 (40.41-46.03)	P=.84
PST‡	47.69 (44.24-51.14)	45.76 (42.56-48.97)	P=.41
PSDIΔ	44.83 (39.46-50.21)	50.85 (46.99-54.71)	P=.072
SCL-90-R Support person (67 responded)			T-test
GSI†	45.60 (43.67-50.27)	46.52 (43.39-49.66)	P=.32
PST‡	46.00 (42.18-49.82)	43.78 (40.95-46.61)	P=.35
PSDIΔ	43.06 (39.46-50.21)	45.56 (41.23-49.90)	P=.50

*Gender is given as frequency. Age and distance as median with max and min. Implant type, social status, employment status and support persons are listed as frequencies and proportions given as a percentage value. Relationships are tested with Fisher's exact test, except for SCL-90-R, where the students' t-test was used, and results are presented as mean (95% CI). *Birmingham Hip Resurfacing. †Global Severity Index, Designed to measure overall psychological distress. ‡Positive Symptom Total, Reports number of self-reported symptoms. ΔPositive Symptom Distress Index, Designed to measure the intensity of symptoms.*

There were no differences in psychopathology in the Global Severity Index, Positive Symptom and Total Positive Symptom Distress Index at baseline, when comparing the patients in the intervention and control groups, and there were no differences when comparing the support persons (Table 4). When comparing

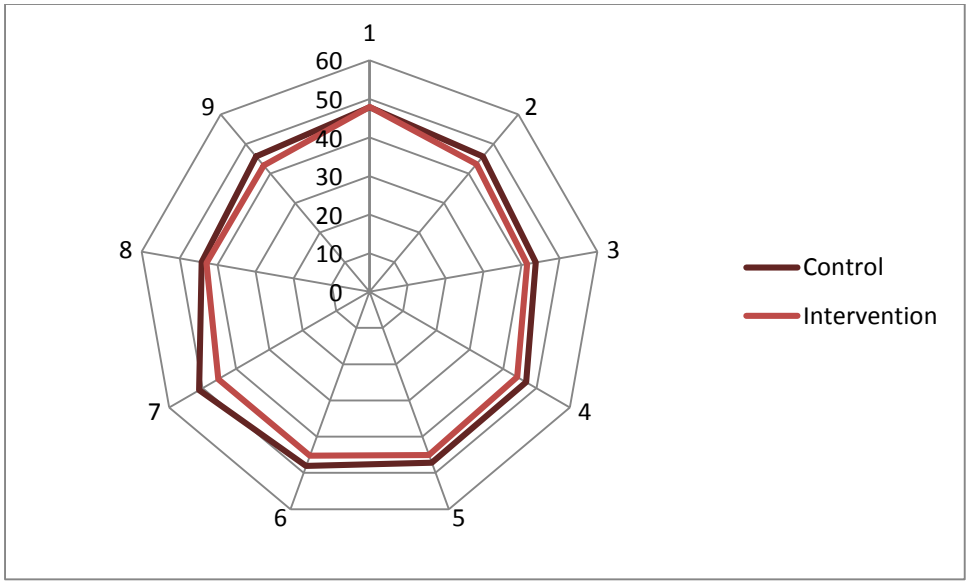
the nine elements of the SCL-90-R, no significant differences between the two groups were observed (Figure 12, Figure 13).

FIGURE 12 SCL-90-R PATIENTS



Elements of the SCL-90-R; 1 Somatization; 2 Obsessive-compulsive; 3 Interpersonal sensitivity; 4 Depression; 5 Anxiety; 6 Hostility; 7 Phobic anxiety; 8 Paranoid ideation; 9 Psychoticism

FIGURE 13 SCL-90-R SUPPORT PERSONS



Elements of the SCL-90-R; 1 Somatization; 2 Obsessive-compulsive; 3 Interpersonal sensitivity; 4 Depression; 5 Anxiety; 6 Hostility; 7 Phobic anxiety; 8 Paranoid ideation; 9 Psychoticism

ADVERSE EFFECTS

One patient was readmitted two months after the operation, due to what was considered an unrelated episode of Diverticulosis Coli. The additional LOS after discharge was not included in the overall estimation of LOS for the intervention study. In the intervention group, one patient was readmitted for three days so as to exclude infection, but nothing was found. The additional LOS was included in the total LOS. One patient in the intervention group was admitted for five days because of post-operative bleeding, low blood levels and dizziness, for which reason it was not possible to conduct the first videoconferencing, nor the home visit. Nevertheless, the videoconferencing and the home visit were still included in the cost-minimization evaluation. With only one episode of complications leading to readmission, no significant difference in complications was observed (P<0.33).

LENGTH OF STAY (LOS)

In the intervention study, LOS had a median of 2 (IRQ=0, range 1-4) for the control group, and the intervention group had a median of 1 (IQR=0, range 1-5) (P<.000) (Table 5). The mean difference of 1.86 (95%CI 1.66-2.06) and 1.14 (95%CI .91-1.37) yielded a reduction in LOS of .72 (95%CI 0.42-1.02) day in favour of the telemedicine intervention (P<.000).

TABLE 5 DISTRIBUTION FROM THE EFFICACY STUDY

Group \ Day	1 day	2 days	3 days	4 days	5 days
Cont. (n=36)	22.2%	72.2%	2.8%	2.8%	0%
Intv. (n=36)	94.4%	2.8%	0%	0%	2.8%

More patients in the interventions group were discharged on the first day: 34 of 36 in the intervention group compared with eight in the control group. This led to a NNT of 1.39 (95%CI 1.2-1.92) for the telemedicine-supported intervention compared with the existing intervention.

HEALTH-RELATED QUALITY OF LIFE

The incremental improvement of patients' HRQOL, measured six times over a 12-month period showed no differences (P=0.35), when comparing the two groups in the intervention study. HRQOL increased significantly from baseline to twelve months after surgery: 0.26 (95%CI 0.19-0.33, P<.000) for the control group and 0.28 (95%CI 0.21-0.34, P<.000) for the intervention group. When analysing the support persons, we observed a significant increase of 0.068 (95%CI 0.012-0.12 P<0.02) in HRQOL from baseline to the measurements performed at the three-month stage. We found no difference between the groups in the incremental improvement of HRQOL over time (P=0.32).

FIGURE 14 HRQOL AT BASELINE FOR PATIENTS

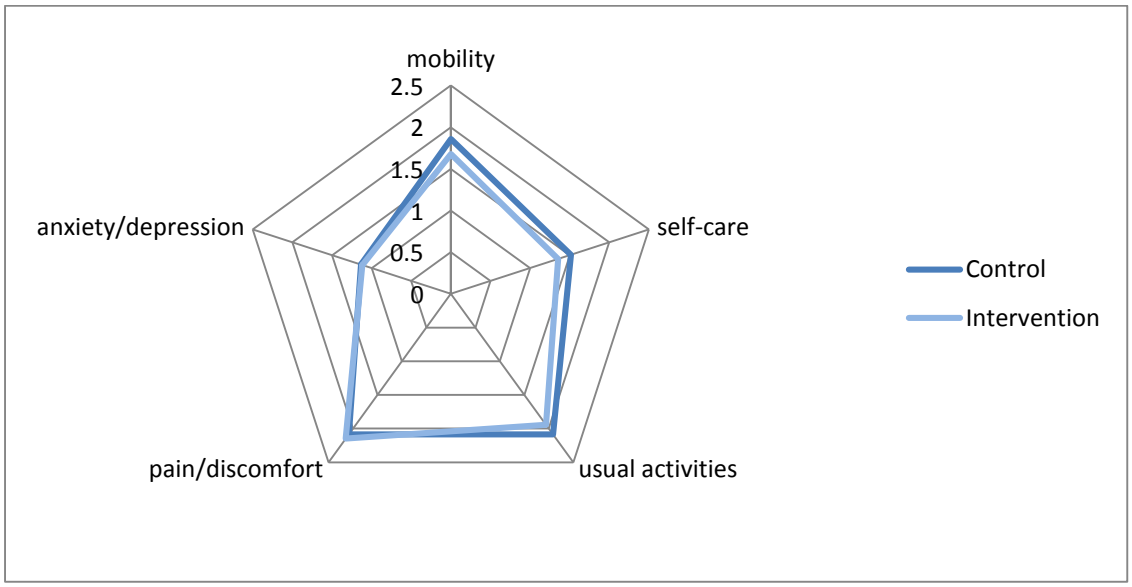


FIGURE 15 HRQOL AT 12 MONTHS FOR PATIENTS

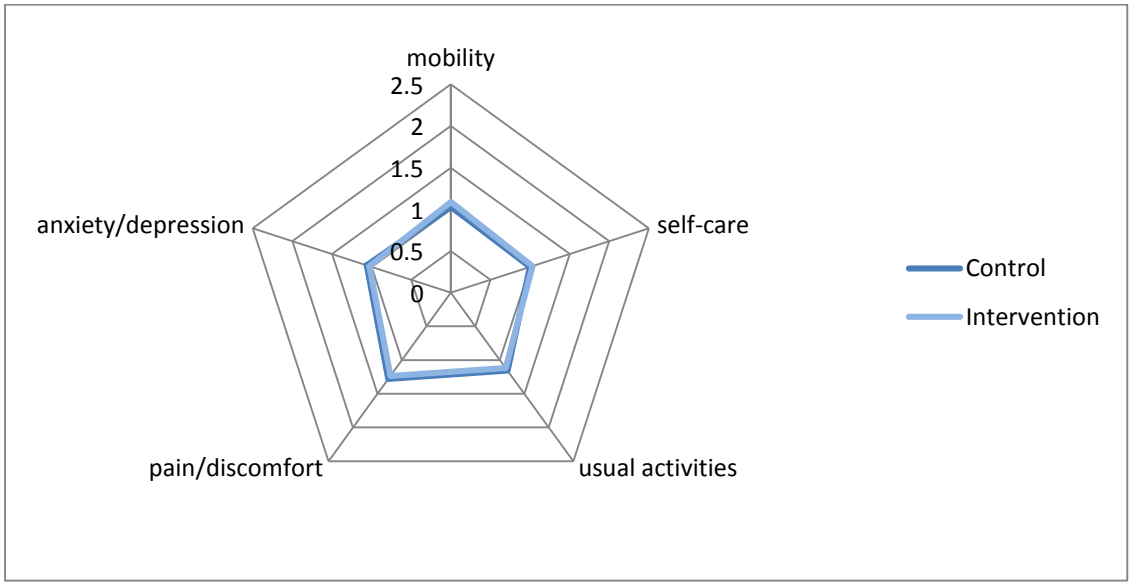


FIGURE 16 HRQOL AT BASELINE FOR SUPPORT PERSONS

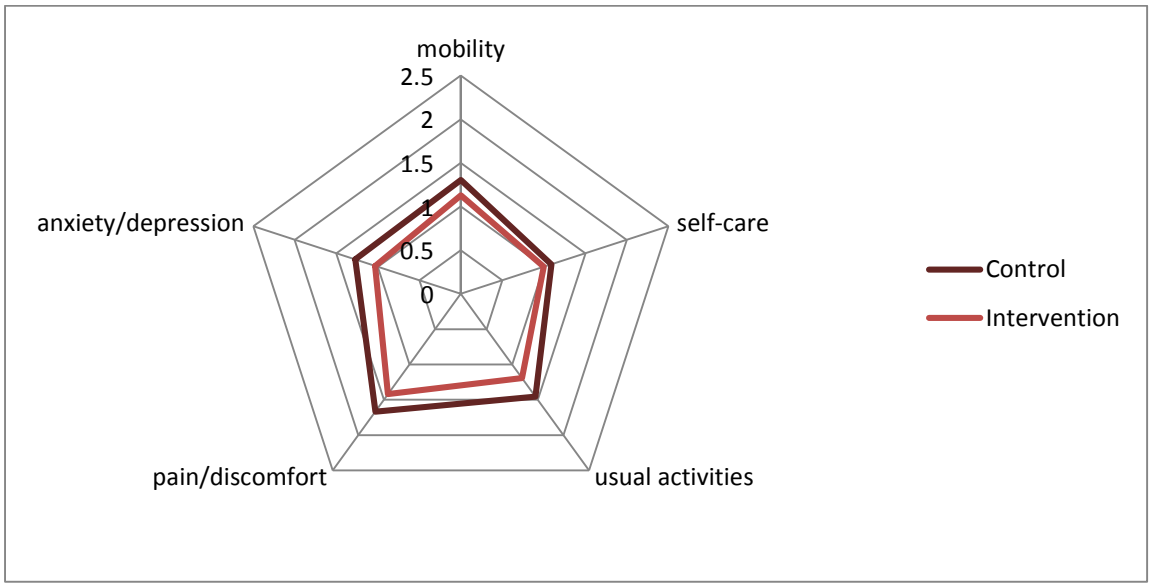
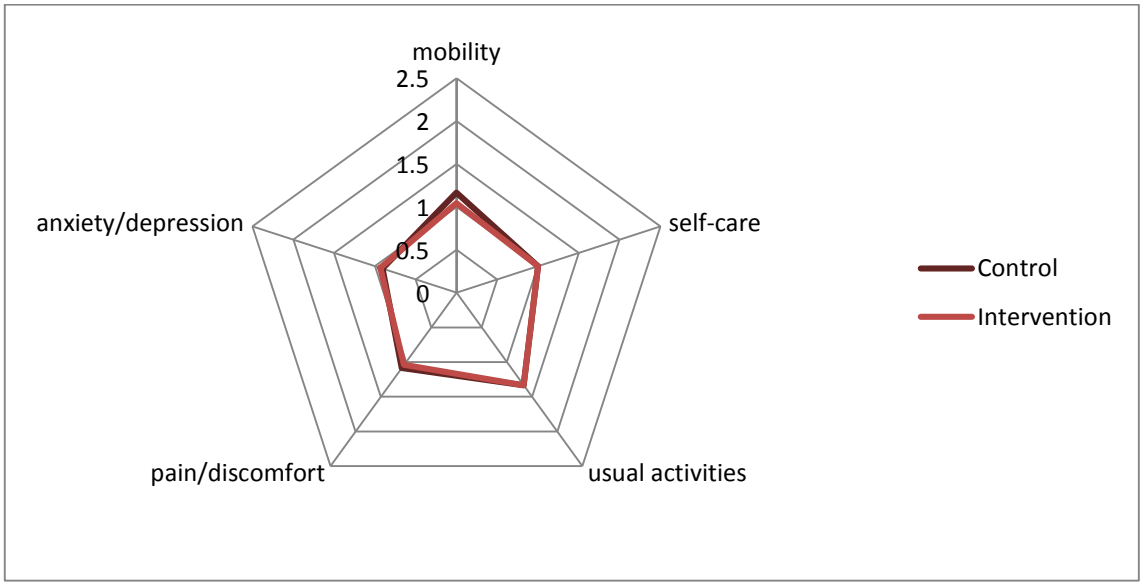


FIGURE 17 HRQOL AT 3 MONTHS FOR SUPPORT PERSONS



OXFORD HIP SCORE

The incremental improvement of the patients' OHS measured six times over a twelve-month follow-up period showed no differences (P=0.35) when comparing the two groups in the intervention study. The patients in both groups gained significantly, when comparing baseline with outcome at twelve months.

VAS-ANXIETY

VAS-anxiety was reduced significantly: 20.50 mm. (95%CI: 14.67-26.32, P<.000) from baseline to 90 days post-surgery. We found no difference between the two groups in incremental development over time

(*P*=0.15). VAS-anxiety was also reduced significantly: 12.25 mm (95%CI: 7.19-17.32, *P*<.000) from baseline to 90 days post-surgery for the support persons. Again, we found no difference in incremental development between groups over time (*P*=0.32).

TIME UP AND GO (FUNCTIONAL TEST)

The mean improvement in the control group was 1.42 seconds (95%CI: 0.91-1.93, P<.000). For the intervention group, the mean increase was 2.05 seconds (95%CI: 1.39-2.71, P<.000). There was no difference in incremental development of TUG during the first three months after surgery (P=0.09).

USE OF THE TELEMEDICINE SOLUTION

Analysing the 35 individual users' interactions with the telemedicine solution, we saw a total of 5,348 hits. A hit is an event where a user of a set-top has opened a "page". This is logged and presented as a SQL file. It is not possible to know the intention of the users' actions. The numbers of hits yields an average of 153 and a median of 125 hits (min 9 – max 489, IQR 227) per unit. For the information pages that were used the most, including videos and animated material, please refer to Table 6.

TABLE 6: THE INTERACTIONS WITH THE TMS - THE TEN PAGES WITH THE MOST HITS.

Use of Telemedicine solution	Hits based on 35 units	Percentage of hits
Medication	234	(24.5%)
X-rays	216	(22.6%)
Animated intro to THR	147	(15.4%)
Contact info - hospital	95	(9.9%)
Training video # 24	51	(5.3%)
Training Video # 28	46	(4.8%)
Info on what to do when	43	(4.5%)
Training Video # 25	42	(4.4%)
Info on treatment of pain	41	(4.3%)
Training Video # 23	41	(4.3 %)

POST-DISCHARGE EVENTS

TABLE 7 POST-DISCHARGE EVENTS

Type of event (Hospital)	Control (n=36) (Frequency)	Intervention(n=36) (Frequency)	Mann-Whitney test
Phone calls to hospital	55	33	P=0.04
Unscheduled visits to hospital	11	9	P=0.48

Type of event (Home) (12 weeks)	Control (n=35) (Frequency)	Intervention (n=34) (Frequency)	
Visits to GP	29	22	P=0.24
Physiotherapy/Rehab	35	16	P=0.30
Home care/Home nurse	10	2	P=0.49*

** Fisher's exact test*

COST MINIMIZATION

The total amount of time spent on the TMS procedure per patient was calculated based on the WSA 217 minutes. When making a distinction between financial hospital costs and societal costs, we have the following outcomes in DKK:

TABLE 8: COST

Financial hospital costs	Intervention	Control	Difference
Total	334256	358303	-24047
Per patient	9284	9953	-668
Societal costs			
Total	7022	13888	-6866
Per patient	195	386	-191
Combined costs			
Total	341278	372191	-30913
Per patient	**9480**	**10339**	**-859**

The patient-related work undertaken by the support persons (hours spent supporting the patient) during the first 12 weeks showed a mean of 43 hours (95%CI: 24.05-62.41 P<.000) for the control group and 27 hours (95%CI: 14.72-40.92 P<.18) for the intervention group. The costs were assessed by applying a minimum wage of DKK 105 per hour (Table 9).

