CONNECARE

WP6 – DEPLOYMENT OF CLINICAL STUDIES

D6.3: RESULTS FROM CASE STUDY 2

H2020-EU.3.1: Personalised Connected Care for Complex Chronic Patients

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Abstract	This deliverable focuses on Implementation Study 2 - Preventive patient-centred intervention in complex chronic patients undergoing elective major surgical procedures - and describes the implementation studies carried out in all four sites along with final results. The deliverable is divided into five sections: 1. Introduction 2. Overall Concept of Implementation Study 2 3. Implementation Study Performance Report 4. Results of the deployment of CONNECARE in all four sites 5. Roadmap toward digitally supported perioperative care.

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Executive Summary

CONNECARE "Personalised Connected Care for Complex Chronic Patients" is a HORIZON 2020 Research and Innovation Project funded under Call: H2020-PHC-2015 - Topic: PHC-25-2015. CONNECARE is essentially a technologically-oriented initiative aiming at exploring digital tools to support two key requirements of integrated care services for chronic patients, namely: (i) Smart adaptive case management (SACM) of patients with multimorbid conditions; and, (ii) Collaborative work among the various stakeholders, including patients and their families across health and social care tiers, involved in the services. The CONNECARE model consists of two major components: an organizational model for integrated care and a technological platform to support the integrated care organizational processes. From the outset, the aim of the project has been to deploy the CONNECARE model in real life situations in each of the sites. Consequently, the CONNECARE approach has been an implementation research approach, using an observational study design focused on implementing the CONNECARE organizational model and technology in real life situations with an intervention group and matched control group in four implementation sites: Barcelona, Lleida, Israel and Groningen. The CONNECARE platform has been deployed in two situations:

- Community-based prevention of unplanned hospital-related events in chronic complex patients with high risk for hospitalization (Implementation Study 1).
- Preventive patient-centred intervention in complex chronic patients undergoing elective major surgical procedures. (Implementation Studies 2 and 3).

This deliverable focuses on Implementation Study 2 - Preventive patient-centred intervention in complex chronic patients undergoing elective major surgical procedures - and describes the implementation studies carried out in all four sites along with their results. The deliverable is divided into five sections:

1. Introduction – describes the context and the rationale underlying the CONNECARE project from the perspective of the developments in both integrated care and digital technology underlying movement towards evolving and deploying digitally enabled integrated care which is the aim of the CONNECARE project.
2. Overall Concept of Implementation Study 2 – addresses the rationale for choosing to implement the CONNECARE intervention in the population of complex chronic patients undergoing elective major surgical procedures; describes the commitment to implement CONNECARE in real life situations and the consequent heterogeneity among the implementation scenarios in order to meet real life challenges, with the intent that major aspects of the implementation will continue to evolve after project's end.
3. Implementation Study Performance Report – describes in detail the implementation in each of the four sites – site by site - addressing the following components:
    - Site adaptation of the Concept;
    - Pilot description, inclusion criteria and study design;

- Pilot experience - progression and changes over time
    - Brief description of the Intervention;
    - Recruitment and Sustainability Challenges;
    - Difficulties, problems and barriers – how they were overcome and the changes they necessitated to enable successful deployment;
- Summary of Implementation Study Performance in all four sites;

4. Final Results of the deployment of CONNECARE in all four sites – site by site – based on the number of patients that had completed the CONNECARE Program in each site at project's end. The results reported in this deliverable include:
    - Patient assessment of the Implementation of the Integrated Care Services and Processes
        - Patients rating of the integrated care services using the Person Cantered Coordinated Care Experiences Questionnaire (P3CEQ and the Nijmegen Continuity Questionnaire (NCQ)
        - Organisational and Process Issues that were reported in the implementation logs and the evaluation of implementation process indicating those that were successful and could be replicated and those that did not work
    - Clinical Staff Engagement and Assessment of Project Implementation
    - Assessment of Patient Engagement and Use of ICT tools and devices
        - Use of the Pedometer
        - Use of the SMS app functionalities including messaging, questionnaires, simple tasks and monitoring vital signs
        - Patient Satisfaction with the Fitbit and App as measured by Likert scales and Net Promoter Score (NPS) and the System Usability Scale (SUS)
        - Issues with the use of digital tools as recorded in the implementation logs including both usability issues and technical issues as well as integration with other digital systems
    - Clinical Staff assessment of and satisfaction with ICT Tools
    - Clinical outcome measures
    - Cost assessment.
    - Summary of the Results in All Sites.
5. Roadmap toward digitally supported perioperative care.