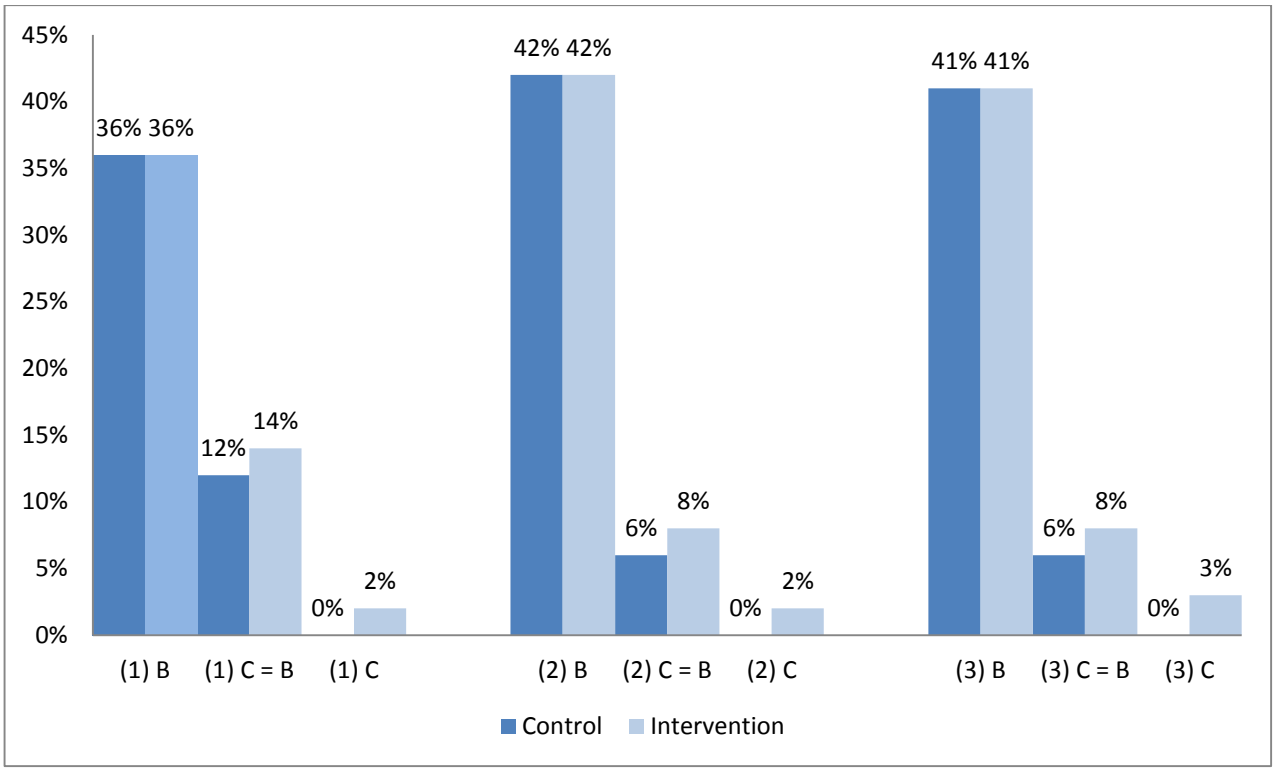
TABLE 9: COST FOR PATIENT-RELATED WORK PERFORMED BY SUPPORT PERSONS

Cost for work	Intervention	Control	Difference
Total	105173	163404	-58231
Per patient	**2921**	**4539**	**-1618**

PATIENTS' SELF-EVALUATION OF COST/BENEFIT

We observed that most patients in both groups perceived the benefit of the procedure as higher than the cost. The term cost was presented as including the economic, physical and psychological resources used. We obtained the results by asking about three different possible beneficial outcomes of the procedure. When analysed, we found no difference between the perception of "cost/benefit" in the control and intervention groups for society (P=1.00), patient (P=1.00) and support person (P=0.64).

FIGURE 18: THE DISTRIBUTIONS OF PATIENTS' PERCEPTION OF COST/BENEFIT



(1) Is with regard to society, (2) Is with regard to patient, (3) Is with regard to support person. B is the percentage of answers benefit>cost, C=B is the percentage of answers cost=benefit and C is the percentage of answers cost>benefit (n=66)

11. AIM III - EFFECT ON DAY-TO-DAY PRAXIS

DAY-TO-DAY PRACTICE, EFFECTIVENESS

To evaluate effectiveness, data samples of hospital productivity and patient characteristics were obtained in an anonymized form through the hospital's administration system. The selected three-month period, February, March and April, were the last before the intended start of the efficacy study in 2009. We included all patients receiving primary THR. With an inclusion of the normal number of THR patients (more than 100) operated on at the department during three months, we would be able to detect a relevant difference in LOS of 1.5 day from the pre-implementation period in 2008 until 2010. This could be done with an alpha set at 0.05 and a beta set at 0.95 (SD 2.5). We included patients from the same periods from 2008 to 2012. The effectiveness was calculated using cohort 1 (2008) and cohort 4 (2011) (Figure 5). The two procedural changes (PC1 and PC2) were implemented in 2008 and in 2010. Adverse effects were not part of the routine monitoring of THR patients at RHS. Therefore, data were obtained through the Danish Hip Arthroplasty Register DHR [90]. These previously published data were included in the triangulation process [91] later described. To evaluate any additional spontaneous development in effectiveness cohorts 4 and 5 were compared. Finally, LOS from the RCT (efficacy) is compared with LOS from day-to-day praxis (effectiveness).

TRIAL PARTICIPANTS.

Altogether, 696 patients, who underwent THR in the months of February, March, and April in the years 2008 to 2012 at RHS, were recruited consecutively in the effectiveness study.

METHODOLOGICAL CONSIDERATIONS, AIM III

SELECTION OF STUDY DESIGN IN THE EFFECTIVENESS STUDY

The before-after measurements of the effectiveness study was part of the monitoring at the department, which had begun in connection with the full implementation of EHR. The selected data were based on their relevance and availability. The decision to optimize the fast-track procedure, used in day-to-day practise, made by the department changed the initial comparator and presented a challenge in terms of the design of this study. The design was altered to include patients at defined periods in time between implementations of new procedures in the day-to-day praxis.

ATTEMPTS TO REDUCE BIAS IN EFFECTIVENESS STUDY

The before-and-after measurements of the effectiveness study were part of the monitoring at the department, and no special effort was done. The reason for this being that the data used were pulled from the Health Records; and used to report to the DHR. One could fear that the staff forgot to register the specific discharged time for the patient. We found no feasible way to validate this data.

MASKING OF PATIENTS AND HEALTHCARE STAFF

Data used to evaluate effectiveness were obtained from the hospital administration system and were part of the normal and usual monitoring at RHS. Data were obtained for 2008 to 2009 from two wards at RHS, while data from 2010 to 2012 were obtained from only one of the wards that were assigned all THR

patients. The wards are considered to be similar. All contacts and questionnaires were part of the monitoring already taking place at the hospital. We used anonymized data generated though the EHR. The patients and staff were not aware of the on-going study.

Attempts to reduce observer bias

Doctors who were not otherwise involved in the study decided, in agreement with the patient, when discharge criteria were fulfilled, as was also the standard at the department. All data were obtained through public registers.

Representativeness

We evaluated the internal representativeness of our cohorts, by comparing data for gender, age and procedure codes.

Efficacy compared with effectiveness

We used cohorts B2 and 5, which both received an accelerated intervention with the same logistical setup and with the goal of an LOS of one day, but this was performed in two distinctive orthopaedic wards at RHS. The aim was to describe how efficacy results in a best-case scenario (cohort B2) compared with effectiveness results in a real-case scenario (cohort 5) (VI, Figure 5).

Outcomes, Aim III

The primary outcome was LOS from admission to discharge, while readmission within 90 days was a secondary outcome measure. Data on all patients operated on in the months from February March and April in the years 2008 to 2012 were collected via the hospital administration system. The readmission rates from within the 90 days were obtained from public data [90] on all THR patients operated on at RHS for 2009 to 2011.

Statistics, Aim III

Day-To-day praxis

The statistical analysis was performed using STATA software V. 10.0 (SPSS Inc., Chicago, IL). LOS did not have an equal variance. The incremental development was tested by means of the Kruskal-Wallis rank test and presented as proportions given as a percentage value and as a median with inter-quartile range (IQR) and range (Max. and Min.). Age and gender were chosen for the evaluation of changes in the patients' profiles. Comparison of efficacy and effectiveness was tested by means of a *t-test*, even though results (LOS) were right-skewed. Our choice of test was due to the high (n) and the robustness of the test.

Study outcomes, Aim III

The majority of the results for this dissertation are reported in the individual manuscripts. Summary and selected results are given below.

Patient Characteristics

The patients from each cohort, collected in three months periods in time, over 5 years were comparable with regard to age and gender.

Length of Stay

When analysing effectiveness, we found a significant reduction in LOS of 3.77 days (95%CI 3.22-4.32) from a LOS of 5.67 days (95%CI 5.10-6.25) for all patients receiving the current procedure for the three-month pre-study period in 2008 to 1.90 days (95%CI 1.68-2.12), and for all patients receiving the optimized intervention in the first three months after termination of the study in 2011 ($P < .000$). Effectiveness, furthermore, improved significantly over the next year (2011-2012) to a LOS of 1.39 days (CI95% 1.52-1.77; $P < .000$) (Table 10). From 2008 to 2012, the overall reduction in avg. LOS was more than 75%.

Table 10 Distribution of LOS for THR patients at RHS from 2008 to 2012

Year \ Day	1 day	2 days	3 days	4 days	5 days	6 days	7 - 10	11 - 15	15 +
2008 (n=107)	0%	0.9%	2.8%	39.3%	16.8%	16.8%	19.6%	2.8%	0.9%
2009 (n=170)	1.8%	27.6%	38.8%	14.1%	4.7%	4.1%	1.1%	7.0%	0.6%
2010 (n=125)	11.2%	45.6%	20.8%	10.4%	2.4%	3.2%	6.4%	0%	0%
2011 (n=146)	46.6%	36.3%	8.9%	4.1%	1.3%	0.7%	2.1%	0%	0%
2012 (n=148)	69.6%	23.0%	6.8%	0.7%	0%	0%	0%	0%	0%

Adverse effects

Readmission for THR at RHS was evaluated by data obtained from the DHR [90], covering readmission-rates caused by medical complication within the first 90 days. Data were available for 2009 to 2011. The rates were 0.7% (95%CI 0.2-1.9) in 2009, 1.4% (95%CI 0.6-2.7) in 2010 and 0.3% (95%CI 0.0-1.5) for 2011. The rates were lower than the national average reported every year.

Efficacy compared with effectiveness

LOS from the RCT (efficacy) compared with LOS from day-to-day praxis (effectiveness) in the selected period in 2012 yielded a difference in favour of the TMS intervention used in the RCT. We found a difference in LOS of 0.25 day (95%CI .007-.49; $P<0.04$).

12. AIM IV – TRIANGULATION OF DATA

DESIGN OF THE MIXED METHODS RESEARCH

The mixed methods research (MMR) that was conducted in this study included qualitative and quantitative data from the formative research, the RCT, the embedded ethnographic study and the before-after study of the day-to-day praxis (Depicted as VII in figure 5).

Interdisciplinary and mixed-methods research is gaining a strong foothold in the healthcare sector, as also seen by the increase in the number of publications and journals focusing on mixed-method studies [92-94]. MMR can be traced back to 1959, when Campbell and Fisker formalized the practice of triangulating data from more than one research method as part of a validation process [95]. During the 1980's, MMR became a methodological movement in social and behavioural sciences [96]. In 2007, Johnson et al. defined MMR in the Journal of Mixed Methods Research as: "*Mixed methods research is the type of research in which a researcher or team of researchers combines elements of qualitative and quantitative research approaches (e.g., use of qualitative and quantitative viewpoints, data collection, analysis, inference techniques) for the broad purposes of breadth and depth of understanding and corroboration*" [95]. Creswell describes MMR as "*focusing on collecting, analysing and mixing both quantitative and qualitative data in a single study or series of studies*" [60]. Furthermore, MMR can include published results to the triangulation [60].

The development of new and innovative technology, insight into organizational changes and qualitative documentation of the patients' experience called for research skills that did not exist in the initial study group and an ethnographer were therefore brought in to the project. Qualitative research, used as a wide-angled lens for exploration and bringing to light the patients' needs and behaviour in the natural environment, had a tremendous impact as a method for creating the final solution and thereby the intervention [75]. This inductive work gave inspiration to specific hypotheses, which were tested in the narrow-angled lens quantitative study. The final MMR design, used in the RRS Project emerged during the initial phase of the project. The choice of research method is based on the researchers' assumption that quantitative or qualitative studies by itself would be insufficient for testing multi-faceted interventions as implemented in the RRS Project [97].

The ethnographer did all the qualitative research and analysed all the data. In this thesis, however, only a small part of this is accounted for in order to give insight into some of the work [75,98] that is included in the triangulation. I can in no way take credit for this work.

EMBEDDED QUALITATIVE STUDY (ALL CARRIED OUT BY THE ETHNOGRAPHER)

The formative ethnographic study carried out in 2008 should not be confused with the embedded study. An ethnographer carried out an anthropological study in 2009, focusing on the experiences reported by the patients, support persons and staff members. The study was carried out in both the intervention and control group (cohorts B1 and B2, Figure 5). A broad set of inclusion criteria guided the inclusion: an even distribution of gender; an even distribution between the intervention and control group; a broad age distribution; and the presence of both spouses and others as close relatives. Seven patients (four women and three men) from the intervention group and five from the control group (two women and three men),

as well as their support persons, were included in the study. Eight of the patients had their spouse as their support person and four had other relatives/friends (two of these did not participate in the anthropological study). Patients were included by the researcher following a review of patient records, or by the researcher who met the patients, for instance, at the pre-operative information meeting. Seven staff members (two nurses, one physiotherapist, one doctor, two coordinators, and one occupational therapist), who represented the staff with the most involvement in the pathway, were recruited for interviews. Several other staff members (e.g., secretaries, surgical staff, out-patient clinic staff and laboratory technicians) were observed during their work and participated in unstructured interviews. All the staff interviewed and observed worked with patients in both the RCT and day-to-day praxis. The observations were applied to include focus on activities, behavior and relationships and the interviews allowed reflections, views and experiences to be included [93,99]. The observations, and if applicable with the researcher participating in the activities, were undertaken at the hospital and in the patients' homes. Observations were documented by field notes and photos. The foci of observations were the interactions between the patient and the close relatives, between the patient/close relative and the staff at the hospital, the process of returning home, the use of technology and the work environment of the staff. The foci covered the different steps in the fast-track THR procedure, the research interests of the interdisciplinary work group and the social aspects of healthcare and the use of HIT. The primary methods applied were participant observation and semi-structured interviews[100]. The combination of these methods took into account the possible discrepancy between what people do and what people say they do. Data was first coded and then studied for emergent themes, their nuances and coherences [93]. 'Security', 'patient screening' and 'staff coordination' were some of the themes. An analytical understanding of these themes was developed by relating them to each other and by looking at them through the theoretical lenses of phenomenology [101] and practice theory [102]. In terms of the ethical considerations, patients, support persons and staff were informed orally and in writing about the study and of the possibility of withdrawing their consent at any time. Anonymity in the presentation of the results was guaranteed. Staff members were promised that their names would not be disclosed, but that complete anonymity could not be guaranteed.

METHODOLOGICAL CONSIDERATIONS, AIM IV

ATTEMPTS TO REDUCE BIAS IN THE TRIANGULATION

We attempted to minimize analytical bias by using only the processed qualitative and quantitative results in the triangulation. By using the qualitative results as the lead outcome, any detection and reporting bias that they might have suffered from when they were embedded in the RCT, could be inherited and even increased or decreased by similar issues from the quantitative results.

Using the summary table, we tried to structure the many forms of data in a simple and user-friendly way in order to help the qualitative and quantitative researchers understand and gain insight into the different methodologies and in that way help merging data in the best possible way.

TRIANGULATION

The qualitative findings were listed on the left side of a qualitative summary table [60] in order to create a typology used as a framework for a side by side comparison with the quantitative data [103]. The rankings of the qualitative results were done based on their relevancy to the research questions of the effects of the RRS Project on the organization. They were listed based on type of outcome, event or individual. Each qualitative result listed was first correlated with relevant quantitative outcomes form the RCT, and then evaluated with regard to convergence, complementarity and discrepancy [104]. Thereupon the same process was repeated with the quantitative data from the before-after study (Process VII, Figure 5). The final transformation of the quantitative data to descriptions was done by using what can be referred to as *qualitizising techniques* [105] and then re-evaluated for convergence, complementarity and discrepancy. Data was then merged. The aim was to evaluate changes in process and behavior inflicted by the processes and research of the RRS Project; and if possible document if any knowledge sharing occurred at the clinic.

OUTCOMES, AIM IV

TRIANGULATION OF DATA

The triangulation included all qualitative and quantitative data collected during Aim II and Aim III (Process VII, Figure 5). After merging the data in the summary table, the results were reported only when found relevant by both the quantitative and qualitative researchers participating in the process.

RESULTS OF TRIANGULATION

Overall, the triangulation of findings showed a large degree of complementarity of data. In a few instances convergence or discrepancy was seen. Below 'qual' refers to results from the qualitative study while 'quan' refers to results from the quantitative studies.

The qualitative component showed that in obtaining the goal of a short LOS it was important that patients experienced a staff who signaled that they believed that the individual patient was capable of being discharged early. Staff confidentiality in the procedure and the appropriateness of discharging patients at day 1 seemed so well adapted by staff that data from the RCT showed that eight patients in the control group were discharged after day 1 instead of the planned day 2. In day-to-day praxis we documented LOS getting close to the results from the RCT.

The home visit was considered important for patients in order for them to feel ready to be discharged after day 1 (qual). This is supported by the results from the VAS-anxiety (quan), where we found no difference after one or two days between the intervention and control group. Hence the day of discharge was different. The results from the VAS-Anxiety reported from the relatives also showed equal findings in the two groups. The video-conferences were considered important by patients in the intervention group in order to feel safe (qual) and this is supported by the fact that it was the video-conference feature which patients had used the most (quan). In the day-to-day praxis, post-surgery telephone calls were included as part of procedural change 2.

A very structured running of the procedure and a small group of staff involved in the contact with the individual patient increased the confidence in the treatment (qual). Conversely, failure to obtain a

structured running of the procedure or procedures that were too vague led to increased feelings of insecurity on the part of the patients and their relatives and an increased need of more support. Both during hospitalization and after the discharge, home visits, video-conferencing and access to the interactive information were seen to significantly reduce the number of postoperative phone calls from telemedicine-supported patients to the hospital.