It is highly recommended to read the following deliverables:

Number	Title	Description
D2.1	Cook-book	The document provides an overall view of the CONNECARE project, and describes the procedures for its development. The deliverable indicates the different phases of the project, with an emphasis on how PDSA cycles will be structured. Overall, the CONNECARE project does not aim at a rigid integrated care solution that needs to be adopted by all potential deployment sites but to a flexible solution that has high potential for generalization at the EU level. In this sense, innovative methodologies involving both global and local stakeholders have been adopted.
D6.1	Study release feasibility for the three clinical studies	The CONNECARE document D6.1 covers the operational aspects required to: i) Initiate the implementation studies at site level; ii) Do a proper follow-up of their progress until the final release of the system at the end of the second co-design period; iii) Perform assessment of the five main dimensions of the project (1. Service workflows design & cost-effectiveness; 2. Technological developments; 3. Health risk assessment & service selection; 4. Innovative assessment aspects; and 5. Transferability analysis & service adoption); and, iv) Prepare the elements required for accomplishment of Tasks 7.4 and 7.5 (Recommendations of final services and proposals for scale-up integrated care) which constitute the core activity of the third co-design period, from M36 to M42.
D7.1	Evaluation plan for the entire project	The document defines the steps and tasks required for the entire project evaluation. It analyses the criteria used for identification of the different modalities of indicators, the methodological approach including clinical study designs, as well as the three main phases: (i) Initial co-design process; (ii) Clinical studies; and, (iii) Refinement & fine tuning process, defining and overall strategy for CONNECARE assessment. The document also indicates synergies established with other EU projects showing complementary goals, namely: ACT@Scale and SELFIE. Assessment of the value generated by the CONNECARE approach and identification of determinants of scale-up of the clinical studies are central goals of the project. Moreover, the document identifies the two final outcomes of the project: (i) refined CONNECARE ICT-supported integrated care services; and, (ii) generation of guidelines for transferability of CONNECARE to other EU sites beyond the project life span.
D7.2	Evaluation results of the initial co-design phase until Study Release	The D7.2 document summarizes the results of co-design from the project start to end for the main project dimensions, namely: i) Implementation studies covering service workflows design, effectiveness and operational cost analyses; ii) Technological developments to support integrated care services; iii) Health risk assessment and service selection; iv) Innovative assessment aspects proposed by the project; and, v) Transferability analysis & recommendations for service adoption at European level. The document summarizes the lessons learned

1. Introduction

With the increasing life expectancy of the world population, particularly in the developed world, there has been an increasing burden of chronic illness and disability that, together with increasingly limited resources, has necessitated a change in the way we view and provide health and social care. Integrated care has been seen as a response to the fragmented delivery of health and social services being an acknowledged problem in many health systems. While the notion of integrated care was already being discussed in the late 1990s, a first attempt to define integrated care was offered by Kodner and Spreeuwenberg in 2002 (Kodner & Spreeuwenberg, 2002). In 2016 WHO proposed the following definition: "Integrated care is a concept bringing together inputs, delivery, management and organization of services related to diagnosis, treatment, care, rehabilitation and health promotion. Integration is a means to improve services in relation to access, quality, user satisfaction and efficiency." (WHO Europe, 2016). The integrated care literature distinguishes between different ways and degrees of working together and between horizontal integration (linking similar levels of care like multi-professional teams) and vertical integration (linking different levels of care like primary, secondary, and tertiary care).

Side by side with the movement toward integrated care, the rapid development information and communication technology has provided new digital tools that are catalysing the transformation of health care and given the concept of integrated care new meaning. There is technology for sharing medical and care information among professionals and increasingly we think in terms of patient-centred care supported by digital tools. The digital transformation of health care is high on the agenda in all developed countries, and is receiving especially high visibility in the European Union with its publication on 25th April 2018 by the European Commission of the Communication on Digital Transformation of Health and Care in the Digital Single Market. One of the three major priorities is citizen empowerment with digital tools for user feedback and person-centred care using digital tools to empower people to look after their health, stimulate prevention and enable feedback and interaction between users and healthcare providers. There is a growing conviction and preliminary evidence that mobile apps can support chronic disease management (Quinn et al., 2011; Bexelius et al., 2010; Carrasco et al., 2008; Lester et al., 2010).

This is the context for the CONNECARE project. The aim of the project was the development and implementation of a model and platform for digitally enabled integrated care, specifically for elderly, chronically ill patients. The CONNECARE platform was intended from the outset to be implemented in two situations:

- Community-based prevention of unplanned hospital-related events in chronic complex patients with high risk for hospitalization;
- Preventive patient-centred intervention in complex chronic patients undergoing elective major surgical procedures.

2. Overall Concept of Implementation Study 2

As Complex Chronic Patients undergoing elective surgical procedures show increased rate of post-surgical complications, the aim of the intervention in implementation Study 2 is to reduce undesirable post-surgical events and enhance health outcomes (i.e., length of hospital stay, re-admission rate) by a digitally supported and integrated patient-centred preventive intervention in the peri-surgical period - before, during and after the surgery. CONNECARE is essentially a technologically-oriented initiative aiming at exploring digital tools to support two key requirements of integrated care services for chronic patients, namely: (i) Smart adaptive case management (SACM) of patients with multi-morbid conditions; and, (ii) Collaborative work among the various stakeholders, including patients and their families across health and social care tiers, involved in the services. The CONNECARE model consists of two major components: an organizational model for integrated care and a technological platform to support the integrated care organizational processes.

From the outset, the aim of the project has been to deploy the CONNECARE model in real life situations in each of the sites. Consequently, the CONNECARE approach has been an implementation research approach, using an observational study design focused on implementing the CONNECARE organizational model and technology in real life situations with an intervention group and matched control group. The dedication to real life implementation in each of four implementation sites has led to a high level of heterogeneity among the implementation scenarios in order to meet real life challenges, with the intent that major aspects of the implementation will continue to evolve after project's end.

In order to enable the degree of necessary heterogeneity among sites, it was decided to conceptually divide the implementation of CONNECARE into two components:

- The organizational integrated care service component;
- The technological component to support the integrated care service.