Anxiety was experienced by both relatives and patients (qual). Both the patients' and the relatives' anxiety increased right before the surgery, after which it decreased significantly (quan). The intervention group had a marginally lower anxiety score compared with the control group. The use of the telemedicine intervention was observed to follow the same anxiety levels. The animated information film, for instance, was the telemedicine service that was the most frequently used right before the admission, whereas the medicine module and the patients' X-rays were the most frequently used right after the operation. The exercise films that were produced for the last part of the rehabilitation program, where the anxiety level was supposed to be low, were not used very much.

Access to information was perceived to be important by both patients and their families. The patients and relatives emphasized the importance of the availability of the different sources of information, and that they could access them when they needed it, and thus not have to trouble the staff at the hospital (qual). This was mirrored in the quantitative results, where a significant decrease in the intervention group's phone calls to the hospital was observed compared with the control group. In addition, the intervention group for instance showed a tendency to require fewer home care services, physiotherapy and visits to the general practitioner. The number of unscheduled visits to the hospital was low and similar between the intervention and control groups. There was no increase in the need for resubmission due to complications. We also found low and stable complication rates in the day-to-day praxis.

The active role of the patients and the increased involvement and responsibility entrusted to the close relatives increased the need for education and information (qual). However, if education and information are provided, the hours of work recorded by the relatives are seemingly fewer in the intervention group compared with the number of hours recorded by the relatives in the control group. This is in spite of the fact that the intervention group spent more time at home and was given more tasks and responsibility (quan)

In the evaluation period and especially at the beginning, we observed that the hospital staff felt insecure about discharging the patients early. With time the insecurity decreased and was replaced by a new understanding of what is normal and a commitment to the project (qual). The staff embraced the new way of thinking and applied it in the continued development of the procedure and their work after the completion of the project. It may reasonably be argued that this has had an impact on the fact that LOS measured in the day-to-day praxis in 2012, and after the project period, approached the level of the intervention group, but without the telemedicine support and the home visits (quan).

13. DISCUSSION

The complexity of the RRS Project offers a possibility to discuss many elements. In the following, we have selected some topics that we consider relevant in order to challenge the Iron Triangle or important for future work.

POSSIBLE MECHANISMS AND EXPLANATIONS THAT CHALLENGE THE IRON TRIANGLE

Do the RRS Project and its results challenge the claim that cost, access and quality are in competition with one another and that there will be a trade-off?

The observed reduction in LOS of 0.72 days between the telemedicine-supported intervention and the existing intervention in the RCT was achieved primarily because of the multi-disciplinary intervention. The reduction of LOS in the day-to-day praxis was primarily achieved by means of procedural changes based on knowledge and experience gains from working with the RCT. In addition, the organisational changes that increased the possible implementation effectiveness [106] may have facilitated the reduction in the studies. Both ways of reducing LOS lead to a direct cost reduction for the department. That a cost reduction can be achieved have been seen in other studies [12,107]. That there was no cost shifting found in the RCT may also indicate that the patients and their relatives carried out the tasks by themselves [108]. Nevertheless, we did not find any studies that were this close to an average LOS of one day for standard primary THR patients, nor did we find any studies that tested the use of telemedicine in relation to THR

The idea of setting up a group with different professional backgrounds working together to create an innovative disruptive solution has been used in the private sector for many years - e.g. in engineering and software design [109]. As an integrated part of the Danish healthcare sector, we are not used to this interdisciplinary approach of including competences and people who are not usually working in the healthcare sector. However, agile development, different professional profiles of the members of the project group may indeed help the RRS project to succeed, both on the political level in the organization and by making it easier to implement the solution as seen in other work settings [106].

The high level of focus on a solution that would address clinical as well as patient and social needs, as well as the attempt to enable the department to benefit economically from the RRS project most likely eased this project's realization. This need-driven approach has been successfully used in relation to the development of Medtech devises [110]. Taking the needs of all stakeholders into account may also have helped to create a social movement, as was intended, and in that way made the implementation easier.

The researchers made no attempt to perform research outside of their specific areas of expertise. This may, however, have limited the possibility of obtaining additional benefits from the interdisciplinary set-up when developing the intervention. The mixed-method design for the evaluation research was created alongside the innovation process in an emergent mixed-method design [60]. Qualitative results obtained through formative research, as part of the innovation process, were considered relevant for the design of the evaluation research. The interventions included in the efficacy study could unintentionally have been designed to address the outcomes based on the quantitative results obtained during the innovation.

process, and as a consequence there was a risk that the project group would not sufficiently address the patients' needs. This could be regarded as information bias, and we were aware of the potential problem that it could cause. Considerations for safeguarding user-interests had to be made. By combining a participatory design [47] process with an innovation design approach and by a constant and deliberate presentation by the ethnographer, of the identified needs of patients and relatives ensured that the focus on user-interests, and involving patients and relatives was maintained [110,111].

When LOS is used as the end-point, as in the RCT, standardized discharge criteria are important. The reduction in LOS for the control group compared with the existing intervention supports the view that the study protocol has been followed, and that the patients have been discharged when they were clinically and personally ready. Creating a solution and intervention with a principal focus on reducing anxiety and increasing the feeling of connectivity between the hospital department and the patients and their social network contributed to the favourable results. In terms of the educational options offered to the patients, the animated material had a considerable effect in the reduction of anxiety. This is also supported by other studies [77,78,112] . Based on the number of hits, we also have to assume that medication and X-rays were important to the patients too.

With the possibility for the patients to access the interactive educational material used in the RCT, at their own discretion, before the "day of surgery", we created a 'pull environment' for their education compared with the usual 'push' educational approaches in face-to-face teaching. In this way, we could easily let the patients take part in their own treatment, hence installing in them a feeling of ownership and greater control with regard to their rehabilitation, which in turn could led to a higher degree of empowerment. This could also explain why, in the RCT, we were able to hand over more tasks and responsibilities to the patients without negatively affecting patient-perceived outcomes [69]. In the same way, it seems that the support minimizes the workload of the support persons. We find this interesting, especially as the patients' who received the intervention returned home faster than the control group.

The intervention applied in the RCT was less costly than control, and we believe that we could have reduced cost even more, if we had been able to use a 3G or 4G connection. However, we found that the risk of "offline time" would be too high, for which reason we opted for the more costly ADSL solution.

The implementation of the RCT and PC1 and PC2 were carried through with only few problems. We believe that this was helped along by the full support from the management of the hospital, the ratification of the white paper and the acceptance of the need for agility in a usually varied hierarchical organization. In addition, the time spent on the ward and in the out-patients' clinic enhanced staff familiarity with the project group's way of working and our intentions. The use of the "greenhouse concept" and the possibility of presenting results from the formative qualitative study, taking place in the department, and in the innovation part of the project contributed to the ease of implementation. The results from the workshops and pilot test, which were shared with the entire department, were important in terms of making the staff feel comfortable with the solution; easing acceptance and reducing resistance to change in the department. A top-down support and actively committed staff and patients in the bottom-up implementation are close to the optimal conditions for implementation of a solution like the one applied here. Working with agile development creates an environment, that when evaluated with Consolidated

Framework for Implementation Research (CFIR) Constructs [106] is close to optimal for implementation effectiveness.

The very tight schedule and the fact that the patients always knew when they could talk to, or meet staff virtually the next time could help explain the revealed differences in unscheduled phone calls from the patients to the hospital after the discharge.

The importance of the support persons was established in the formative qualitative study and the findings were supported by an increase in HRQOL for the support persons shown in the RCT. The emphasis on involving support persons in the whole procedure was decisive in order to be able to bring forward the day of discharge [113]. As it was a factor in both groups, it may explain the reason why eight patients in the control group felt ready to be discharged on the day after surgery – just like the patients in the intervention group. This observation may also be explained by the patients and their support persons being mentally ready to go home on day one, because they knew that this was an option right from the day where they were informed about the study. Some patients conveyed disappointment at not receiving the telemedicine intervention, which made us wonder whether these patients would still have wanted to return home after one day, also if they did not receive the same support as the intervention group.

The reduction in LOS that was found in the day-to-day praxis occurred most likely because of the impact from the RRS project, but a natural development and a spontaneous optimization, which is also experienced elsewhere in Denmark [90], may also have been contributing factors for some of the change. A general increased staff confidence, in the use of fast-track methodology treating orthopaedics patients cannot be ruled out. External factor and thereby possible change in culture at the hospitals could affect the results. The median LOS for THR patients at six Danish Fast-Track departments, part of the Lundbeck Foundation Center for Fast-track Hip and Knee Replacement, is 3 in 2011 [114]. Compared to the median LOS from RHS in 2011 of 2 (range 1-9) and the 2012 LOS median of 1 (range 1-4). The results support that the RRS Project is a mechanism and part of the explanation for the short LOS in day-to-day clinical setting at RHS.

The cost reduction generated by this shortening of LOS and the possibility of taking in more patients, thereby increasing productivity, may have explained the high level of administrative and organizational motivation. We cannot rule out that that knowledge sharing did not come exclusively from the RCT to the before-after study. It might also have been the other way around and thereby effected the outcome of the RCT. We find this observation essential. The possibility in the use of resources on local development or adaption of existing solutions could prove less costly than focusing only on the implementation [106].

COMPARISON OF RRS FINDINGS WITH RELEVANT FINDINGS IN OTHER STUDIES

More studies have documented a reduction in LOS in connection with THR and the use of fast-track methodologies [11,12,115]. We did not find any studies, however, where the aim was to discharge consecutively invited patients directly to their home on day one after surgery, nor did we find any studies on the use of telemedicine in connection with THR. An observational cohort study of 1,453,493 patients[116], who underwent primary THR and 348,596, who underwent revision THR, found a decrease in hospital LOS, but an increase in the discharge rates to post-acute care and readmission. This is dissimilar to the

results of this study, other recent Danish studies [12,90,114] or reported by the Danish Hip Arthroplasty Register. Although the proportions are somewhat different, it could indicate a cultural difference, or that the incentives for reducing LOS are different. The research on pre-operative interventions with regard to THR is inconclusive. A meta-analysis [117] found a limited effect of pre-operative exercises and education on pain and function post-operatively. None of the studies included information technology, and LOS was not an outcome in relevant studies, so comparison is difficult.

A study from 2010[118] found that it was possible to enrol 36% of eligible patients, below the age of 65 years, as outpatients. Of these, 77% returned home on the day of surgery. The average age of those who were discharged on the day of surgery was 53.5 years. When compared to the average age of 62.5 years for the intervention group in the RRS study, and 67.9 years for the last cohort from 2012 in the effectiveness study, there are indications that age plays a role with regard to the possibilities of bringing forward the day of discharge.

In a study [119] from Australia, where telemedicine was used in connection with patients undergoing knee replacement, it was established that "*participants in the tele-rehabilitation group achieved outcomes comparable to those of the conventional rehabilitation group*" at six weeks. When compared with the findings of this study, there were borderline differences in the physical test in favour of the intervention group, but no difference when evaluated with repeated measurements. The intervention's effect on the physical outcome is not clear, but the patients being treated with conventional procedures do not seem to be better off.

A study using a descriptive phenomenological approach to evaluate relatives' experiences of patient recovery in a fast-track programme for patients treated for colon cancer, revealed that the "*relatives seem to suffer in silence*" [120] and that relatives should be seen as a distinct group this is also supported by other work [74]. We think that this is perhaps the most important finding in this study. Addressing the relatives' needs and considering them a resource to be included in the procedure could be a cost-effective and healthy way of supporting the patients. Furthermore, we found that, even when entrusted with more tasks, the support persons' perception of the workload was less in the intervention group compared with the control group. In addition, after twelve months, the perception of the resources used by the support person was the same in the two groups. We found no other studies to support these findings. Examining the results from this study against the Iron Triangle, one could contend that we succeeded in obtaining a cost reduction, which in no way reduced the quality or the patient's access to a THR. In connection with fast-track THR, one explanation could be the support person's involvement in the intervention. If this is the case, we could also conclude that the cost was perhaps not reduced, but instead moved to the patients and the support persons, and therefore difficult to account for. In the future, cost could be looked at in a new context, and include all resources spent in connection with the perioperative treatment and rehabilitation until the best possible results have been achieved. When evaluating cost, we could leave out personal resources, such as empowering, or other resources that are difficult to calculate, but which are nevertheless important for making a cost reduction, although the physical and psychological resources contributed by the family must be taken into account too. The cost-minimisation analysis have the perspective of the hospital, GPs and the municipality. The selected costs are not sufficient to estimate cost

from the societal perspective. This perspective is considered the most relevant and the one to determine the threshold where the telemedicine solutions is cheaper than the conventional method.

SCALABILITY AND GENERALIZABILITY

The investigated patient samples in the interventions study were representative of a regional population, and the sample in the effectiveness study was representative of most Danish orthopaedic departments, when compared for age and gender.

Standard treatments are performed to fit most patients receiving the procedure, and while de Vinci's Vitruvian Man is not chosen as the standard patient, the standard patient profile is based on averaging responses from large cohorts. "Outliers" may have difficulties coping with the standard procedure. With the dawning of personalized medicine from the area of systems biology [121] and pharmacology [122] and the enhanced possibilities of creating individualized solutions with the use of HIT, the chance of developing procedures based on individual patient needs and continued interactive involvement emerged. The RRS project and its scalability and generalizability may be based on the possibility of personalization of the solution. The RRS intervention for the RCT was designed as a 'pull' setup, meaning that the patients were able to use it when they needed it; therefore, it fitted most THR patients. However, we think that many of the elements from the intervention are able to be copied in order to reduce LOS in a cost-and-quality-preserving manner, as seen in this study. This is also supported by an increasing interest in conducting more studies in elements from the RRS Project and the creation of a interactive solution for supporting patients having THR, inspired by this project [123], are now part of new research projects and used at different hospitals in Denmark.

THE USE OF AGILE DEVELOPMENT AT THE HOSPITAL

The tradition for empirical data in generating new solutions or hypotheses and theories is not that strong in the art of medicine. Here the traditions for deductive tests and verification of hypotheses or theories flourish. However, with the need for new ways of innovating and developing new solutions for the challenged healthcare sector, the necessity of inductive ways of finding solutions to a need seem to have gained a foothold. This can be seen, in the use of participatory designs, user-driven innovation, frugal innovation, need-driven innovation and Lean for optimising organizations or improving productivity. For some people who work in the healthcare sector, however, this adoption of innovation models from areas such as business schools, as described by Christensen's *Innovator's Prescription* [124], are not always immediately accepted. Furthermore, some people have the, perhaps legitimate, perception that the "art" of medicine does not and should not care about market dynamics. A position like this could be regarded as being in direct contrast to that of the hospital management/administration, where the position is to have a strategy for improving the possibilities of innovation, not only for creating incremental solutions, but for transformational or disruptive solutions.

Innovation is a buzzword and an increasingly popular item on the agenda from governments to hospital departments. The excitement of being innovative, however, must never obscure the evidence that every new treatment or procedure should have. Therefore, it is important that researchers support the innovators with existing evidence, which should be based on on-going ethnographical qualitative work

defining needs in combination with extensive literature search on topics in relation to the specific field of interest. The results of the initial research are important for focusing the development of solutions on relevant needs with appropriate evidence for the possibility of increasing the benefits of the innovation for the user.

The agility of some methods of software development [44,45,125] and design [47,126] - and their characteristics of being a social movement - are in sharp contrast to the regulatory and programmatic approaches that are used for developing and testing new drug treatments. The social movement and the self-governing form of co-operation and their power to achieve fast results, support innovation, change and implementation in a clinical setting [127,128] are strongly interlocked with the setting in which they take place. Reproducing the process is unimaginable, but, in clinical testing, reproducibility, for instance, when testing new drugs or implants, is important. With elements of the agility needed for innovation and the robustness of a clinical trial for documentation, we argue that we will be able to create the best possible solution for a specific setting and generate reproducible evidence of the effects of the intervention to be used in a more generalized manner. This would come from a combination of the team based agile development of the innovation process with a MMR set-up. We coin this new way of conducting agile development, test, research and implementation the Mixed Method Innovation Model.

In the SCRUM article from 1986, Takeuchi and Nonake described that the teams "*begins to operate like a start-up company*"[44]. Little did they know that close to thirty years later, one of the most popular articles in the HBR would be Steve Blank's "Why the Lean Start-Up Changes Everything" [109]. Steve Blank has been working with agile development for many years and is the creator of the Lean Start-Up (LSU) methodology. LSU is termed the scientific approach to creating and managing a start-up. LSU has a team-based approach and many similarities with what was observed by Takeuchi and Nonake and presented in their article. Steve Blank conclude in his article, that: "*in the long term some of its biggest payoffs may be gained by the large companies that embrace it*".

In a way, the circle is hereby full. The inspiration for the overlapping iterative development processes came from large companies, such as Fuji-Xerox, Canon and Honda. SCRUM became formalised and used for programming and to inspired the agile development movement, a movement that highly influenced the creation of the Lean Start-Up methodology for creating new businesses (start-ups). LSU is now been taught at major corporations, such as Google and the National Science Foundation. Here named NSF Innovation Corps. We think the methods that were developed and applied in the RRS project support the idea of creating start-ups within large companies. In the RRS project, the company is the Regional Hospital Silkeborg.

The inclusion of different tools for innovation has proven to be important. If companies did not use a model for innovation, some claim that the return of investment would only be obtained 4% of the time [129]. Our observations support the view that the innovation tools applied in the healthcare sector has their bearing, but also that the sector has to embrace the interests of all stakeholders working in the interdisciplinary teams and aim to address the needs of the patients and end-users. Merely relying on only one way of defining the right need for innovation, selecting an area for creating a solution could turn out to be of limited benefit, of no benefit at all, or even of potential risk to the patients.

The idea of combining agile development and MMR (as in the RRS Project) has also served as an inspiration and is used today at INNO-X Healthcare, Aarhus University [130]. Here the combination of agility development in the innovative process, with the need for robust evidence of effects in connection to cost, quality and access form the basis for the learning and for the way the curriculum was put together. The course is to be thought to researcher at the institute of Clinical Medicine, Aarhus University and as a Ph.D. course. This also supports the relevancy for this new way of optimizing and innovating for the healthcare sector. Verification is needed on the use of agile development in combination with MMR and the quality of results that it produces.

14. STRENGTHS AND LIMITATIONS

SELECTION BIAS

The objective of using consecutive inclusion and broad inclusion criteria in the efficacy study was to reduce any risk of selection bias. The exclusion of patients who were mentally disabled, unable to communicate in Danish, without a support person, had an inadequate Internet connection or no possibilities of having one set up led to the preclusion of only nine patients (7.5%). In 14 cases (11.7%), the telemedicine solution, including the Internet connection, could not be set up in the time interval between the assessment at the outpatient clinic and the day of surgery. Some 24 out of 120 patients or the associated support persons (20%) refused to participate, perhaps out of fear of the shorter LOS, or perhaps because they were unfamiliar with the use of information technology. This could indicate that patients with a certain profile are more likely to take part in research projects than others, resulting perhaps in biased samples. In general, it is assumed that patients, without close relatives, are in greater need of support when receiving treatment. By choosing patients who have a support person, we have made a selection that could affect the outcome. More patients with a job were allocated to the intervention group. We have no explanation but it could also affect the outcome.