There were significant differences among the sites in the level of maturity of the organizational integrated care service component at project start. For example, Barcelona had already implemented a pre-habilitation program for comorbid complex patients undergoing major abdominal surgery (see D6.4 "Results from Case Study 3" for detailed description) whereas this component did not exist in any of the other sites. Moreover, Catalonia generally, and Barcelona specifically is more advanced in many ways in the development of integrated care services at a Regional level than the other sites.

This resulted in a significant difference in focus among the sites. For Barcelona, the focus was on testing of the digital tools, embedded into integrated care services, carried out in real-life settings wherein large scale adoption of the services is a central objective. Barcelona, therefore, focused on solutions that could be integrated into existing integrated care services already in place with existing digital systems in Hospital Clinic as this had implications the for the entire AISBE region (Integrated Health District of Barcelona-Esquerra, 520 k citizens) as well as Catalonia as a whole. In Lleida, Israel, and Groningen, the focus was on the implementation of the technological component as a part of the development of

new integrated care services. This led to a compartmentalization of the technology with a division between the Adaptive Case Management platform (the SACM) and the patient empowerment tool (the SMS) as it became clear early in the project that the SACM could not easily be integrated with existing legacy systems in any of the sites.

The target group is high-risk patients undergoing an elective major surgical procedure in all four sites. While the objectives and desired outcomes are the same in all four sites, the organizational processes implemented have been adapted to the specific contexts and needs of each site. Barcelona and Israel focused on patients undergoing several different types of major surgery whereas Lleida focused exclusively on orthopaedic surgery and Groningen on patients being operated for a solid tumour. Two sites (Barcelona and Israel) implemented a structured pre-habilitation process operated by the hospital for all patients in the project whereas Lleida implemented a pre-habilitation plan for selected patients monitored by primary care and Groningen did not do pre-habilitation at all, but monitored vital signs and physical activity both pre and post-surgery.

3. Implementation Study Performance Report

3.1 Barcelona

CONNECARE is essentially a technologically-oriented initiative aiming at exploring digital tools to support two key requirements of integrated care services for chronic patients, namely: (i) Smart adaptive case management (SACM) of patients with multimorbid conditions; and, (ii) Collaborative work among the various stakeholders, including patients and their families across health and social care tiers, involved in the services.

In Barcelona, the testing of the digital tools, embedded into integrated care services, is mostly carried out in real-life settings wherein large scale adoption of the services is a central objective. The rationale and methodology behind site adaptations of CONNECARE in Barcelona for all three Case Studies carried out at Hospital Clinic de Barcelona (HCB) are described in detail in D6.4 “Results from Case Study 3”.

The current document describes three study protocols carried out as part of the process of designing a perioperative care program aiming at generating healthcare efficiencies at HCB looking for transferability at regional level. The content of the document is highly complementary of the information provided in D6.4 “Results from Case Study 3”. The latter is purposely devoted only to the deployment of one specific intervention at HCB; that is: pre-habilitation in high risk patients before major surgical procedures. Briefly, based on the results of the randomized control trial (RCT) on pre-habilitation conducted from 2013-2016[1], the prehabilitation service has been deployed as a mainstream intervention for high risk candidates to major surgical procedures at HCB during the lifetime of the project. The results of the initial RCT also served as the foundation for the prehabilitation program in Israel.

As indicated above, the current document describes three studies focusing on perioperative care including: (i) prehabilitation; (ii) perioperative care during hospital admission, and, (iii) support to the postoperative period, within the context of CONNECARE implementation of Case Study 2. In the document, the first implementation study explores the process of recovery after surgery[2]. The second protocol investigates key modulators of adherence to pre-habilitation; but, it also explores factors associated with surgical complications (see ***APPENDIX I - 1.1***). Finally, the third study evaluates the adaptation of two digital tools as enablers of perioperative care services, namely: (i) adaptation of

[1] Barberan-Garcia A, Ubré M, Roca J, Lacy AM, Burgos F, Risco R, Momblán D, Balust J, Blanco I, Martínez-Pallí G. Personalised Prehabilitation in High-risk Patients Undergoing Elective Major Abdominal Surgery: A Randomized Blinded Controlled Trial. Ann Surg. 2018 Jan;267(1):50-56.
[2] A. Barberan-Garcia, M. Ubre, N. Pascual-Argente, R. Risco, J. Faner, J. Balust, A. M. Lacy, J. Puig-Junoy, J. Roca and G. Martinez-Palli. Post-discharge impact and cost-consequence analysis of prehabilitation in high-risk patients undergoing major abdominal surgery: secondary results from a randomised controlled trial. British Journal of Anaesthesia, 123 (4): 450e456 (2019).

MyPathway® (developed by ADI); and, (ii) adaptation of the SMS developed in CONNECARE (X-Care) (see ***APPENDIX I - 1.2*** *and* ***APPENDIX I - 1.3***).

Barcelona has been a full partner in the co-design of the CONNECARE technology as have all of the Implementation Site partners. However, the technological risks identified in terms of: timeline, robustness, and potential for scalability, triggered the following proposals in order to comply with the needs of CONNECARE in Barcelona, namely:

1. To address the different technological elements – the SACM and the SMS separately, in addition to testing the whole platform
2. To explore alternative digital tools, consistent with the CONNECARE concept, easily adaptable to the site requirements for large scale deployment of the services, and
3. To take into account the interoperability requirements at site level in order to address both technical and functional integration with local health information system during the lifetime of the project.

Barcelona has focused its energies on the development and/or adaptation of different interoperable digital tools ensuring the two key CONNECARE functionalities: Smart Adaptive Case Management (SACM) and collaborative work, with high priority on functional and technological integration with different healthcare providers in the area.
To this end, adaptations of two different digital tools have been addressed, namely: (i) MyPathway® for perioperative care; and (ii) the CONNECARE SMS adapted to Barcelona's specific needs. A third digital tool, Health-Circuit (see D6.4), will not be tested for perioperative care during the project lifetime.

MyPathway®, offered by ADI (https://mypathway.healthcare/), a CONNECARE partner, was already deployed in Sheffield Teaching Hospitals (UK) as a browser and mobile app that connected patients and caregivers in a simple and robust way, in order to share information about treatment, making appointments and answering questions about patients' progress. The decision was to adapt MyPathway® to support the pre-habilitation service in Barcelona in a way that it could capture signals from a pedometer that registered daily-steps. This would encourage patients to perform physical activity and it would allow off-line remote monitoring by healthcare providers.

As indicated above, ***APPENDIX I - 1.2*** summarizes the results of the trials carried out with MyPathway® and the adapted CONNECARE's SMS; but, the overall assessment of the technological aspects of CONNECARE in Barcelona is done in detail under a specific subheading in D6.4 "Results from Case Study 3".

3.1.1 Implementation Studies Description

3.1.1.1 *Protocol I – Post-discharge impact of pre-habilitation*

The two main goals of perioperative care are: (i) Prevention of postoperative complications immediately after the surgical procedure and post-hospital discharge; and, (ii) Enhance postoperative functional recovery of the patient. Protocol I in Barcelona addresses the following questions:

1. Does prehabilitation have impact on early (1-month) post-discharge complications and on functional recovery at 3-month period after initial discharge?
2. Is it feasible and useful to perform a short-term (1-month) remote, off-line, post-discharge follow-up of the patients? What are the practicalities to be taken into account?

In June 2016 (M3), as part of the design of the clinical studies associated with Implementation Study 2, the Barcelona team designed a cost-consequence analysis (CCA) using data collected during the RCT carried out to explore the effects of pre-habilitation in high-risk patients' candidates for major digestive surgery at HCB. CCA is a form of healthcare delivery evaluation in which cost and impact of the intervention are presented separately. One of the aims of the study was to evaluate sustainability of pre-habilitation-induced clinical benefits and its impact on use of healthcare resources beyond the initial surgery. High-risk patients previously enrolled in the RCT were evaluated during a six-month period after the initial surgery, assessing the effects of pre-habilitation on postoperative complications after hospital discharge.

Main study inclusion criteria were: (i) scheduled for major elective digestive surgery; and (ii) High-risk for surgical complications defined by age > 70 and/or American Society of Anaesthesiology (ASA) index 3-4. Patients with a Duke Activity Status Index above 46 were not included in the study. Subjects who consented to participate were blindly randomized (1:1 ratio) to control (n=71) or intervention groups (n=73).

Control group – They followed the standard preoperative protocol at HCB. It included physical activity recommendation, nutritional counselling and advice on smoking cessation and reduction of alcohol intake. Moreover, patients suffering from iron deficiency anaemia received intravenous iron and for those at high risk of malnutrition (Malnutrition Universal Screening Tool[3] ≥ 2), a nutritional intervention was carried out by a registered dietician.

Intervention group – In addition to the standard preoperative protocol described for the control group, the intervention group was enrolled in a pre-habilitation programme with two main objectives: (i) to increase aerobic capacity; and, (ii) to enhance physical activity. The pre-habilitation programme covered three main actions: (i) motivational interviewing; (ii) outpatient exercise training; and, (iii) promotion of physical activity. A specialized physiotherapist was the case manager guiding the patients included in the intervention group throughout the pre-habilitation programme. The length of the intervention

[3] Malnutrition Advisory Group a SC of B. Malnutrition Universal Screening Tool Available from: www.bapen.org.uk

depended on the waiting time to surgery. A minimum waiting period allowing 4 weeks of programme was required at inclusion criterion. Patients attending the program for less than 4 weeks were still included in the intention-to-treat analysis.
See the complete manuscript reporting on Protocol I, published in[4] on October 2019, in ***D6.4*** *(ANNEX IV)*.

3.1.1.2 *Protocol II – Determinants of program completion and postoperative morbidity in patients undergoing pre-habilitation*

Protocol II[5] addressed the issue of customization of the pre-habilitation services to patients' characteristics that was an unmet need. Thus, the aim of Protocol II was to identify factors associated with pre-habilitation program completion, and postoperative morbidity, in patients undergoing to digestive, gynaecologic and urologic major surgeries.

Protocol II was a cohort study including patients enrolled in the pre-habilitation unit of Hospital Clinic de Barcelona, from June 2017 to December 2018. The pre-habilitation program included 5 main interventions: i) motivational interviewing; ii) supervised exercise training; iii) promotion of physical activity; iv) nutritional optimization; and, v) psychological support. Prehabilitation completion was defined as attending ≥ 80% of appointments.