The average age of those who participated in the RCT was lower than for those who were not included, which is a key issue. Compared with an average primary THR patient, the patients included in the RCT could have a higher level of empowerment.

In the effectiveness study (day-to-day praxis), all the patients operated on, in the defined periods of time, were included, and when evaluated, we were not able to identify any clinically relevant differences in their profile when compared with the DHR [90].

It may be argued that in the process of triangulation, the given interpreters and their level of experience may have influenced the validity of the reported outcomes. We believe, however, that the structured manner this part of the study was conducted in, the friendly work environment and respectfulness for the different research methodologies, and the fact that the qualitative and the quantitative researchers had participated in the entire project from day one and had access to all the obtained data created a good foundation for the merged data analysis. The familiarity with the nomenclature use by both researchers also supports the legitimation of the results. None of the two researchers mastered the mixed methods approach, and many decisions were therefore based on theory and not experience, both in regard to the planning and the conduction of the study.

INFORMATION BIAS

By our choice of data collection, outcome and end-points, we believe that we have done our utmost to reduce information bias.

Public register data and validated questionnaires were used for most of the data collection. We consider the quality of the data obtained from registers to be good, since all data used were obtained from available

official Danish registers, or from automated systems such as the EHR. The questionnaire, we chose, is widely used and has undergone a validation process. One exception was the cost/benefit questionnaire. Our intention was to mask the researchers making the TUG test in the efficacy study, only, and we believe that we succeeded in doing that. No obvious contamination in the control group in the RCT was identified from the observational study. However, the results with regard to LOS in the control group in the RCT, where patients and healthcare staff were aware of being under study, was significantly lower than those observed in the day-to-day praxis, where the involved subjects were unaware that they were taking part in a study. A Hawthorne effect cannot be ruled out, and is also in accordance with previous observations [115]. Selecting LOS as the primary outcome may be rather problematic, because it is also part of the intervention. It must be seen in relation to other outcomes and cannot stand alone. As in previous studies, [115] we used HRQOL and adverse effects, and furthermore evaluated anxiety, OHS and TUG. However, when using LOS as the primary outcome, keeping discharge criteria unchanged for the groups in the study was also considered important. The follow-up period in the RCT was twelve months for the patients and three months for the support persons. We believe that we collected most of the relevant outcomes and effects with a follow-up time of one year.

THE INTERVENTION

The intervention, being multi-modal, is a challenging test that limits the possibility of pinpointing the main reason for the results in this study. The home visits and the improved possibility of meeting the same staff during the entire procedure may have been regarded by some as the most important aspect, while the possibility of coming home to sleep in familiar surroundings may have been the most important factor for others.

DESIGN AND TESTS USED IN THE RCT AND COST EVALUATION

All calculations of LOS were based on automatically generated timestamps carried out by the staff on discharging the patients in the EHR. In 2008, this system was new, and the staff could therefore have lacked the skills required to do this at the right point in time, or erroneously have logged the actual time when doing it. This could of course result in bias in the data collection – a bias that would probably have become less significant as the staff became more familiar with the system. Therefore there is a chance that LOS has been reported longer at the beginning of the project in comparison with later on. In that way, it could also have boosted the gain in effectiveness. This method of collecting data was new to the department, and had not been through any form of validation.

The embedded qualitative study was used in an attempt to collect information and knowledge in the areas, where the selected quantitative outcomes were falling short. The MMR design helped to document the effects, although many possible explanations could still lie undiscovered. The final comparator was the RRS-inspired intervention with a standard LOS of two days. This intervention is perhaps not representative of the procedures performed at most Danish hospitals, which could limit the extrapolation of the results a great deal. However, when the average LOS for the comparator is shorter than the present average LOS in Denmark, the results ought to be of interest to most departments performing THR.

Calculating LOS in hours in the future could be more relevant as the use of LOS calculated in days, when getting this close to an average of one day, is problematic. The difference of one day or twelve hours may have been relevant. In this study, we have defined one day as a day, where the patient spent the night at the hospital. The same definition is used by the hospital administration system and consequently in the effectiveness study. Filling in baseline data, including VAS anxiety and HRQOL, after the patients were introduced to the TMS, could in some ways have empowered the patients and the support persons, and thereby influenced the first data. A pilot study has indicated that some patients witness a decline in their VAS-anxiety score after having watched the animation we used to illustrate some of the material available. The whole idea of the introduction to the TMS was to ensure that the patients were comfortable with the use of an IT solution, but we cannot rule out that this might have positively affected the outcome of the baseline data from the intervention group. The baseline scores on HRQOL and VAS-anxiety by the intervention group support this. A ceiling effect on HRQOL (EQ5D) was found, and we found similar problems with our other patient-reported outcome measures. Findings from this study imply that a follow-up period of 3 months may probably be sufficient in future studies. TUG was not able to identify any changes. A more sensitive physical instrument should be considered in future studies. We acquired complete data from 66 of the couples, or more than 90%, as is expected for a study of this type. Even though patients and relatives had to fill in many different questionnaires at both short and long intervals in this study.

Design and tests used in evaluating day-to-day praxis

Data were obtained for all patients receiving primary THR. We decided that the study periods were to be of equal length and run in the timeframe of the RRS project. In the effectiveness study, nobody was aware that they were participating in a study for the RRS Project, taking it all as part of the normal monitoring. Being evaluated on productivity could, in some ways, affect the outcome and theoretically create a Hawthorn effect. Any competition between the individual wards could have influenced the effectiveness study. The department's intention to increase the overall productivity by stimulating competition between departments could be one way of achieving this. But also the general focus on increased productivity in the healthcare sector may have affected LOS. Nowadays, there is a tendency for LOS to be reduced in Denmark as a whole. A factor we could not rule out or subtract from when analysing the data. Comparison with adverse effects in the day-to-day praxis could only be achieved indirectly, as we only had access to anonymized data.

Triangulation

The emergent MMR design may have limited the potentials of the interdisciplinary design. The inexperience of the researchers could also adversely have affected the presented results. The long-term connection and attachment to the project by the qualitative and quantitative researcher could also bias the selections and the relevancy of the presented results from the triangulation.

15. CONCLUSION

With the RRS Project, we set off to test the Iron Triangle. We managed to create a multifaceted intervention, including a telemedicine solution. During the same agile development process, we helped create and implement two procedural changes in day-to-day praxis. With a RCT including an embedded ethnographic study, we tested the intervention and found that it was possible to bring forward the patient's day of discharge after surgery, thus contributing to further reduction in the healthcare costs without compromising patient safety or affecting the quality of treatment, functionality, anxiety or other patient-perceived parameters. A before-after design documented a significant reduction of LOS in the day-to-day praxis for patients. A reduction that continued to improve one year after termination of the RRS Project and included all patients in need for access to surgery. With triangulation, we merged qualitative and quantitative data. This meant that we were able to obtain better insight into how the interventions worked and the impact of the RRS Project had on the organisation, the social movement and agile organisation it was part of.

The RRS Project showed how a mixed-method intervention research approach combined with agile development for innovation and the intention of focusing on needs for everyone connected with the THR procedure made it possible to implement a new multifaceted intervention. An achievement that would not have been possible without the interdisciplinary setup, the close corporation with the staff, and the hospital management's willingness to run a risk.

With the results from Aims II a & b, Aim III and the triangulation in Aim IV we were able to show that it is possible to reduce costs while retaining the high level of quality and access.
- And in that way the fundamental principal of the Iron Triangle's absolute trade-off has proven obsolete.

16. FUTURE RESEARCH AND PERSPECTIVES

The consensus is that education is relevant and should be part of any fast-track procedures. However, the evidence for this is weak. Few studies have looked at best practice for educating THR patients and their relatives. None has looked into the use of interactive education with the use of IT. With the future prospects in telemedicine, the possibilities in interactive learning and pervasive solutions supporting the patients' outlook in research within this field are great, and greatly needed. However, we need more knowledge regarding the possibilities in pre-operative stratifications of the patients and their support persons, and we need more research regarding the effects of individualized interactive education and the active inclusion of support persons in the fast-track procedures. Which type of educational approach works the best on which type of patients? Is it possible to let the patients themselves select the information and education they need without compromising the quality of the operation, and can we reduce or remove the in-hospital education? Will it be sufficient, in the near future, to only see the patient on the day of surgery?

Inspired by this study, we have worked on the theory of Total Resource Potential (TRP), where we looked at the resources required for going through a specific fast-track joint replacement procedure and the rehabilitation as a theoretical constant. We coined this constant the Total Resource Demand (TRD). The resources for going through the procedure, including the total rehabilitation, need to be present in the patient, but also in his or hers close family and network, and need at least to match the TRD. By evaluating the total pre-operative resources of the patient, including the contribution by the close family and the network, we can try to assess whether there is a match. Today this happens in a somewhat unstructured manner, based on experience and common sense exercised by the clinician working with the individual patients. If the clinician considers that the patient is unfit for a fast-track procedure or an operation, a different treatment will be offered. By offering education and support before and after the procedure, the patients and the close family and network can experience an increased empowerment, which means that they have gained more resources [131]. When we take the patient's resources, adding those of the close family and network, and the increase to be gained through education and support, we have the TRP. In our future work, we will try to apply this theory to make a shift from the standard treatment to a personalized treatment. The overall goal is to reduce cost for the healthcare sector and offer the right amount of resources from the healthcare sector depending on the total resource potential. The RRS Project examines the investments (e.g. better education, family involvement, telemedicine solution) that are needed to increase the latent resources that are sometimes suppressed by anxiety or just not realized in the individual patients, and even more so in the close societal setting that is involved in and influenced by a major surgical procedure and the following rehabilitation. There are two important theoretical outcomes to this theory. If the TRP is not met the patient could suffer, and the fast-track procedure should be changed to a less resource-demanding procedure, often with a longer LOS, or the patient should be discharged to another type of postsurgical care. It is an ethical problem if the patient is discharged and the TRP is lower than TRD. The other option is that the patient receives a less resource-demanding procedure, under-matching the TRP, which may be considered a waste. The ideal point is reached when the TRP matches TRD and the costs can be reduced both at the hospital and from a societal perspective. Besides

risk stratification for risk reduction [132], resource stratification for cost reduction could also be argued. This stratification cannot stand alone and can in no way change the need for allaying clinical conditions with the potential of increasing risks for the patient. We must look at the individual patient's optimal length of stay, where the need for resources from the hospital and the resources available from the patient and the relatives (Total Resources Potential) are a perfect match, where there is no increase in the societal cost, and where the quality level and access of today's THR are retained. Perhaps this could also increase the chances of selecting the patients that will benefit the most from the THR procedure. A task that can be difficult [133,134]. To find a way to match TRP and TRD, interdisciplinary teams for innovation and research, including professionals who are not usually working with fast-track methodologies, could perhaps turn out to be the best method for finding the best solution, but we need more research.

We have not been able to find examples of the use of "agile development" by hospitals for patient-oriented solutions or processes. Lean and the Lean Six Sigma[79] are sequential and even though some of the terms used in the different lean methodologies are similar, they should not be confused with the agile movement. The main principle in Lean manufacturing is to eliminate waste it is therefore used mostly when optimising exiting procedures and processes [79]. Lean is relevant for clinical settings and not contradictive to agile development, but not ideal when the focus is to create innovative new solutions. Some opinion leaders even find that Lean is counterproductive for disruptive innovation [109,135]. Another fundamental difference between lean manufacturing and agile development is the connection between the team and the decision makers. In Lean manufacturing, the connection to management is strong and predefined, in agile development the process and team is loosely connected and almost detached from the rest of the organisation, where the management role is more about creating space and supporting incentives for creating new innovative solutions. Innovation, organisation and implementation research in the area of healthcare have great potential.

The knowledge obtained in this study has also led to a start-up that develops and supplies an interactive IT-platform for animated educational material [123]. The solutions are used in connection with the support offered to orthopaedic patients and their close relatives at some hospitals in Denmark. Research are ongoing. Furthermore, The RRS Projects way of educating (including elements of computerised cognitive behavioural therapy) is now being tested with healthcare staff in regions of African. The same animators that worked on the RRS project created the solution for the Maternity Foundation. The goal for the Maternity Foundation and the Red Cross is to use some of the knowledge that was obtained in the RRS Project to reduce maternal mortality [136]. Research on those subjects are ongoing at both Aarhus and Copenhagen University.

The RRS project have inspired to major parts of INNO-X Healthcare's BioMedical Design education that was launched in 2013 [130]. BioMedical Design is a national initiative at the Aarhus University and Aarhus University Hospital and is a team-based agile development approach for innovating the healthcare sector. The possibilities in regard to this new educational approach are yet to be determined. BioMedical Design is part of a Ph.D. study evaluating the effects of the education. The study is supposed to start ultimo 2014 in corporation with INNO-X Healthcare, Aarhus University, BioDesign Stanford and the research unit at Centre for Planned Surgery, Region Hospital Silkeborg.

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18. APPENDIXES

TELEMEDICINE –SUPPORT IN TOTAL HIP REPLACEMENT; LENGTH-OF-STAY HALVED WITHOUT LOSS OF QUALITY. A RANDOMIZED CLINICAL TRIAL OF

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ABSTRACT

Context The healthcare cost spiral in developed countries might be partially off-set by reducing hospital admission lengths. The application of telemedicine-support (TMS) could lead to earlier discharge through the empowerment of patients. Further, TMS may affect patient-perceived therapeutic quality.

Objective To determine whether the use of novel TMS technology would simultaneously permit a reduction in the length-of-stay (LOS), and reduce complication or readmission rates, without loss in functionality or patient-reported outcomes.

Design, Setting, and Participants A randomized controlled trial in 72 patients (654 screened for eligibility) scheduled for elective fast-track total hip replacement (FTHR) with 12-month follow-up.

Interventions Participants used a newly developed telemedicine platform (videoconferencing, educational animations, training video-clips, X-rays and medication charts) 14 days prior FTHR. The TMS box was installed at participants home TV set. One post-surgery home visit.

Main Outcome Measures The primary intent was to shorten length-of-stay (LOS) by 1 day (50 percent). We tested for differences between groups in readmission and complication rates, post-operative hip function (TUG), Oxford hip score (OHS), health-related quality-of-life (HRQOL), anxiety and a cost-estimate was performed.

Results LOS in FTHR (controls) was reduced from median 2 (1-4) days to 1 (1 -5) day with TMS-intervention (P<.000). There were no differences between groups in complications/readmission rates, TUG (P=.09) or OHS (P=.75) at 3-months. HRQOL increased in both groups (P<.000), but there were no differences between groups (P=.38). The number of postoperative contacts was lower in telemedicine-support patients. Telemedicine-support reduced costs.

Conclusions Length of stay was shortened by a telemedicine-solution, without compromising central issues such as clinical parameters or patient-perceived qualities in elective fast-track surgery patients. These results indicate that telemedicine-support can be used as health cost-limiter and may facilitate LOS reduction in other therapeutic and patient categories.

Trial Registration clinicaltrial.gov Identifier: NCT00969020;
http://clinicaltrials.gov/ct2/show/NCT00969020

INTRODUCTION

The cost of health care poses major challenges in developed countries [1-3]. This challenge can be met by reducing time and resources consumed during in-hospital admission by reducing the Length-of-Stay (LOS) and readmission rate. But this may well lead to inadvertent decline in patients' perception of -perceive the quality of the provided therapy. Can this cost reduction be achieved *without* negatively affecting quality– or accessibility, in what is referred to as the 'iron triangle' of healthcare [4]? - Or do we simply transfer more responsibility and challenging tasks to patients and their families? Conversely, could we, if we educated and supported in the right way do exactly that? - and in so doing, "make use of" resources from patients and their relatives? Might this not be one the path and avenue that leads both to lower modern healthcare expenditure and at the same time optimizes all three elements in the iron triangle: quality, access and cost?

Modern fast-track surgery methodology is a means of reducing LOS [5-9]. Shortening of LOS, however, makes it more difficult for health care providers (HCP) to coordinate logistics and educate/train, and in this way improve, patients' confidence in their own abilities. Physical and psychological stress response on the first postoperative day often coincides with the intake of analgesic [10] and renders practical education and learning difficult in these patients [11].

Preoperative patient 'education' has become standard in total hip replacement (THR) [12-14], but no validated procedure exists. Different guidelines exist on how to compose written information for THR patients [15,16], and one guide recommends that families are addressed in the material and refers to the use of DVDs, websites and patient-networks [17]. A Cochrane-review concluded, based on studies using verbal, written or audiovisual tools, that there is no authoritative evidence to support the use of preoperative education in THR and total knee replacement surgery [18]. Specifically, no studies have examined the use of telemedicine-support (TMS) in conjunction with THR and its effects on LOS, adverse outcomes, physical outcomes, anxiety, hip-related function and pain Oxford Hip Score (OHS), health-related quality-of-life (HRQOL) and expenditure. Nor the effect of TMS on partners, relatives or trusted friends (in this study named support-persons), and by some considered a potential resource to the healthcare sector [19,20]. We propose that the use of fast-track methodologies for THR gives rise to the need for new ways to educate, empower and support our patients and *their* support-persons.

A possible solution to these issues could be to include health-care information technology (HIT). We conducted a study to determine whether a novel and multifaceted TMS-intervention would allow early discharge of THR-patients, thus reducing costs and without detrimental effects to clinical safety, physical and patient-reported outcomes or negative affect to patients' relatives. We here report a randomized, controlled clinical trial with 12-month follow-up that consecutively enrolled patients referred for elective fast-track total hip-replacement and we describe the *de novo* development of a TMS-platform used as the intervention.

MATERIALS AND METHODS

Study Design and Participants

The current study, termed '*the Remote Rehabilitation and telemedicine-Support project*' (*RRS)*, is a randomized clinical trial that compares standard fast-track total unilateral hip replacement therapy (FTHR) to patients undergoing a telemedicine-procedural supplement to FTHR.

The study took place at a public university-affiliated orthopedic department in Denmark between October 5, 2009 and February 2, 2012. The study was conducted in accordance with the CONSORT Statement [21] and adhered to applicable national regulations. The regional Ethics Committee deemed approval unnecessary. Organizational innovation and development of the TMS set-top box and software were based on 'need-driven innovation' and a 'participatory design approach' [22] (Appendix I). A sample size of 74 was calculated in advance based upon a power > 99% to show a difference of 1 day in length-of-stay (LOS) at α=.05.

Randomization, Masking and Procedure

Patients who were referred for evaluation by an orthopedic specialist for hip arthrosis eligible for surgical treatment were at outpatient clinic consecutively screened for possible inclusion in the study.

Exclusion criteria were; distance to hospital >60 km, prior hip surgery of any kind, mental disability, inability to communicate in Danish, no relative or support-person recruitable, inadequate home internet–connection or no possibilities of setting one up.

Written, informed consent was obtained from both patient and support-person before randomization. Eligible patients were then randomized to either control-arm or intervention two weeks before surgery.

Group allocation was by random draw of sealed, opaque envelopes containing group entry allotment and was performed by a secretary not in contact with patients or the investigation otherwise. No attempt was made to -blind investigators or participants to the intervention, this was considered to impractical.

Table 1 The telemedicine solution worked as a TV set-top box and contained the following;

Interactive written information	With added speak and visualizations
Animation	A narrative story with elements of exposure. Describing the background for primary hip arthritis, the anatomy of the hip, the operating procedure and the importance of rehabilitation, risks and limitations
Films of all recommended exercises	Simply described and with a supportive speak
Films of how to use supplied aids	Simply described and with a supportive speak
Films of how to do daily tasks	E.g., 'get down and up from the floor', 'in and out of bed', 'in and out of a car'
Medicine	An interactive overview of prescribed medicine. What to take when. Pictures and descriptions of each standard medication
X-ray	Pre- and postoperative X-rays
Videoconferencing	Could be initiated by either the patient or the hospital. Camera was mobile and could be used for close-up.

The control-arm followed the standard fast-track hip replacement (FTHR) procedure, whereas the intervention-arm (TMS) followed the new TMS plan developed for this study. This consisted of patients and their support-person participating in a 2-hour information meeting. The protocol for data collection was introduced to all patients. The individuals in the intervention-arm were introduced and presented to the TMS set-top box and its features. They were instructed to set up the box and connection by themselves. They were informed of the primary goal on one day of hospitalization, and that no patients would be discharged against their will. The use of the set-top box was entirely voluntary, but it was emphasized that some of the films and material would be relevant to watch before surgery.

Table 2 Procedure for TMS-arm and FTHR-arm

	TMS (Intervention)	**FTHR (Control)**
Day -14	Information meeting	Information meeting
Day 0	Surgery	Surgery
Day 1	Discharge to home	Training and rehabilitation
Day 2	Videoconference	Discharge to home
Day 3	Home-visit by Physiotherapist	
Day 6	Videoconference	
Day 21	Visit to outpatient clinic	Visit to outpatient clinic
Day 90	Visit to outpatient clinic	Visit to outpatient clinic

All patients were hospitalized at the same surgical ward on the day of surgery and all operations were performed by the same surgeon (Table 2). Perioperative therapeutic goals concerning anesthesia, blood loss, pain relief, nausea control, nutrition, etc. were identical in both arms, as were discharge criteria. Study data acquired from a designated folder in which patients were required to enter data which was returned at day 90. Data from days 182 and 365 were obtained by mail from participants.

Outcome Measures

- **Primary outcome**: Length-of-Stay (LOS) was determined as the time of discharge and cross-checked using local electronic health records (EHR).
- **Secondary outcomes**: Complications, unscheduled phone calls, visits to hospitals and readmission were noted from patient's study-protocol and from questionnaires. The data were verified using local EHR and the Danish e-Health Portal [23]. This included data from any Danish hospital during the subsequent 12-month follow-up.
- **Oxford Hip Score** (OHS) [24,25] is a 12-item questionnaire that provides data on patient's perception of hip-related problems and was used to assess hip function and pain.
- **Timed Up-and-Go** (TUG) [26] is the time (in sec) taken for a patient to rise from a chair, walk 3 meters, turn, walk back to the chair and sit down. Patients use personal footwear and aid if normally used at the time of the test.

- **EuroQOL** (EQ5D) [27] was used to determine participants' assessment of their Health-Related Quality-of-Life (HRQOL). It provides a singular index value for health status covering 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression.
- **Visual Analog Scale – Anxiety** (VAS-A) [28]: A 100-millimeter scale evaluated anxiety levels at specified time points (0 mm = no anxiety and 100 mm=worst imaginable).
- **Economic evaluation** was done as a cost-minimization analysis (ref. Appendix II). It includes costs related to the development, production and operation of the telemedicine-solution. Cost expenses identical in the two groups, i.e. surgical procedure, implant and medicines were not included. The cost of hospitalization was calculated, including readmissions until the end of 12-month follow-up. Danish public staff salaries were quoted [29]. Unscheduled patient telephone calls, visits and evaluation at the hospital were registered and a cost-average estimated.
- **Symptom Check-List 90 R** (SCL-90-R)[30] evaluated preoperatively a range of psychological problems and symptoms of psychopathology. SCL-90-R contains 90 questions covering somatization, obsessive-compulsive, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation and psychoticism. The outcomes presented are Global Severity Index, Positive Symptom Total and Positive Symptom Distress Index.

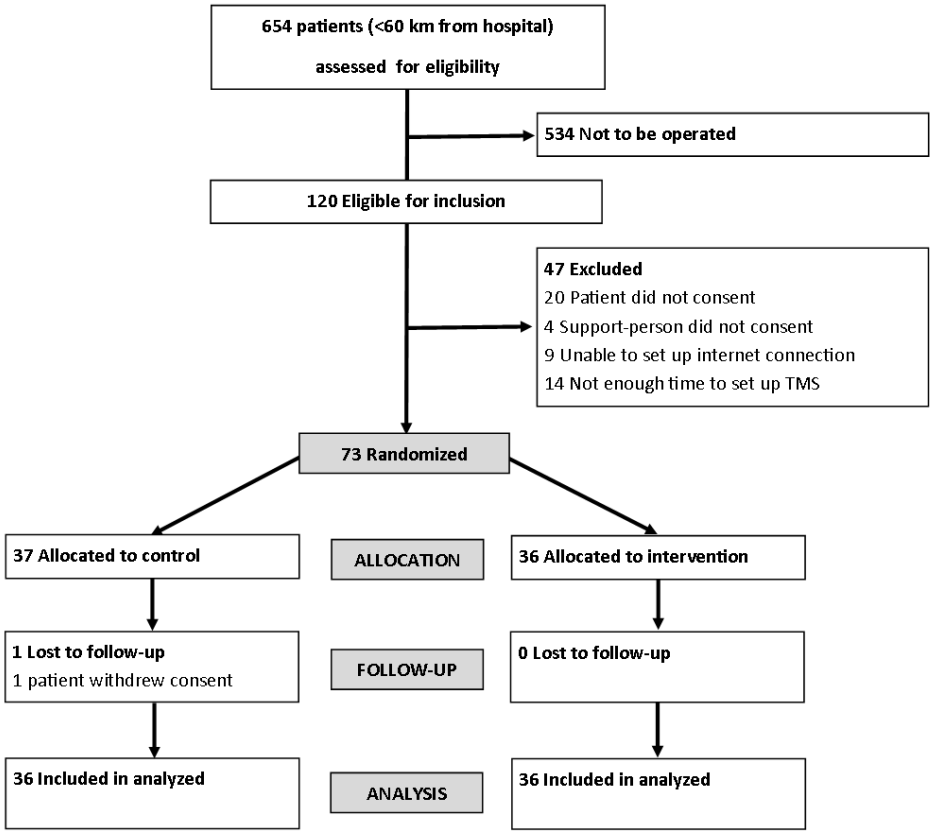
Statistics analysis

Primary outcome measure (LOS) was reported as median (range) whereas most secondary outcomes were reported as mean (95% confidence interval). A *P*-value of < .05 was considered significant. Secondary outcome measures were tested for equal development of mean over time by repeated measurement (RM) analysis and presented as Wilks' lambda *P*-value. Where relevant, Students' *t*-test was used. Non-parametric outcomes were compared by 2-sample Mann-Whitney test. Differences in baseline data were analyzed with Fisher's exact test for categorical variables and Students'*t-test* for continuous variables. EpiData, V. 3.1 (EpiData Association, Odense, Denmark) was used for data entry. Statistical analysis was performed using STATA software V. 10.0 (SPSS Inc., Chicago, IL).

RESULTS

From August 2009 until February 2011, 654 patients residing <60 km from the hospital and who were referred to out-clinic assessment for hip replacement were screened for eligibility to enter the investigation (Fig. 1). 73 patients were consecutively enrolled. The study was terminated before the calculated size of 74 was met, because a contract with the telecommunication company expired due to inclusion period prolongation. In one participant (intervention) the internet connection failed, however the patient adhered to the protocol and telephone calls were used instead of videoconferencing. One control group patient withdrew study consent before surgery and was lost to follow-up.

Figure 1 Enrollment Flowchart



Both demographic and clinical characteristics at baseline were comparable in patients and support-persons (Table **3**).

Table 3 Demographic and Clinical Characteristics in FTHR (Control) and TMS (intervention) Groups

	FTHR n=36	TMS n=36	Ineligible
Female / Male (n)	17 / 19	17 / 19	271 / 287
Age, years	63.5 (45-84)	62.5 (43-80)	66.0 (27-92)
Dist. (Km) from Hospital	40.45 (1.8-56.8)	33.10 (0.4-56.7)	
Social status (66 responded)			**Fisher's exact test**
Alone/With partner	5/27 (8%/41%)	2/32 (3%/48%)	P=.25
Employment status (66 responded)			
Working	11 (17%)	19 (29%)	
Sick leave	0 (0%)	2 (3%)	P=.051
Retired	20 (30%)	13 (20%)	
Other	1 (2%)	0 (0%)	
Support-person (66 responded)			
Partner	26 (40%)	32 (48%)	
Friend	2 (3%)	2 (3%)	P=.26
Son / Daughter	2 (3%)	0 (0%)	
Other	2 (3%)	0 (0%)	
Implant type (n=72)			
Corail/BHR*	29/7 (40%/10%)	31/5 (43%/7%)	P=.75
SCL-90-R (70 **responder**)			**T-test**
GSI†	46.97 (43.67-50.27)	46.52 (43.39-49.66)	P=.84
PST‡	47.69 (44.24-51.14)	45.76 (42.56-48.97)	P=.41
PSDIΔ	44.83 (39.46-50.21)	50.85 (46.99-54.71)	P=.072

*Gender is given as frequency. Age and distance as median with max and min. Implant type, Social status, Employment status and Support-persons are listed as frequencies and proportions given as a percentage value. Relationships are tested with Fisher's exact test except SCL-90R where Students T-test has been used and results presented as mean (95% CI). *Birmingham Hip Resurfacing. †Global Severity Index. ‡Positive Symptom Total. ΔPositive Symptom Distress Index*

Hospitalization: Median LOS was 2 (1-5) days in FTHR (Control), whereas TMS (Intervention) shortened LOS to 1 (1-4) day with intention-to-treat (P<.000).

Clinical Safety: No differences in complications that caused readmission were found. Mean readmission event was 0.00 (95%CI: 0.00-0.00) for FTHR and 0.03 (95%CI: -0.028-0.084, *P*<.33) for TMS. One TMS patient with elevated temperature was readmitted for 3 days with suspected deep wound infection, but

none was found. There were lower numbers of patient-initiated enquiries by telephone: 1.47 (95%CI: 1.06-1.89) for FTHR vs. 0.92 (95%CI: 0.56-0.73) (P<.04) with TMS. No difference was found in postoperative unscheduled hospital visits: 0.31 (95%CI: 0.04-0.57) for FTHR vs. 0.17 (95%CI: -0.005-0.34) (*P*<.38) for TMS.

TUG: Both groups made improvements in TUG from baseline to 3-month follow-up. The mean gain in controls was 1.42 seconds (95%CI: 0.91-1.93, *P*<.000). For the intervention group the mean gained was 2.05 seconds (95%CI: 1.39-2.71, *P*<.000). There was no difference in development of TUG over time when tested by RM analysis (*P*=0.09) (Figure 2a).

Oxford Hip Score: Both groups improved OHS from baseline to 12-month follow-up. The gain in FTHR was 21.43 (95%CI: 18.42-24.45, *P*<.000), whereas for TMS patients it was 18.94 (95%CI: 16.27-21.61, *P*<.000). However, we found no difference in development in OHS over time between groups (*P*=0.72) (Figure 2b).

EQ5D: Both groups gained HRQOL-score from baseline to 12-month follow-up. Mean gained in FTHR was 0.26 (95%CI: 0.19-0.33, P<.000). For TMS, the gain was 0.28 (95%CI: 0.21-0.34, P<.000). There was no difference between groups in development of HRQOL (P=0.35) (Figure 2c).

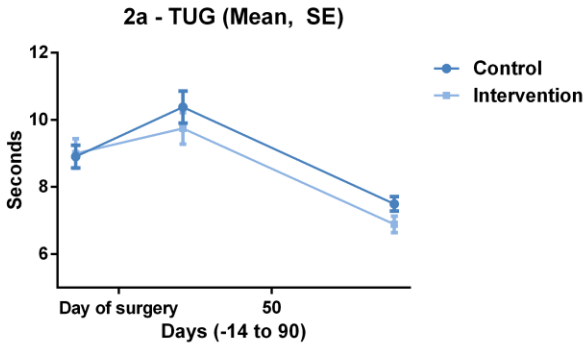
VAS-Anxiety: There was a significant reduction in anxiety from baseline to 90 days post-surgery. The reduction for all patients was 20.50 mm (95%CI: 14.67-26.32, *P*<.000). We found no difference in development in anxiety over time (*P*=0.15) (Figure 2d).

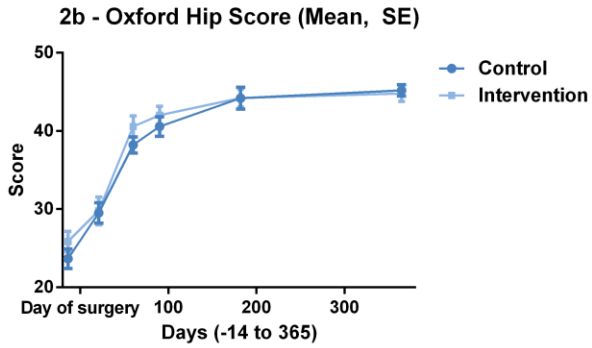
Support-persons EQ5D: The gain was 0.11 (95%CI: 0.01-0.22, *P*<.032) in FTHR, and 0.023 (95%CI: -0.03-0.07, *P*<.34) in the TMS group. We found no difference between groups in development of HRQOL over time (*P*=0.32) (Figure 2e).

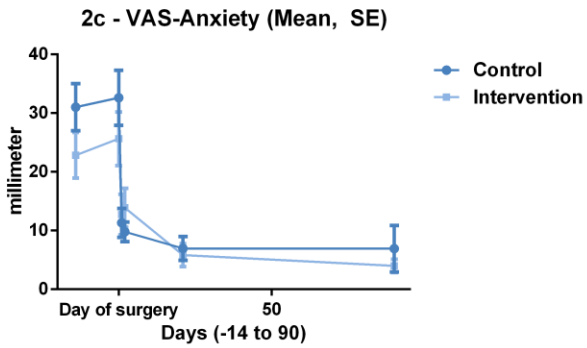
Support-persons VAS-Anxiety: There was a reduction in anxiety from baseline to 90 days after surgery. The reduction for all support-persons was 12.25 mm (95%CI: 7.19-17.32, *P*<.000), but we found no difference between groups in anxiety over time (*P*=0.32) (Figure 2f).

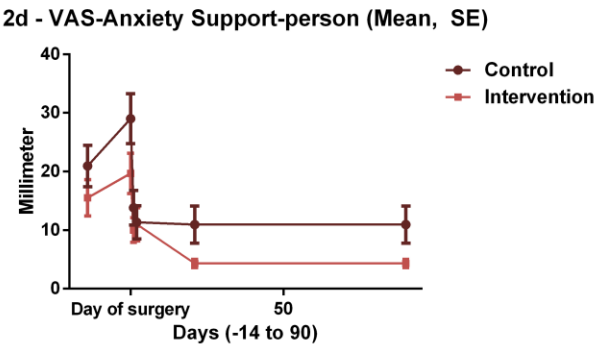
Cost: The estimated total cost of the procedure was US$ 65184 (FTHR) compared to US$ 59771 with TMS (Appendix II). Cost reduction per with TMS patient was US$ 150. Total time spent on the TMS procedure was 7812 minutes or 217 minutes per TMS patient.

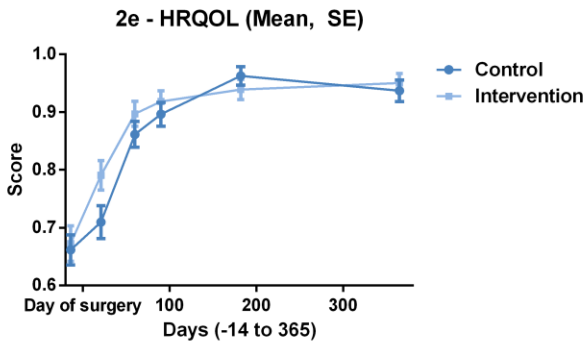
Figure 2 a-f Secondary Outcomes

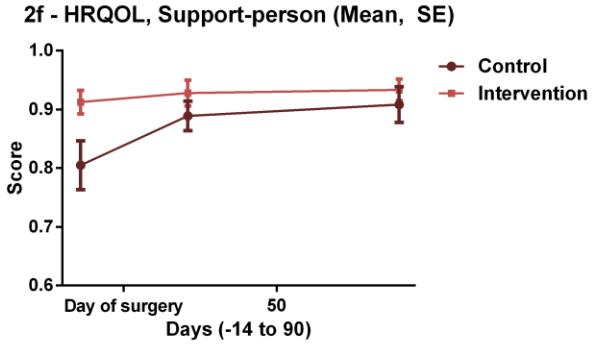












COMMENT

This randomized, clinical investigation demonstrates that length-of-stay was reduced by 50 per cent in fast-track hip replacement without incurring detrimental risks to clinical or patient-perceived outcomes. It was possible to significantly reduce total in-hospital time, and concurrently the costs to the hospital, by the use of a telemedicine-support (TMS) device and perioperative patient education. The development and operation of the TMS-device was included in the economic result and it should be noted that the longer the solution can be maintained, the greater the accumulated cost saving. Moreover, no significant differences could be demonstrated by comparing groups in a comprehensive array of clinical and patient-perceived factors, including readmission or complications, clinical hip function, patient-reported pain, anxiety and anxiety in next-of-kin during the postoperative follow-up period.