The sample size was of 200 patients and the study analysed patient characteristics – both demographic and clinical and health outcomes associated with program completion as compared with patients who did not complete the program.

3.1.1.3 *Protocol III – Evaluation of digital tools enabling perioperative care*

MyPathway® support to PreHab - MyPathway® was tested in 8 patients undergoing the prehabilitation programme at HCB to assess patients' usability and acceptability. The inclusion criteria were: i) Candidates to major elective surgery (abdominal, gynecological, cardiovascular, urologic and thoracic); ii) Patients presenting a high surgical risk defined by more than 70 years old and/or an ASA score III/IV [11]; iii) A tentative surgical schedule allowing for at least 4 weeks for pre-habilitation; and iv) Access to a mobile phone or tablet with Internet connection and an operative system (OS) version compatible to the application. In this phase, only Android OS was considered, as versions of the app for other OSs, such as iOS, were not mature. As part of this study, endurance training sessions with patients were attended in order to install the app in patients' mobile phones, and to give support with incidences and questions about the app and pedometer. Different questionnaires to assess usability, satisfaction and

[4] Barberan-Garcia A, Ubre M, Pascual-Argente N, Risco R, Faner J, Balust J, Lacy AM, Puig-Junoy J, Roca J, Martinez-Palli G. Post-discharge impact and cost-consequence analysis of prehabilitation in high-risk patients undergoing major abdominal surgery: secondary results from a randomised controlled trial. Br J Anaesth. 2019 Oct;123(4):450-456.
[5] See APPENDIX I - 1.1.2 for the complete manuscript reporting on Protocol II, that has been submitted for publication.

perception of continuity of care were completed by patients (with or without assistance) using the app for at least 2 weeks, namely: i) Person-centered coordinated care experience questionnaire (P3CEQ)6 ; ii) System Usability Scale (SUS)7; iii) Overall Satisfaction and Net Promotor Score8; and iv) Niejmegen Continuity Questionnaire (NCQ)9.

CONNECARE's SMS adaptation - The App was tested in 20 patients admitted into the prehabilitation unit on October 2019. They were followed-up during one-month period using the methodological approach described above for MyPathway®.

3.1.2 Evolution of ICT Support & Health Technology Assessment for Case Study 2

The developments associated to the CONNECARE platform: SACM + SMS, while being conceptually attractive, showed three main weaknesses regarding its use in the implementation studies in Barcelona. These limiting factors were: (i) Well justified delays in the technological developments due to several reasons described throughout the project; (ii) Poor robustness of the platform during 2018 precluding its use in the implementation study conceived as a real life deployment initiative; and, (iii) Need for further debates within the consortium regarding materialization of the ACM concept and the requirements of collaborative tools. For all these reasons, we triggered the contingency plan (March 2018) described in D6.4 aiming at covering the technological requirements of the implementation studies, but also to prepare interoperability with the health information system at HCB, as well as scalability of the clinical programs. The following three types of digital tools were selected for testing:

MyPathway® The adaptations began on March 2018 and the clinical testing was initiated in January 2019. It was concluded that the simplicity of the solution, if it were robust, would be attractive to cover current unmet needs regarding interactions between patients and professionals. This digital tool was tested in Case Study 1 (*See D6.2 - ANNEX III*) and in Case Study 2 (current document, ***APPENDIX I - 1.2)*** It is of note that MyPathway® showed limitations to support two key requirements of the CONNECARE project: (i) the ACM concept; and, (ii) It does not show potential to support collaborative work, in a flexible manner, involving multiple players: patient/carer and several professionals. Consequently, the results of the testing led to the decision not to consider the digital tool as an option for perioperative care.

Adapted CONNECARE SMS – An adapted CONNECARE SMS, including the interface, consists of an adaptation to the requirements of the multimodal pre-habilitation service currently deployed at HCB. The

[6] Helen Lloyd, Ben Fosh, Ben Whalley, Richard Byng, James Close, Validation of the person-centred coordinated care experience questionnaire (P3CEQ), *International Journal for Quality in Health Care*. 2018; 1-7.
[7] Aaron Bangor,Philip T. Kortum &James T. Miller. An Empirical Evaluation of the System Usability Scale. International Journal of Human-Computer Interacion. 2008; 24 (6): 574-594.
[8] Reichheld FF. The One Number You Need to Grow. Harv Bus Rev. 2003; 81(12): 46–54, 124.
[9] Uijen AA, Schellevis FG, van den Bosch WJ, Mokkink HG, van Weel C, Schers HJ. Nijmegen continuity questionnaire: development and testing of a questionnaire that measures continuity of care. J Clin Epidemiol. 2011; 64(12): 1391-9

system has been developed by EURECAT with close and continuous iterations with the prehabilitation team at HCB-IDIBAPS. An operational version of the adapted CONNECARE SMS was not mature enough to be applied in the clinical arena until mid-October 2019. For this reason, the initial protocol design described in the preliminary version of D6.3 was changed for the current protocol reported in ***APPENDIX I - 1.3*** In parallel, we currently are progressing towards its integration with the health information system at HCB, as part of the setting developed in the prehabilitation unit,

Health-Circuit - Barcelona is currently exploring the adaptation of a new digital tool, HEALTH-CIRCUIT covering collaborative work among multiple stakeholders with an ACM approach. The tool shows further potential to assist case management through complex care paths and generate decision support using intelligent bots. In this regard, HEALTH-CIRCUIT is conceived as a digital tool complementary to xCare (the EURECAT backend based on microservices that is the core of the CONNECARE SMS). We believe that its potential to foster large scale deployment of prehabilitation must be taken into account, but it will not be tested within the context of perioperative care. Further information on testing of HEALTH-CIRCUIT in Case Study 1 (primary care setting) can be found in D6.2 “Results from Case Study 1” – ANNEX V. Moreover, a deeper analysis on the potential of Health-Circuit as enabler of collaborative work with intelligent support is available in D6.4 “Results from Case Study 2”.