Denmark already had the shortest length-of-stay (LOS) *by all-causes* in 2010 in the E.U., averaging 4.6 days [31]. By comparison the U.S. average all-causes LOS in 2009 was 4.9 days [32]. However, LOS cannot be regarded as a single primary outcome entity nor be linked directly to cuts in health expenditure but must be related to other outcome measures like readmissions, hospital contacts or adverse effects. All outcomes in the current investigation indicate that both groups had equal positive development over time with minor differences that at times slightly favored TMS-intervention, e.g., the reduction in preoperative anxiety level and the quicker gain in functional score, *TUG*.

Tasks and responsibilities for postoperative care and training can be transferred to patients and their support-persons, as also indicated by our results. This too can be accomplished without weakening patients' perception of the benefit of THR after 12 months. Currently, we devoted attention to uncovering the needs of patients and their relatives by pre-randomization observational studies. With this knowledge at hand, we devised a simple and interactive TMS-solution containing educational material inspired by Illeris' model for learning [11], and included elements of CCBT [33]. We attribute this elemental work to the success of the study, targeting LOS-reduction which was achieves by discharging 94% of TMS-patients on day 1 after major surgery. No previous studies have reported on the beneficial effects of telemedicine in THR patients. A previous study comprising knee replacement surgery reported that "participants in the tele-rehabilitation group achieved outcomes comparable to those of the conventional rehabilitation group" after 6 weeks [34]. Interestingly, fast-track methodology in THR has not increased readmission rates in Denmark [35]. All-cause 90-day readmission rate for all primary THR in Denmark was 6.8% in 2011 and has remained fairly constant for 16 years [36]. A U.S. study indicated that there was a connection between decreased LOS and increased all-cause 90-day readmission rate, from 7.4% for 2003-2004 to 11.9% in 2007-2008. This is despite 34.3% of U.S. patients are discharged to skilled- or intermediate care facilities [37]. A practice rarely used in Denmark, where patients are discharged to their home [38].

The standard structured care system for FTHR patients is based on a "push" structure: Standards for providing patients with what discharging personnel *think* they need, almost regardless of resources they, or their network, possess or their potential for empowerment. This entails a high risk of wasting hospital resources. With the focus on education and telemedicine–solution, the optimized possibility of accessing knowledge, information or direct hospital contact, we hoped to create a "pull" structure for supporting our patients and their relatives that entices discharge-to-home based upon evidence and efficiency. The overall study result seems to indicate that patients utilize their own resources or the low-

cost features of telemedicine *before* turning to the high-cost use of the hospital. Standard FTHR was synonymous with more costly support and hospital resources, without any improvements in outcomes, as compared to TMS.

The main limitation of this randomized clinical trial using technology as part of a multi-faceted supplementation intervention is bias control. We have attempted to minimize selection bias by using broad inclusion criteria and consecutive enrolment. Of the out-clinic patients that lived less than 60 km from the hospital, almost 90% were excluded because they were not eligible for hip replacement. Of the remaining 120 candidates, 20% declined to participate. In 1/5 of these, decisions were made by the support-person. Patients who declined participation may possibly have done so because they did not feel comfortable using a TMS-solution, leading to recruitment of best-motivated participants.

Second, the risk of being randomized to early discharge may also have felt too challenging. Most likely we therefore conducted the study with a selected group of patients with a higher level of IT-skills and self-efficacy than on average. The demographic data was similar for the groups but employment status was borderline significant. No explanation to this was found, but it could influence outcomes. People in jobs could well be better motivated for fast rehabilitation.

Masking was logistically difficult to set up and economical challenging. Further, a contamination effect cannot be ruled out by for instance disfavoring the control group. To counter this, data was acquired *via* anonymous questionnaires and data was cross-checked with local electronic health records. The discharge criteria were identical to both groups and the decision to discharge patients was handled uniformly by a small staff group. Patients were informed of the criteria, and that they could stay admitted if they were not ready to be discharged. No participant asked to remain admitted. The fact that 8 patients from the control group were discharged after only a single day supports that the criteria were followed.

The TMS-group viewed animations of the procedure before answering baseline questionnaires, possibly causing interventional bias. Our data showed a tendency towards lower anxiety and better HRQOL score at baseline in the TMS-group. A small unpublished pilot-test in THR-patients at pre-operative educational class supports this hypothesis. Patients that see animations after class have a tendency to score lower on VAS anxiety. A control study is now being conducted.

In view of the significant healthcare benefits that can be envisaged based on TMS and patient empowerment, we find it well-warranted to research wider into evidence-based approaches in fast-track patients, on education, on the effects of actively including family or relatives in fast-track procedures, studies on organizational innovation, and in the use of HIT in connection to fast-track procedures. The potential for waste reduction and minimizing cost are major. There have been many suggestions to future THR fast-track studies [39] [40] [41] [42]. Most western governments have calculated on HIT as a mean for cost and waste reduction [43,44].

Further, this study could hopefully have a positive impact beyond the area of fast-track and elective surgery. Expectedly, this way of "making use of" much needed resources form patients and their support-persons and retaining high quality, reduce LOS, lower risk of readmission and preserve patients' perception of benefit can spread health-care cost reduction in other specialized fields and on a global scale.

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Acquisition of data: Vesterby
Analysis and interpretation of data: Vesterby, Laursen, Larsen, Pedersen
Drafting of the manuscript: Vesterby, Laursen, Larsen
Critical revision of the manuscript for important intellectual content: Vesterby, Mikkelsen, Laursen, Larsen, Pedersen, Søballe
Statistical analysis: Vesterby, Pedersen
Obtained funding: Vesterby, Mikkelsen
Administrative, technical, or material support: Vesterby, Laursen, Larsen
Study supervision: Vesterby, Mikkelsen, Laursen, Larsen, Søballe
Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Vesterby reported to be partaking in a startup, developing animations for education of HCP, patients and relatives.
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Additional Contributions: Posthumous, Kristian Larsen, PhD. Study concept and design.

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APPENDIX 1: INNOVATION AND DEVELOPMENT

The organizational innovation and the development of the TMS set-top box were based on need-driven innovation and a participatory design approach [(1)], and carried out in co-operation with CareTech Innovation (Part of the Alexandra Institute, Aarhus University, Denmark).

The concept of agile software development was combined with the hospital's use of the lean methodology. This multidisciplinary process involved healthcare providers from all professions, working with fast-track treatment as well as computer scientists, ethnographers and architects. The healthcare providers chosen to participate in the innovation process were selected based on an evaluation from the project manager and leaders at the hospital. Selection criteria were: extrovert personality, excellent networking and knowledge sharing capabilities and experience with treating fast-track patients. The project manager at the hospital was in charge of the quantitative research, the logistic innovation and of coordinating the work of everyone in the various hospital groups.

The Project manager at CareTech Innovation handled the design and development of the hardware and software for the set-top box. A physiotherapist, responsible for the new guidelines for the THR-procedures, participated in meetings with all the development groups. A ward nurse, selected to take care for the recruited patients, consecutively evaluated and contributed to the work. Furthermore, with the intention of easing the implementation, the ward nurse also kept the ward updated on progress.

The logistic limitations and the need for optimization of the existing fast-track procedure were defined in an Accelerated Development Environment (ADE), specifically designed for this project. The environment was inspired by IT-companies with experience in working with agile software development, and the manifesto for this concept [(2)]:

-Individuals and interactions over processes and tools
-Working software over comprehensive documentation
-Customer collaboration over contract negotiation
-Responding to change over following a plan

In the course of two ADE sessions, the participants defined almost 200 specific possibilities for optimizing the existing fast-track THR procedure.

Observational studies and interviews with patients and relatives defined and documented the needs that the solution was intended to address. The interface, information and educational material were created to also target patients suffering from health literacy [(3)]. We focused on the use of visualization and a minimum of text. One group produced video films of all the training exercises recommended for THR patients and instructional videos of the use of supplied aids. One group worked together with professional animators to produce educational animations, describing the causes of osteoarthritis of the hip, the surgical procedure, postoperative restrictions, including elements of exposure and computer-aided cognitive behavioral therapy (CCBT)[(4)].

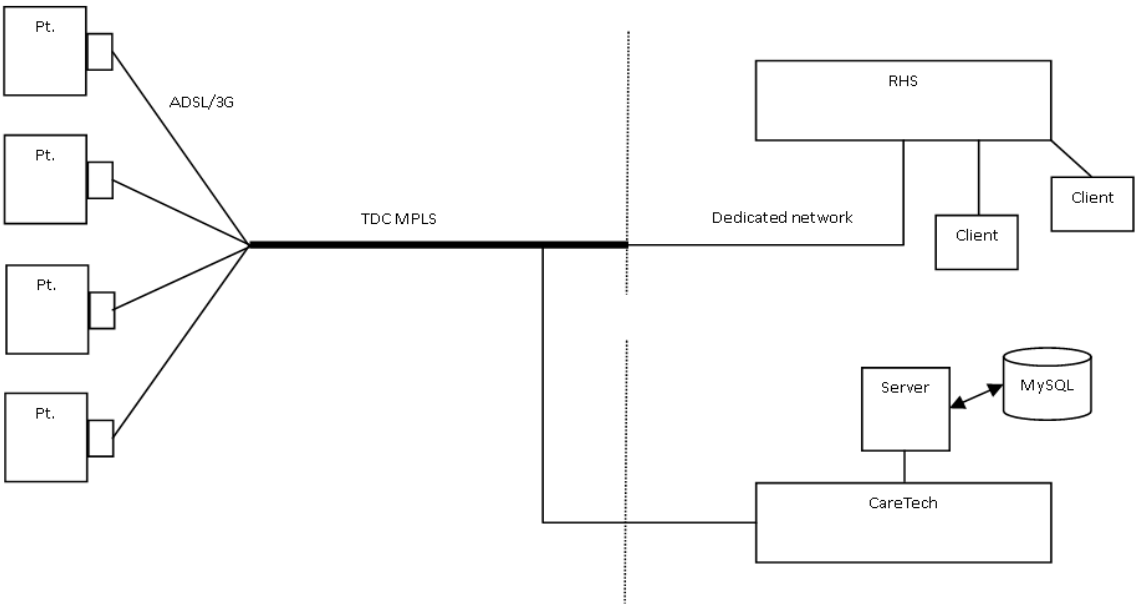
CareTech Innovation created the set-top box, user-interface and integrated all the material developed in the different groups. Hardware and software mock-ups and prototypes of the TMS were developed, presented to and tested with patients, support persons and health care professionals. A test environment at the hospital was installed, in which the support persons could stay the night. The procedure of discharging on day one was tested in this setting for nine patients. Three patients agreed to participate in a pilot study and the final TMS procedure and the HIT solution were set up and tested in the patients' homes prior to the study enrolment.

eFigure 1 Set-Top box

Set-Top Box and video camera in a patient's home.

The TMS had an integrated video-conference system and a feature for problem-solving issues with the TMS or the internet connection used. The application was developed in Python 2.5 with embedded Skype4Py, Mozilla web-browser and Flash player 10. A CherryPy webserver was chosen, as was as a MySQL database. For a description of the network, see figure 2.

eFigure 2 The RRS Network



A dedicated network from the Regional Hospital Silkeborg (RHS) was connected to a multi-protocol label switching network (MPLS). The server, located at CareTech, used the same MPLS and the connection to each patient's home was handled by an ADSL connection. In-house, we span a Wi-Fi network dedicated to the set-top box.

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APPENDIX 2: ECONOMIC EVALUATION BY COST-MINIMIZATION ANALYSIS

An economic evaluation of the intervention in this study was condensed to a cost-minimization analysis [1-4] because the health related outcome measures (Timed Up-and-Go (TUG), Oxford Hip Score (OHS) and health related quality-of-life (EQ5D) were not statistically significant when comparing the intervention and control groups. Presently, the state-of-the-art of economic evaluation in telemedicine is not very high, in part due to the fact that an economic evaluation is not usually carried out alongside the clinical trial [5]. However, in the present case, the primary outcome, LOS, points directly towards an economic evaluation [6,7].

The perspective of an economic evaluation may be either societal or from the point of view of budget impact for a given party, i.e. the hospital or primary care providers. Societal costs include all costs, e.g. in relation to patient time, absence from work, costs to all service providers, whereas budget impact only include expenditure consequences to one or more service providers. The perspective here is that of the hospital, GPs and the municipality.

Number of services used, i.e. in-patient days and home visits, were collected alongside the trial through a combination of registers, questionnaires and dairies, while unit costs, i.e. the cost of home visits or unscheduled visits were calculated in a bottom-up manner and based on an analysis of the relevant work processes, e.g. time used by staff and equipment used. For in-patient days and out-patient visits, elements of the hospital DRG-rates were used. The cost of the set-box and the Internet were supplied by the IT-developer and telephone company. We did not include work sequences or interventions that were identical to the two groups, e.g. pre-planned and pre-scheduled post-surgical contacts with healthcare providers in the outpatient clinic, time spent at group-information meetings, introduction to the study-folder and the costs of any surgical implant and medication.

Estimated time to handle the TMS procedure, including introduction to the TMS (avg. 17 minutes), video conferencing (avg. 50 minutes) and transportation and visits (avg. 150 minutes). Total amount of time spent on the TMS procedure per patient is therefore 217 minutes. Introduction to the TMS was often done in the presence of more than one patient, and transportation could often be coordinated, so that more than one patient could be visited in one trip, thereby saving time. Real time consumption and cost for the intervention was consequently less than the calculated amount.

The resulting cost-minimization analysis is presented in table 1. The cost per patient (across hospital, family physician and municipality) is DKK 859 (US$ 150) lower for the TMS group. The reduction for the in-patients is the most important explanation for the difference. It is noteworthy, however, that the expenditures in the primary healthcare sector, i.e. after hospital discharge, are also lower for the TMS group, which means that there are no cost-shifting as a result of the TMS.

It has not been possible to estimate costs from the societal perspective in a reliable manner due to missing observations. However, the information about the time used by spouses, children or relatives is complete. If the economic value of the help provided by this group is calculated by means of the average wage rate, it is evident that the TMS group also on this count uses fewer resources than the FTHR group.

eTable 1: Cost-minimization analysis DKK

	TMS (Intervention, n=36)			FTHR (control, n=36)		
Cost component	**volume/number of units**	**unit costs**	**total costs**	**volume/number of units/hours**	**unit costs**	**total costs**
TMS	22	1850	40700	0	1850	0
Internet	18	1279	23022	0	1279	0
Intro to TMS	36	61	2192	0	61	0
Home-visits	36	478	17200	0	478	0
Transportation of HCP	2167	2	4659	0	2	0
Video conferencing	72	90	6300	0	90	0
In-patient days in connection with hip replacement, incl. readmission	44	4800	211200	67	4800	321600
Telephone calls	33	101	3333	53	101	5353
Unscheduled visits	9	2850	25650	11	2850	31350
Surgery & implants			***Similar across control and intervention group***			
Time spent on group-information meetings & introduction to study			***Similar across control and intervention group***			
Hospital expenditures			**334257**			**358303**
Training & rehabilitation	16	243	3888	35	243	8505
GP consultations	22	127	2794	29	127	3683
Home Nurse	2	170	340	10	170	1700
Primary Sector costs			**7022**			**13888**
Cost per patient			***9480***			***10339***
TOTAL COSTS			***341279***			***372191***

US$ - DKK exchange rate Cost Assessment (US$) exchange rate at 3th of December 2012 (5.7098)

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Length of Stay reduced with 75% for patients' receiving total hip replacement; understood through the theoretical frame of SCRUM. A case study based on the Remote Rehabilitation and Support project.

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ABSTRACT

Introduction: Healthcare sectors around the world face a wide range of economic challenges. Long admissions of patients, challenges in discharging and risk of readmission are costly and demand innovative solutions. Fast-track procedures have, at many places be implemented, and through an evidence-based approach, reduced length of stay (LOS) significantly. Hence, a short LOS creates new needs and challenges for hospitals with regard to logistics, education/information and rehabilitation. The Remote Rehabilitation and Support project, launched a new way for supporting patients with a procedure and solution that includes telemedicine for support. Development of the solutions, done in corporation with staff, patients and relatives, using agile development. The preliminary results were so inspirational that the staff and management at the department chose to implement new procedures in day-to-day based on the work in the RRS Project. A 75% reduction in LOS in the clinical setting, achieved from 2008-2012 for patients receiving total hip replacement came as a spin-off to the RRS Project.

Aim: In this paper, we seek to understand a 75 % reduction in LOS with the use of SCRUM Dynamics as a theoretical lens.

Methods: Using SCRUM Dynamics as a theoretical lens, we will try to get understandings on how working with agile development could have affected the successful implementation and reduction of LOS. First by unfolding the RSS project and the agile development and implementation of the two procedural changers using the six SCRUM Dynamics. Secondary, evaluate implementation effectiveness.

Results: By the use of agile development in the RRS Project, we created not only the procedural changes for the day-to-day praxis, but an social movement that embraced innovation and the need for procedural changes and thereby made close to optimal condition for implementation effectiveness.

Key lessons learned: An organization can obtain an innovation culture that continuously share knowledge, thrives and contributes to cost reduction without compromising key aspects of quality. The combination of mixed method intervention research and agile development can facilitate innovation and beneficial organizational changes and in that way create a fertile environment for change, improvement and implementation of new solutions.

INTRODUCTION

Reducing length of stay (LOS) and risk of readmission are possible ways of constraining healthcare costs within the area of major orthopedic surgery. LOS has in this area been reduced significantly over recent decades from an average of more than ten days to more than 5 days at project start. Fast-track procedures have played a major role in creating short, safe and evidence-based procedures, especially in connection to total joint replacements [1-5]. Was it possible to reduce LOS even more and get close to one day of submission without negatively influence quality and patient risk?

The Center for Elective Surgery, Regional Hospital Silkeborg (RHS), has worked intensively with fast-track procedures. It has a large number of patients receiving an artificial hip in Denmark, with approximately 750 primary total hip replacements (THR) in 2011 [6]. The highly specialized department in the field of elective orthopedic procedures contributes to research at the Lundbeck Center for Fast-Track Hip and Knee Surgery [7].

The project reported on in this paper took place at the department at RHS from 2008 to 2012 and aimed to optimize the existing fast-track THR procedure with an average LOS of 5.7 days. The project was initiated as clinicians at RHS gradually observed that a majority of patients were comfortable with being mobilized at the day of surgery and walked by themselves from the hospital ward to a hotel-like facility part of the hospital. Consequently, this led to a questioning among the clinicians for the reasons as to why these patients were not discharged after 1 day's stay. There were no legitimate reasons for this to be found with regard to medical risks or ethical considerations. However, clinicians worried about a further reduction in LOS potentially increasing the need for post-discharge support and rehabilitation of these patients. It was at the time hypothesized that, if patients could gain a perception of safety especially in relation to early discharge and the department concurrently implemented a stronger focus on empowering patients, then patients could be discharged earlier to their home. Subsequently, the Remote Rehabilitation and Support Project (RRS) was set up to develop and test a new fast-track THR procedure, including telemedicine with the aim to facilitate early discharge without compromising safety, patient-perceived quality of the surgical treatment and outcome in relation to hip function and quality of life. Furthermore, it was not to increase cost for the hospital department. Based on former experiences with implementing information technology, the department wanted to ensure best available knowledge to minimize negative, non-foreseeable effects on the organization (e.g. logistic limitations and adverse effects on work environment), patients' experiences and clinical endpoints. However, it called for innovation and research skills that were not available at the department that usually carried out clinical research. Collaboration, therefore, was made with Caretech Innovation (Alexandra Institute, Aarhus University) [8] a venture by the Central Denmark Region regarding information and communication technology for healthcare.

The two aim purpose of the RRS project was first and foremost to report on the effect of implementing a new fast-track THR intervention in a clinical trial, holding organizational changes, involvement of patients and relatives and the use of telemedicine, and how this three-component intervention may influence LOS for THR patients, in a efficacy study("can it work?") [9].

Secondary, to monitor the effect of working with innovation and developing a new intervention for THR patients in close corporation with the orthopedic department and documenting the impact on day-to-day praxis with an effectiveness study. A work being more relevant when the administration of the

department decided on implement new procedural changes based on the work done using agile development when creating a new telemedicine supported solution.

The initial study design consisted of a quantitative efficacy study and a quantitative effectiveness study. However, an interdisciplinary innovation group had been established and its members observed different interesting research topics. For instance, the computer scientist, based in a research group focusing on human-computer interaction, identified interesting research topics in regard to the working of telemedicine in private homes. Additionally, the anthropologist pointed to research topics in regard to organizational changes and the potentially changing staff, patient and relative roles. Thus, a qualitative study was added to the initial study design focusing on social aspects and non-foreseen consequences of implemented Healthcare Information Technology (HIT) and new procedures to a clinical setting and the impact on the organization. The project used participatory design [10] and thereby a setup is made for gaining knowledge of ideas and insight to the problems from the staff, relatives and patients for which the project group were developing solutions. However, it became clear that knowledge sharing was not unidirectional but a process where knowledge kept being shared multidirectional. We got interested in the effect of this process as a topic of our research [11].
A work environment where normally two-thirds of organizations' efforts to implement change fail managed to highly successful implement two procedural changes, need understanding [12,13].

AIM

We seek to understand a 75 % reduction in LOS with the use of SCRUM Dynamics from agile development methodologies as a theoretical lens.

METHOD

First, we will present the methods and the results of an effectiveness study estimating the 75% reduction in LOS. Then we will present the RRS Project and thereby the development of - and the procedural changes 1 and 2. We will present the theory on SCRUM Dynamics and attempt to analyze the impact of the RRS Project on the organization through the lens of agile development using the SCRUM Dynamics explaining the LOS reduction. Finally in the discussion, we will present the theories of the CFIR Constructs and evaluate the possible effectiveness of implementation in connection to the RRS Project.

Monitoring changes in LOS: A before-and-after measurement of the effectiveness of clinical practice was part of the monitoring at the department, which had begun in connection with a full implementation of EHR. The selected data were based on their relevance and availability as part of the RRS Projects aim to monitor natural improvements, thereby reduction in LOS during the Project periode. The decision to optimize the fast-track procedure, used in day-to-day practise, made by the department changed the initial comparator and presented a challenge in terms of the design of this study. The before-and-after design was preserved but data was altered to include patients at defined periods in time between implementations of new procedures in the day-to-day praxis.

Effectiveness study (before-after) (n=696): Data samples of hospital productivity and patient demographics were obtained through the hospital's administration system, as a means of evaluating the effect on LOS under usual circumstances of healthcare practice.

The two procedural changes evaluated were implemented in 2008 and in 2010. The data for the before-after study were gathered each year among patients admitted in February, March and April, from 2008 - 2012. Procedural change 1 was implemented in 2008 and procedural changes 2 was implemented in 2010. All data were collected automatically, and part of the routine monitoring at the hospital department.

Adverse effects were not part of the routine monitoring of THR patients at RHS. Therefore, data were obtained through the Danish Hip Arthroplasty Register DHR [6]. These previously published data were included in the triangulation process [14] later described.
LOS was not with an equal variance. It was tested with a Kruskal-Wallis rank test and is presented as proportions given as percentage values and as median with inter-quartile range (IQR) and range (max. and min.). Age and gender were chosen to evaluate change in the patients' profiles. Data on readmission, age and gender are presented as proportions given as percentage values with 95% confidence intervals (95% CI).

Attempts to reduce bias: The potential bias is considered to be of smaller magnitude. The reason for this being that the data used, were pulled from the Health Records; and used to report to the DHR.

Masking of patients and healthcare staff: Data used to evaluate effectiveness were obtained from the hospital administration system and were part of the normal and usual monitoring at RHS. Data were obtained for 2008 to 2009 from two wards at RHS, while data from 2010 to 2012 were obtained from only one of the wards that were assigned all THR patients. The wards are considered to be similar. We used anonymized register data generated though the EHR.

Attempts to reduce observer bias: Doctors who were not otherwise involved in the study decided, in agreement with the patient, when discharge criteria were fulfilled, as was also the standard at the department. All data were obtained through public registers.

Representativeness: The cohorts were representative as no significant differences in age and gender were detected. No other changes to the procedures were implemented in the department during the study period.

Statistics: The statistical analysis was performed using STATA software V. 10.0 (SPSS Inc., Chicago, IL). LOS did not have an equal variance. The incremental development was tested by means of the Kruskal-Wallis rank test and presented as proportions given as a percentage value and as a median with inter-quartile range (IQR) and range (Max. and Min.). Age and gender were chosen for the evaluation of changes in the patients' profiles. Comparison of efficacy and effectiveness was tested by means of a t-test, even though results (LOS) were right-skewed. Our choice of test was due to the high (n) and the robustness of the test.

Ethical issues: The RRS project took place at a public university-affiliated orthopedic department in Denmark from November 2007 to February 2012. The first formative research took place in the beginning

of 2008. The entire RSS Project followed standards for good clinical practice and applicable national regulations. The regional ethics committee found that under Danish law, the quality-assurance study did not require prior approval. The study was registered with the Danish Data Protection Agency (j. no. 2009-41-3394) and at Clinicaltrial.gov (NCT00969020).

RESULTS FROM THE EFFECTIVENESS STUDY

Patient Characteristics: From 2008 until 2012 696 patients were enrolled. The mean age for the patients (February – April) 2008 was 66.07 years (n=107, SD 10.97). Mean age for the patients (February – April) 2009 was 66.28 (n=170, SD 10.09). Mean age for the patients (February – April) 2010 was 65.36 (n=125, SD 10.84). Mean age for the patients (February – April) 2011 was 67.28 (n=146, SD 9.84). Mean age for the patients (February – April) 2012 was 67.90 (n=148, SD 10.69). The mean age has no difference (p=0.18) in distributions when tested with the Kruskal-Wallis rank sum. When gender was tested we also found no difference in distributions (p=0.35).

Length of Stay: When analysing effectiveness, we found a significant reduction in LOS of 3.77 days (95%CI 3.22-4.32) from a mean LOS of 5.67 days (95%CI 5.10-6.25) for all patients receiving the current procedure for the three-month pre-study period in 2008 to 1.90 days (95%CI 1.68-2.12), and for all patients receiving the optimized intervention in the first three months after termination of the study in 2011 (P < .000). Effectiveness, furthermore, improved significantly over the next year (2011-2012) to a mean LOS of 1.39 days (CI95% 1.52-1.77; P < .000). From 2008 to 2012, the overall reduction in avg. LOS was more than 75%.

The development of LOS shows a difference in distributions (p=.0001). For 2008 the median is 5 days (IQR=2, range 2-29). For 2009 the median is 3 (IOR=2, range 1-18). For 2010 the median is 2 (IQR=1, range 1-9). For 2011 the median is 2 (IQR=1, range 1-9). For 2012 the median is 1 (IQR=1, range 1-4).

TABLE 1 DISTRIBUTION OF LOS FOR THR PATIENTS AT RHS FROM 2008 TO 2012

Year \ Day	1 day	2 days	3 days	4 days	5 days	6 days	7 - 10	11 - 15	15 +
2008 (n=107)	0%	0.9%	2.8%	39.3%	16.8%	16.8%	19.6%	2.8%	0.9%
2009 (n=170)	1.8%	27.6%	38.8%	14.1%	4.7%	4.1%	1.1%	7.0%	0.6%
2010 (n=125)	11.2%	45.6%	20.8%	10.4%	2.4%	3.2%	6.4%	0%	0%
2011 (n=146)	46.6%	36.3%	8.9%	4.1%	1.3%	0.7%	2.1%	0%	0%
2012 (n=148)	69.6%	23.0%	6.8%	0.7%	0%	0%	0%	0%	0%

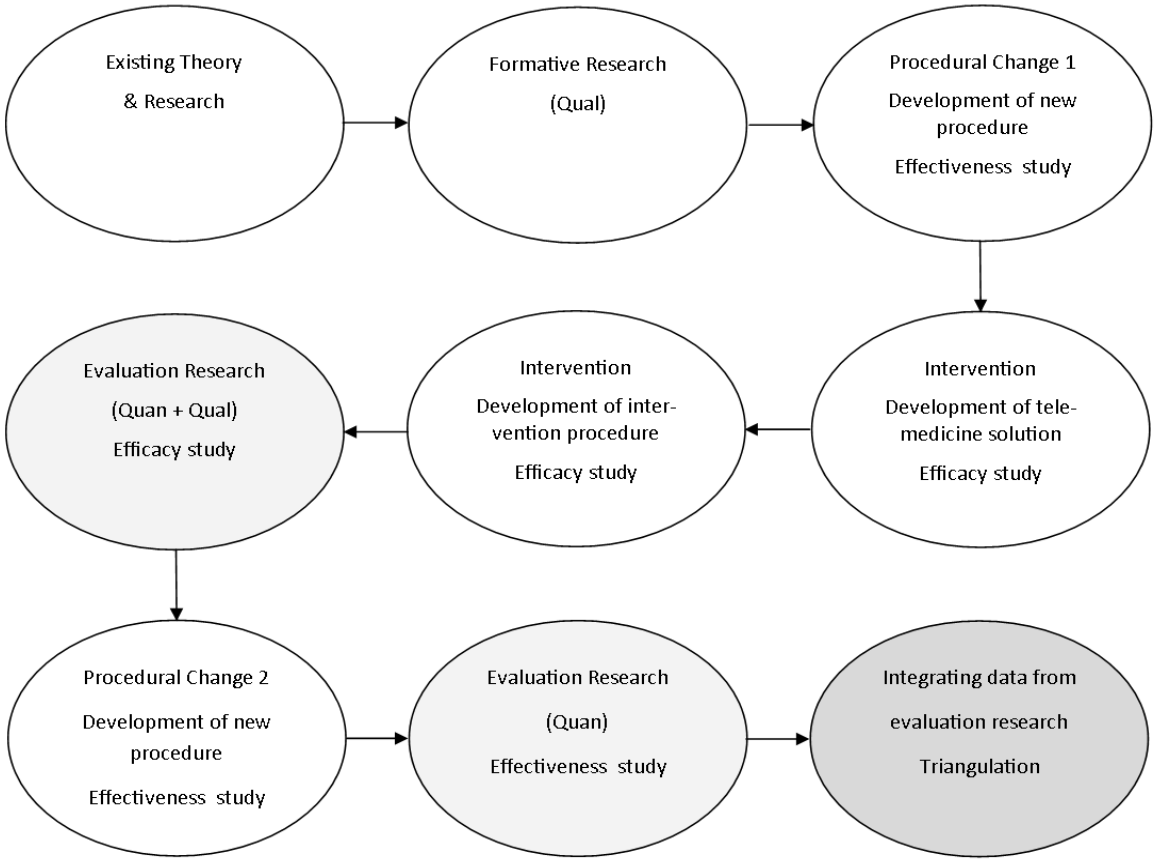
Adverse effects: Readmission for THR at RHS was evaluated by data obtained from the DHR 6, covering readmission-rates caused by medical complication within the first 90 days. Data were available for 2009, 2010 and 2011. The rates for 2009 was 0.7% (95%CI 0.2-1.9) at RHS. The national result was 1.7% (95%CI 1.4-2.0). For 2010 it was 1.4% (95%CI 0.6-2.7) for RHS and 1.7% (95%CI 1.4-2.0) national. For 2011 it was 0.3% (95%CI 0.0-1.5) for RHS and 1.4% (95%CI 1.0-1.8) national. The rates for RHS is lower than the national average reported every year.

THE RRS PROJECT

Iterative research and development: (To understand how the two procedural changes were develop a description of the entire RRS Project is in place).The below figure (Figure 1) describes how the multiyear RRS research and development project was conducted chronologically as an iterative research ↔ intervention process, inspired by Mixed Method Research (MMR) [15], that created three interventions. Two for the day-to-day praxis and one including telemedicine support for the RCT. The Participatory Culture-Specific Intervention Model (PCSIM) inspires this model [16]. The designs relate to different phases of program development research: (a) existing and formative research, Qual →/+ Quan; (b) development of new procedure Qual →/+ Quan (for day-to-day and RCT); (c) development of telemedicine part of intervention, Qual → Quan →/+ Qual →Quan . . . Qual →Quan (for RCT); (d) development of new procedure Qual →/+ Quan (for RCT); (e) evaluation research, Quan + Qual (for RCT); (f) development of new procedure Qual →/+ Quan (for day-to-day); (g) evaluation research, Quan + Qual (for day-to-day) and (h) integrating data, Qual ↔ Quan ↔ Quan.

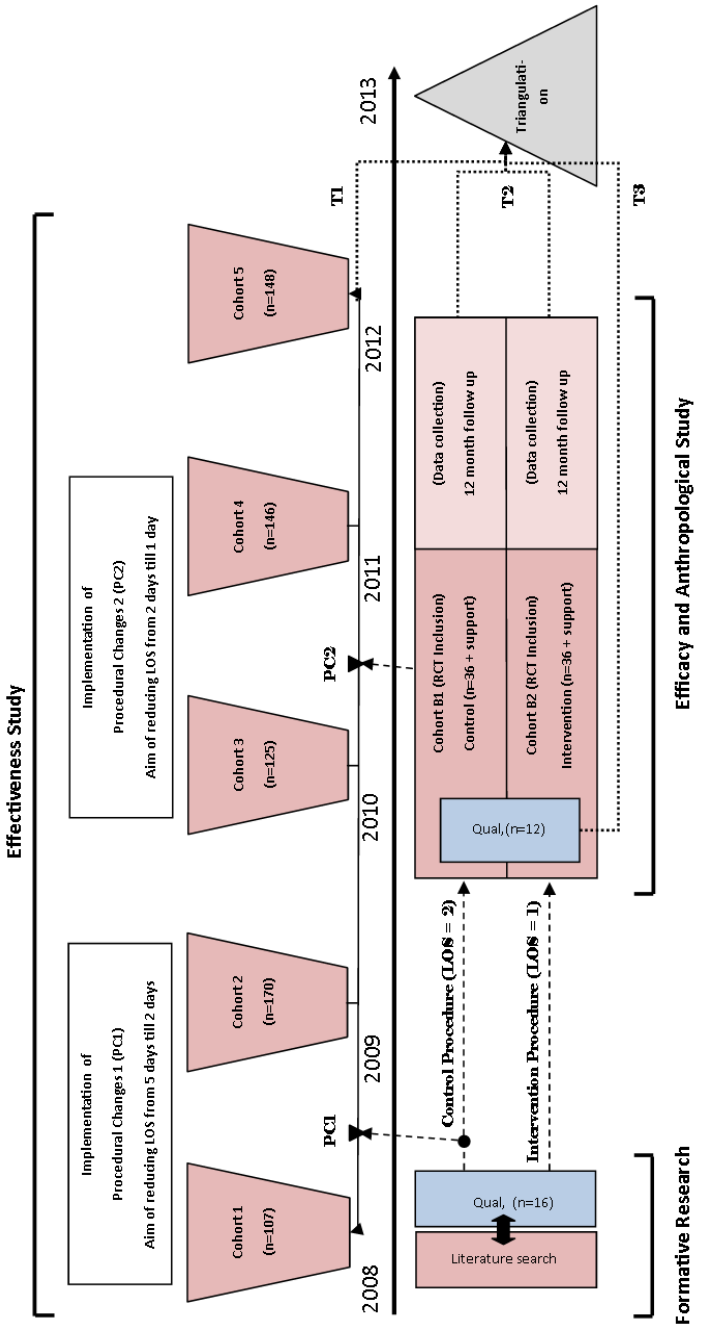
We outline how the application of the MMR design for creating the interventions, including organizational changes, involvement of patients and relatives and the use of telemedicine, was developed for the efficacy study and thus the anthropological study. We find this important based on the assumption that informal knowledge sharing happened during this part of the project. We outline also how the two sets of procedural changes (PC1 and PC2) in the organization, made were for the effectiveness study.

FIGURE 1 CHRONOLOGY OF THE RRS PROJECT



Inspired by the work on mixed-methods in intervention research by Nastasi et al. [16] *an illustration of the chronology of the RRS project was made. The depicted phases are simplified and the distinctions across phases are artificial. Thus, for example, existing theory and research overlapped formative research, as do Evaluation Research (Efficacy) and Procedural Change 2. Furthermore, the first five phases were not sequential but occurred concurrently and with elements of iterations. The development of the Procedural Changes 1 and 2 were conducted as an integrated features to the project RSS.*

FIGURE 2 THE MIXED METHOD STUDY DESIGN AND TIME OF DATA COLLECTION IN THE RRC PROJECT.



Cohorts 1-5 (above the timeline) are THR patients presented with Procedural change 1 (PC1) in 2008 and Procedural change 2 (PC2) in 2010 and included in this paper. Data obtained are from February, March and April 2008-2012(Effectiveness study). Below the timeline is Cohorts B1 and B2, randomized participants in the telemedicine intervention study (Efficacy and anthropological study).
Formative research was completed on current procedure. PC1 = Procedural change 1 (Effectiveness study) is the same as Control procedure (Efficacy and anthropological study). Intervention procedure is with telemedicine support (Efficacy and anthropological study) PC2 = Procedural change 2 (Effectiveness study). T1 are results from the effectiveness study and T2 are results from the efficacy study. T3 are results from the anthropological study. T1, T2 and T3 are all included in the triangulation not reported here.