3.1.3 Organizational Experience and Challenges

The process of consolidation of the Prehabilitation Unit at HCB during the period spring 2016 to December 2018 has been key to the identification of barriers and facilitators for large-scale deployment of perioperative services. The degree of satisfaction of the patients with the service has been always very high such that, both patients’ and health professionals’ engagement has never been a barrier for deployment. It is of note, however, that a certain degree of management change is needed in order to define roles and coordination of the multidisciplinary team involved in these services. Core professional stakeholders are: anaesthesiologists, nurse, physiotherapists, nutritionists, and psychologists. Regarding the technological tools and their integration into the health information system, it is not a major obstacle if they are properly designed and implemented.

The current major constraint in the Barcelona perioperative care program is the lack of capacity of the team to include potential candidates. The current estimation of high risk candidates for major surgery at HCB is approximately 1200 patients/year and the current setting can include a maximum of 250 patients per year. Consequently, the major challenge that HCB is facing is the strategy for scalability of the service which seems to be closely related to two phenomena: (i) transfer of part of the service to the community; and, (ii) use of simple digital tools that fully support collaborative work between patients, the hospital team and community-based services; that is, health and sport clubs, primary care, etc. Accordingly, central activities of the Barcelona team are to redefine service workflows to achieve modularization and personalization of the service while consolidating the technological setting combining tools like xCare and Health-Circuit.

3.2 Lleida

3.2.1 Site Adaption of the Concept

The integrated care efforts in Lleida's health region during the last years have focused on the empowerment of primary care professionals for the appropriate management of chronic patients. To enable this, several programs fostering the transfer of knowledge from the specialists located in the University Hospitals Arnau de Vilanova and Santa Maria, both located in the city of Lleida, and the network of Primary Care centres spread across a large rural area (over 4300 km^2), have been established. However, while transferring the know-how of specialists to primary care professionals has been very successful, the whole setting had several flaws that CONNECARE was meant to address. First, the electronic medical records in the Hospitals and Primary Care centres are based in two different systems (Argos SAP and eCAP, respectively), which severely limits the transfer of information (up to date it is only possible to look at data from one system to the other but there is not a bidirectional transfer of information among them). Second, the professionals treating a given patient determined the patient's treatment plan at an individual level, without consulting with professionals in the other settings of the healthcare system. Finally, the patient empowerment was very low, as patients acted on a mostly passive way throughout the whole care path.

The implementation of CONNECARE in Lleida required, first of all, the deployment of a supporting digital platform common to all settings of the healthcare system. The platform needed to be the hub where all the professionals from different settings involved in the management of a given patient could exchange information, agree on the best management plan for each patient, and take specific actions in terms of treatment, monitoring, and reactions when needed. This implied the need for engaging a broad range of professionals and providing them with a fully functional access to the CONNECARE platform. Moreover, this required the emergence of new roles in the organization of the involved services. The already existing hospital case managers (that used to track a small proportion of patients), needed to be reinforced with a CONNECARE-specific case-manager that took the role of both introducing the patient to the CONNECARE platform, and supervising the monitoring of the patients done by the involved health professionals. Moreover, services such as the surgical units, that had long been working with almost no support or contact from/with the primary care before, during and after a given surgery had to rethink their relationship with other actors in the healthcare. This opened the door to patient's pre-habilitation before surgery, and offered valuable monitoring options for the post-surgery management of patients.

The pilot for Implementation Study 2 in the Health care region of Lleida, Catalonia, Spain, focused on home-dwelling patients 55+ with chronic conditions undergoing a major elective hip or knee arthroplasty surgery. Patients were recruited in the University Hospital of Santa Maria, Lleida, at the time of surgery schedule and were monitored before and after the intervention. Some of these patients, due to their

chronic conditions and the characteristics of the planned surgical interventions, may require a pre-habilitation for the surgery supervised by Primary care professionals. Additionally, all of the patients require a continuum of care between the hospital and the primary care centres, hence the focus of the pilot was on providing integrated care, monitoring and follow up post-surgical intervention for 3 months, and pre-surgical intervention for 1 month when required for an adequate pre-habilitation of the patient that needed it. The case management model supported by the CONNECARE digital platform comprised a mobile app (SMS) and a case management platform (SACM). The main goal of Implementation Study 2 in Lleida was thus to effectively coordinate the peri-surgical and post-surgical care between the University Hospital Santa Maria (in the city of Lleida) and the network of 23 Primary Care centres in charge of the day-to-day management of patients (spread through the whole extension of the health care region), while enabling an active role for patients and/or carers in the preparation and recovery from surgery. Case study 2 assessed: (i) the effectiveness of joint/integrated discharge planning of hospitalized complex patients; (ii) the effectiveness of integrated transitional care in the community post-discharge; and, (iii) the added value of a self-management system app.