The interventions implemented in the day-to day praxis: A short description of the development and the procedures implemented in day-to-day practice.

Procedural change 1: An anthropological study of, the current fast-track THR procedure was completed in 2008 (Figure 1). Based on results from this study and existing evidence [17-32] reported in the literature, an interdisciplinary group consisting of a medical doctor and a physiotherapist developed the procedural changes (Figure 1) implemented in the usual healthcare in 2008. The procedural change had the goal of reducing LOS from five to two days and included treatment goals of blood loss, pain relief, nausea control, and nutrition, mobilization and discharge criteria. It included primarily an optimization of information-giving practices, early post-surgical mobilization and organizational changes with regard to control X-rays, blood samples, for instance, and a bigger focus on including the close relatives. The development was done in cooperation with the staff and the final solution was presented for the whole organization during four meetings. We define the process as informal knowledge sharing and the guide for the procedural change as formal knowledge sharing.

Procedural change 2: This was developed while conducting the efficacy study in 2010. This was based on results from the qualitative study, staff experiences and preliminary results of the quantitative part of the efficacy study. This change was primarily due to the positive preliminary results from the efficacy study. The Procedural change 2 was developed by an interdisciplinary group consisting of those involved in the development of Procedural change 1, the anthropologist from the development of the Telemedicine Intervention and healthcare staff working with fast-track procedures. The aim of Procedural change 2 was to discharge patients at day 1 post-surgery as for the intervention group in the efficacy study, using the same goals for treatment. With Procedural change 2, patients did not receive the telemedicine solution, but received a phone call from a nurse the day after discharge.

Presentation of the theory on "SCRUM": SCRUM was the start of the agile development movement. Introduced 1986 in an article, titled The New New Product Development Game [33], in Harvard Business Review (HBR) by professors Takeuchi and Nonake. They coined the term SCRUM inspired by how a team move in a rugby game being self-organizing and managing. The focus of a team as the main resource was new, "*the product development process emerges from the constant interaction of a hand-picked, multidisciplinary team whose members work together from start to finish. Rather than moving in defined, highly structured stages, the process is born out of the team members' interplay*". The authors listed six elements they described as "*a powerful new set of dynamics that will make a difference*".

Elements in SCRUM Dynamics

1. Built-in instability
2. Self-organizing project teams
3. Overlapping development phases
4. "Multilearning"
5. Subtle control
6. Organizational transfer of learning

Jeff Sutherland and Ken Schwaber formalized the development of SCRUM in 1995 for use in programming [34]. Many consider it the first and most important agile software development process. SCRUM influenced not only the development of software. It effected engineering process's in general and challenged the often-used project management style named "Waterfall" that used isolated sequential phases whereas SCRUM are overlapping phases of development.
The agile movement has been spreading to other disciplines than software programming. It led to the Agile Manifesto created in 2001 [35] also signed by Jeff Sutherland and the Pretotype Manifesto now used at Google and taught at Stanford University [36]. Agile development have a strong foothold in engineering, software development and start-up communities. We use the SCRUM "Dynamics" as framework for evaluating the process of develop and implement PC1 and PC2 as part of the RRS project.

EVALUATION OF LOS REDUCTION THROUGH THE FRAMEWORK OF "SCRUM DYNAMICS"

We will try to understand the process of reducing LOS with 75% in the framework of agile development and compare the results with the framework for implementing named the Consolidated Framework for Implementation Research (CFIR) [31] and published in 2009, to evaluate if the use of agile development created best settings for implementation effectiveness.

1. Built-in instability

Using formative research in 2008, we define the needs of patients, relatives and staff. When the ethnographer concluded on her qualitative findings, we evaluated and compared with relevant literature. The project id not decide on any solution but starts running a series of workshops with patients, relatives and staff and gaining more knowledge. The first workshop was based on a lean-light inspired method. It was held to define the existing logistic clinical THR pathway [37]. An interdisciplinary group consisting of 28 individuals selected from the staff participated in the workshop. As part of the workshop, the patient's journey from start to finish was illustrated with a track-and-trace visualization, where the patient was represented as a "package". The first workshop resulted in defining 194 specific interactions between patients and staff during one THR. When developing the telemedicine solution we used mock-ups and prototypes to get feedback from everyone involved with THR. We did some of these workshops in the clinical setting and at all-time indicate that it was possible to form and change the solution and intervention until the day it was implemented. We decided in primo 2009 on a "prototype" PC1 that we tested with a small group of patients and relatives. The results were evaluated with the organization. Based on the feedback final adjustments were done. We continued to develop the interventions for the control group in the RCT including the telemedicine solution. The organization was still a part of that process and still no final decision on the solution was made. Trying to let the organization now that input is welcome and can affect the final solution and intervention. When a prototype of the telemedicine solution and the procedure were ready, we tested it in a fake "home environment", created at the hospital including nine patients and their close relative. We evaluated the results and made changes based on feedback and tested the telemedicine solution in a pilot test including four patients discharged to there home. PC1 had been used over a year when the RCT were to start. Minor adjustments were made to PC1 during that year. Those done were included in the procedure use for the control group in the RCT. When

the embedded qualitative study was terminated in 2009 the results were evaluated by the researchers' and the managements of the department. Furthermore, the findings were paired with the empirical knowledge gained from working with PC1 in day-to-day praxis. Based on the evidence it was decided to develop and implement PC2 based on the procedures used for the interventions group in the RCT. Again, an interdisciplinary group working interactive with the rest of the organization developed PC2 and implemented it. More important, day-to-day praxis kept improving on the set-up, optimizing the procedure, and reducing LOS.

Focused on develop solutions that could eliminate those initial needs defined in the formative research but not select a solution or a procedure, but being open to the need for to change, or make a pivot [38] was important through the RRS Project. That "Build-in instability" made it possible to interact with staff, patients and relatives and change preliminary solutions for best fit to need and organization. During these workshops, it was possible for the staff directly to influence the work process and in that way the possible outcome. The "instability" of the solutions made it possible to motivate staff and other stakeholders to give feedback and in that way a feeling of ownership to the RRS Project. An ownership based on the possibility to co-create [10,39]. There was a low tension against changes in the department. The reason for this could be the high adaptability of the solution and interventions that is found to positive motivate an organization [40,41] . The organization was of a small size. The structure was with locale and decentralized decision makers and with a high degree of specialization that positively support a successful implementation [42-44]. The instability of the solutions supported the possibility of supporting existing workflow and systems and to be tailored to needs, norms and value also increasing implementation effectiveness [40,45]. All staff in the organization were ask to contribute to the process's. But not all did. One could presume that those with high self-efficacy "signed up". Individuals with high self-efficacy are more likely to make a decision to embrace the intervention and exhibit commitment even with instable solutions [46].

2. Self-organizing project teams

The project group were interdisciplinary. Four individuals with four different professional backgrounds worked in co-operation, leading the project and participating in the decision-making with the common goal of creating a social movement and distancing the project from a programmatic approach. The interdisciplinary project group comprised a physiotherapist in charge of patient information material, guidelines and co-ordination of the surgical fast-track procedures in the RCT, an ethnographer, in charge of all qualitative studies, a computer scientist, in charge of the team designing the telemedicine solution and its software, and a medical doctor (Ph.D. Fellow), responsible for the quantitative studies and ethical considerations. One significant change that was made to the methods applied when designing the solutions was that the leading doctors and highest ranking researchers, e.g. professors, were removed from the workshops and preliminary tests. This because, we observed, during the first workshop, that hierarchy affected outcome and participant contributions. Further investigation showed that the phenomenon had been described previously [10,47] Also supported by evidence for a self-governing team when working with agile development [33]. We concluded that strong hierarchy was counterproductive when holding workshops, as it lowered the level of creativity amongst the staff . As a result, all superiors/professors were excluded from the workshops and tests [43,44]. The removal of the formal

"decision-makers" opened up for achieving more creativity; however, this only lasted for a short period of time before self-regulation and a spontaneous order evolved leading again to a reduction in the level of creativity. As part of workshops to be held in the future, this information was considered important. The internal developed solutions and interventions and the familiarity with key members of the project group gave legitimacy to source and created a grass-root effort and not a direct connection to the hospital management or an external unit [40]. The diversity of members profile in the project group [42] and the almost constant presence of members from the project group during the RSS project also increase possibility for success [43].

3. Overlapping development phases

When using MMR both as formative research and as an anthropological study embedded in a RCT, as the evaluative research, the complexity and the overlapping is tremendous. In the RRS project, we in between those phases of research, did parallel innovation and development of the procedural changes, the telemedicine solution all alongside small clinical pilot testing's. During the evaluative research PC2 was developed and therefore done overlapping. The simplicity of figure 1 do not depict the work across phases. The iterations and the fact that many processes were happening at the same time made it impossible to conduct this project without overlapping development phases. The formative researcher took place at the same time and interacted with the work creating the software architecture lead by the computer scientists and so on. All of the processes have overlapping phases and in all of the phase's members of the project group was in charge. The complexity is high in the RRS Project a fact that could negatively affect the implementation and use of the solutions [48]. However, overlapping phases with many small tests and "pre-implementations" helped design a situation of familiarity and plan for implementation [41].

4. "Multilearning"

Most of the project took place in a working clinical setting. The intention was to enable staff to follow the progression and always know that they could contribute to the process. Furthermore, frequent presentations were made at the ward and at staff meetings and seminars held by the hospital. The idea of letting the staff follow the progress, but not able to interact directly, was maintained throughout the entire project period, including the pilot test and the evaluation research. We named this the "greenhouse concept"; the concept of a shielded test environment, where the staff would be able to observe the progression of the project and share observations, challenges and ideas for improvement with the project group and in that way support knowledge sharing. This also created a way to give open and unregulated feedback to the organization, beside the more formal tests and debriefing and a possibility to reflect and evaluate [49]. We sought to create a sense of acceptance for making mistakes and stated publicly, on several occasions during the process, that it was okay to fail. However, the whole process had to happen fast and all the time in a forward going direction [50], and any errors/mistakes were to be reported as a natural part of the knowledge sharing. Knowledge sharing was used strategically for increasing the possibility of "pulling" knowhow and ideas form staff, patients and support persons. The placement of both the innovation and the clinical test in "plain sight" for the rest of the organization, not only necessary for the

possibility of conducting the project, was seen and deliberately accommodated to benefit the project [51,52]. Knowledge sharing also happened between group members and inspired to the MMR design based on different needs for documentations. Knowledge sharing was considered important but difficult to document and the effect hard to evaluated [11].

5. Subtle control

To stimulate creativity in a group, we found that it could be done by removing the person initially assigned as the "leader", as this caused a "state" of emergence [53] where loss of a regulating/controlling structure gave rise to new and perhaps more disruptive ideas. The management ratified a whitepaper made at the first workshop and herby acceptance full support for the need for agility in a normally varied hierarchical organization. We believe that this helped the management to understand that they should create space for innovation to happen and not lead an innovative process. Which is in accordance with theories from Lean Start-up [38] and agile development [35]. The focus on the need also worked as the main guide for the project. In this way the unmet need of patients and staff controlled the direction of the development process and in the same way made sure that the solutions were important and relevant. Politicians and decision makers at Central Denmark Region were debating cut in cost of the healthcare sector at the time of the RRS project. Motivation and a controlling factor could have been felt by the organization increasing their willingness to change. Champions and opinion leaders at the department who dedicated themselves to the project also helped reducing need for control of the processes, by the project group or management - and helped facilitated the conduction of testes and implementation [38,54].

6. Organizational transfer of learning

Besides the formal transferring of knowledge when implementing PC1 and PC2 in day-to-day clinic many other benefits came from conducting the RRS project to the organization. All the logistic advancements made inspired and directly affected the procedures for total knee replacement and the procedures used for back surgery. This diffusion of innovation is seen before [54] but very important when implementing technology and often needed organizational changes for it to be with a positive outcome[55]. Including relatives were emphasis in the RRS Project and based on the formative research but also that spread to the rest of the organization [56]. Focus on health literacy have inspired to new ways of preoperative education of relatives and patients and changed the way patient information is given [31,57,58]. Elements of the telemedicine solution, made during the RRS project are implemented at RHS through a startup [59] to other hospitals in Denmark. Learning has not only transferred inside the organization but also to similar clinical settings in Denmark.

DISCUSSION

The validity of the quantitative results is considered to be as high as possible when taking place in a working clinical setting. The selected population seems representative compared to the average THR-patient at the hospital department; the instruments used for collecting and analyzing data are validated; and finally the selected outcomes seem clinical relevant.

Consolidated Framework for Implementation Research (CFIR) [49] has been developed to give a comprehensive framework and structure to the complicated process of implementing in the everyday setting of health services. The authors intended that "*CFIR will help advance implementation science by providing consistent taxonomy, terminology, and definitions on which a knowledge base of findings across multiple contexts can be built".* Furthermore, *"CFIR can be used to organize and promote synthesis of research findings, studies, and settings using clear and consistent language and terminology, which will further stimulate theory development*". The CFIR encompasses five parts: the intervention, inner setting, outer setting, the individuals involved, and the process by which implementation is accomplished. When evaluating the findings using SCRUM Dynamics to evaluate the development process of the RRS Project, implementations of the procedural changes 1 and 2 and the effect on day-to-day praxis we find that the project points directly to a high implementation effectiveness.
This study provide valuable information about the possibilities in a structured, evidence-generating, mixed-methods approach to innovate procedures and create new ways for healthcare delivery. We also find that a constant focus for knowledge sharing inside the organization helped facilitated the implementation of new procedures in the day-to-day praxis and find that the evaluation through the CFIR framework support this claim.

Several different ways to make innovative solutions for the healthcare sector or to optimize existing procedures have been tried previously [60,61]. Most have their origin in different areas of expertise - for example, the car industry or engineering [62] [44]. We find the challenges met when innovating in the healthcare sector are many and hard to describe. However, the Danish healthcare system has, like in most countries, been dominated by an education-specific organization. This has led to a silo structure, based on the medical specialties, and within these silos strong group identities of doctors, nurses, physiotherapists and secretaries respectively have thrived. Barriers with regard to sharing responsibility and letting competencies, rather than tradition deciding how to generate evidence and what is best practice, have been immense [13]. Success in creating fast-track procedures for elective surgery patients has, in recent years, developed cultures that we find breaks down the silos and diminishes the specialized group identity. This create a possibility of a team spirit that resembles that of startup [63] However, the new organizations of teams do not by definition created a team spirit or social movement for innovation [64] or sharing knowledge. The optimizations made are mostly based on the ideas and work of healthcare providers but the existence of functional fixations could limit creativity and courage [65,66]. Involving professions normally not related to the healthcare sector and/or actively including patients and relatives in the development of new procedures have, however, not been standard practice at RHS and, presumably, not in many other orthopedic departments either. Different approaches on how to overcome these obstacles and involved professions outside the hospital have been tried [39,67]. The increasing use of, and call for, HIT that engages patients, including elements of social technologies, also increases the need for the interdisciplinary approaches to create new inventions, interventions and rethink healthcare delivery [68]. Agile development in combination with MMR can be useful in both the design of an intervention and research evaluation [16] and as a means for social change in relation to healthcare [69] and will increase the chance for creating an innovative culture and herby support implementation of evidence based practice.

As outlined, the intervention and study design of the evaluation research were developed interdisciplinary. The innovation process, did not only led to the development of technology and organizational improvements but also to a change in staff members' mindset with regard to innovation, improvement [55] and implementation[56]. Much of the innovation took place in a working clinical setting in what was named the 'greenhouse concept,' visualizing a shielded test environment where staff could see progression, be reminded that they could contribute to the process and share observations, challenges and ideas for improvements but not directly disturb the environment. This mindset was taken in to the day-to-day praxis and help support knowledge sharing. Furthermore, frequent presentations were made at the ward, during staff meetings and at seminars held by the hospital. Although this setting for the innovations process was created to make the best possible intervention and to kept the needs of the end users in focus. We theorize that this part of the RRS project helped facilitating the implementation of not only the procedures used in the intervention (efficacy) study but also affects positively the outcome of the two procedural changes and the work conducted in the usual practice for THR patients (effectiveness).

CONCLUSION

A significant reduction in LOS has been documented but more importantly, the procedures, the knowledge gained and the innovative way of working, with the RRS Project, were deliberately and influentially shared with the rest of the organization. This led to the reduction in LOS of 75% over four years for THR patients at RHS; i.e. not only in the project period. This has been accomplished in the day-to-day clinical, fast-track operational environment and without a reduction in patient safety.

Using the SCRUM Dynamics as a theoretical framework, we find it possible to explain that the use of agile development, in the RRS Project; have created an environment that in many ways increases the possibility of implementation and increase the effectiveness of health care.

The use of agile development in combination with mixed-methods interventional research can directly and positively support the implementation of a locally develop procedure and creates in this case an structure for best possible environment supporting implementation when evaluated through the evidence form implementation research (CFIR) [49]. The conclusion is based on the high comparability with the processes and achievements gain working with agile development, listed in this paper using SCRUM Dynamics as a framework, to those that appeared when evaluating the organization and the environment when implementing PC1 and PC2 through the framework of CFIR.

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This declaration concerns the following article/manuscript:

Title:	Telemedicine-Support in Total Hip Replacement: Length-of-Stay Halved without Loss of Quality. A Randomized Clinical Trial
Authors:	Martin Svoldgaard Vesterby, Malene Laursen, Søren Mikkelsen, Kjeld Møller Pedersen, Kjeld Søballe, Jens Rolighed Larsen

The article/manuscript is: Published ☐ Accepted ☐ Submitted ☐ In preparation ☒

If published, give full reference:

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Has the article/manuscript previously been used in other PhD or doctoral dissertations?

No ☒ Yes ☐ If yes, give details:

The PhD student has contributed to the elements of this article/manuscript as follows:

A. No or little contribution
B. Has contributed (10-30 %)
C. Has contributed considerably (40-60 %)
D. Has done most of the work (70-90 %)
E. Has essentially done all the work

Element	Extent (A-E)
1. Formulation/identification of the scientific problem	E
2. Planning of the experiments and methodology design and development	E
3. Involvement in the experimental work/clinical studies	E
4. Interpretation of the results	E
5. Writing of the first draft of the manuscript	E
6. Finalization of the manuscript and submission	D

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Element	Extent (A-E)
1. Formulation/identification of the scientific problem	E
2. Planning of the experiments and methodology design and development	D
3. Involvement in the experimental work/clinical studies	D
4. Interpretation of the results	D
5. Writing of the first draft of the manuscript	E
6. Finalization of the manuscript and submission	E

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