The implementation of the CONNECARE platform was adapted to the specific conditions in the Health care region of Lleida:

1. The CONNECARE digital platform (SACM & SMS) was translated into Catalan and Spanish, that are the co-official languages in the territory.

2. The Electronic Medical Records (EMR) systems of the hospitals and primary care centres are not homogeneous. This posed a challenge for the integration of the SACM, as two different integrations needed to be tackled and, therefore, only partial integrations were feasible.

3.2.2 Pilot Description, Inclusion Criteria and Study Design

The aim of Implementation Study 2 was to reduce undesirable post-surgical events and foster an optimal post-surgery rehabilitation by using a digitally supported integrated patient-centred preventive intervention before (if needed), during and after surgery. The target group was high-risk patients undergoing a major elective hip or knee arthroplasty surgery.

The design corresponded to a pragmatic, prospective, implementation study with parallel groups. The intervention group was compared with a control group. Control patients were selected from the same pool of subjects undergoing a major elective hip or knee arthroplasty surgery and had similar characteristics.

The eligibility criteria were:

- Scheduled elective hip or knee arthroplasty surgery in the University Hospital of Santa Maria.
- Being assigned to a Primary care centre of the region of Lleida.
- Age 55 +.
- Living at home (not in a nursing home) and being discharged back to the community.
- Understanding either Catalan or Spanish.

- No Dementia/cognitive impairment (GDS < 5).
- Charlson ≥ 3 or having at least one chronic disease as comorbidity.
- Complex pharmacological treatment (≥ 4 pills/day).
- Adjusted Morbidity Group (GMA) ≥ 3.
- American Society of Anesthesiologists (ASA) = II or III.
- Successfully passing a basic technological competence test.

Main study variables included:

1. The actual use of the ICT tools by patients throughout the period of the study.
2. Patient satisfaction with the integrated care service as well as the digital tools using the following assessment tools: (i) Person-centred coordinated care experience questionnaire; (ii) System usability scale; (iii) Overall satisfaction and net promoter score; and, (iv) Nijmegen continuity of care questionnaire.
3. Staff assessment of the Integrated Care Service and the digital tools using the following assessment tools: System usability scale; and, overall satisfaction and net promoter score.
4. Patient Outcomes including:
    - Improvement in patient's Health-related quality of life as measured by comparing patient status at baseline and after the 3-month intervention using the SF-12 questionnaire.
    - Service utilization and costs including hospital services (emergency room visits, hospitalizations, other hospital services) and visits to primary care during the intervention period.
    - Cost benefit by addressing the improvement in Health-related quality of life relative to the costs dimension.

3.2.3 Recruitment Process and Participants

The patient recruitment period for the project in Lleida was July 2018 – July 2019. Potential participants were identified by either the surgical team of the University Hospital of Santa Maria. Potential candidates were approached by a case manager that conducted the recruitment process and introduced the patient to the CONNECARE platform (intervention group only). All patients received a face-to-face explanation about the study, its purpose, its benefits and what they would actually receive. Similarly, after the recruitment of each CONNECARE program patient, an active search for a matched control with the required characteristics began, although patients in the conventional management arm were not required to pass the basic technological competence test. The patient's recruitment process included: (i) signature of the patient on the Consent Form, after reading and receiving an explanation of the main points; (ii) preliminary assessment of the patient's health status using several questionnaires, tests, and indexes; (iii) installing the applications and providing guidance on the day-to-day use of the applications; (iv) generating the profile of the patient in the SACM platform, and introducing the information of all the

involved medical personnel (Hospital, Primary care and social care); and, (v) providing all the required contact information.

When necessary, the surgical team elaborated a personalized pre-habilitation plan to be agreed by the primary care personnel in charge of the day-to-day care of the patient (CONNECARE arm only). After discharge, patients in the control group followed standard management in primary care including rehabilitation, physical evaluation and pain control, while patients on the intervention group embraced the CONNECARE program benefitting of a SMS app during 90 days post discharge and a rehabilitation, physical evaluation and pain control plan coordinated by the surgical team and the primary care professionals. All patients regardless of study arm had a 3-months passive follow-up after the initial 90 days standard/CONNECARE management.

3.2.4 Pilot Experience – Progression and Changes over Time

3.2.4.1 *A brief description of the intervention*

After the initial patient assessment at the time of scheduling the surgical procedure a personalized pre-habilitation plan could be implemented, when necessary, in order to enhance the physical status of the patients so they could face the intervention in an optimal status. The plan was monitored entirely from Primary care and consisted of nutritional and/or physical activity actions to be performed by patients at home. The SMS was not used during the pre-habilitation in the community.

After the surgery but before hospital discharge, the hospital team (surgeons, anaesthetists and physiotherapists) and Primary care professionals involved in a given patient's management, agreed upon an initial rehabilitation plan. During the first month after the surgery, the hospital team was in direct charge of supervising the patient's progression and modifying the rehabilitation plan if needed while during the second and third months of the follow-up the primary care professionals took the lead on the supervision of the patient, ensuring a satisfactory continuity of care. The rehabilitation plan not only included the close monitoring of post-surgery recovery (pain control and wound healing) but also the prescription of any required drugs and specific physical rehabilitation tasks and goals. During the 3 months of follow-up, health professionals monitored each patient's automatically and manually generated data from the SMS and Fitbit apps at least weekly using the SACM system, although the first days after hospital discharge required the most effort in terms of monitoring. Based on the information flowing from the SMS to the SACM, health professionals could provide feedback or additional instructions to the patients. This resulted in the adaptation of the rehabilitation plan according to the development of the proposed strategies, thus the tasks and goals could be modified through the follow-up period to respond to changes in the patient's situation. The frequency of any required virtual or in situ interventions was determined by the patient's health status and feedback. The case manager was the primary contact point for any technical issues encountered during the whole process by either patients or professionals.

3.2.4.2 *Main reasons for failure to recruit and for patient drop-out*

The main reasons of failure to recruit were:

- The patient was discharged to a nursing home.
- The patient or the family were not interested in participating because they anticipated difficulties in compliance with the process of monitoring clinical variables.
- The patient had an outdated smartphone in which it was not possible to install the SMS system.
- The patient had an IOS smartphone at the time that the SMS did not support IOS.
- The patients and/or caregivers used a smartphone exclusively for phone calls and messages and they were not keen on learning how to use Apps (SMS).
- The patient didn´t want to overwhelm the caregiver with additional work, especially when this role is held by a family member.

The main reasons for patient drop-out were:

- The caregiver or the patient was not willing to comply with the program, regardless of being appropriately informed during the recruitment.
- The patient reconsidered the decision of participating few days after hospital discharge.
- The patient has the feeling that he is fully recovered before the end of scheduled follow-up period and he thinks that he does not need any additional support or monitoring in the CONNECARE program.
- The patient cancelled the scheduled surgery because of a reconsideration of the potential risks and benefits of the surgery.

3.2.4.3 *Difficulties, problems and barriers encountered*

During the recruitment of patients, some difficulties were found by the case managers and involved medical personnel. However, most of those problems and barriers were successfully resolved through the duration of the study, for example:

a. Difficulties with patients/ families/ caregivers and their smartphones:

- Because initially it seemed very difficult to find patients aged over 65 years with adequate compliance with the use of technology, the limit age to recruit patients was lowered to 55 years or more.
- The case managers, who recruited most of the patients, had problems communicating with the family members that most often carried out the role of caregivers. Specifically, during the morning when doctors visit their patients in their rooms, family members were not available due to job-related obligations. Therefore, case managers had to arrange meetings with these families during the afternoon, thus adapting to their time schedule.
- The process of installation of SMS and linking monitoring devices took more time than expected because of frequent technical issues (30-40 minutes). To avoid this issue, SMS

installation was carried out by a trained case manager with the remote assistance from EURECAT technicians when needed.

- In order to overcome the technological limitations of some patients' smartphones (old versions of Android/IOS and/or smartphone brands with UI personalization layers that interfered with the satisfactory installation and use of the SMS) tablets were supplied to the patients to connect though the Wi-Fi they had already available in their own homes.
- The case manager sometimes had to visit the home of the patient because there was a problem with some devices (e.g., connection of a device to the SMS of a given patient) or she had to solve doubts about the use of the SMS in site.

b. Difficulties with other professionals involved:

The high number of professionals participating in the recruitment and control of patients through the CONNECARE system (in hospital and in primary care), generated the expected occasional technical or usability issues because of lack of training. However, the case manager that was integrated in the hospital team provided any requested support. Such support can be described as follows:

- Training professionals in the use of the SACM and explaining them in which phases of the process they had to participate.
- Providing information on how to carry out any given phase of the CONNECARE process (case identification, case evaluation, work-plan definition/monitoring and discharge).
- Confirming that a response is given to any alert or key message received by the health care team of a given patient.
- Supervising that the discharge summary is performed by the corresponding professional.
- Locating the patient in case of an unexpected hospital re-admission during the follow-up period.
- Helping to solve problems of connectivity of the SACM between hospital professionals and primary care professionals.

c. Difficulties with the space available in the external office:

The recruitment of the patients of use case 2 was carried out in the anaesthesiologist office, several weeks before the patient was admitted to the hospital to carry out the surgical procedure. Therefore, an additional office next to the anaesthesiologist office was necessary for the case manager so she could explain to patients and caregivers all about the CONNECARE study and the SMS system. This office was also necessary for the recording of all the required clinical information without disturbing the timetable of visits to the anaesthesiologist.

d. Difficulties with the performance of the SACM and SMS.

Because of unexpected technological issues, sometimes SMS and/or SACM were shut down or the information on the systems was only partially available or delayed (server fall, dysfunctions, bugs). These problems, although usual and expectable when a new system is created and

implemented, are often unforeseen and have an undetermined duration. Therefore, it was crucial to try to avoid any inconvenience to the professionals, patients, and caregivers operating with the system. Therefore, a parallel communication system (instant group messaging) for technical issues was created to ease communication in real time between the case managers, key professionals and key engineers working in the maintenance of the system (EURECAT). The aim was to enable quick and reliable communication channels to exchange information between clinicians and engineers about any problem and all the solving process that is being carried out. Finally, special attention was given immediately after system upgrades, as it corresponded to well-known potentially critical periods.

3.3 Israel

3.3.1 Site Adaption of the Concept

Despite a technologically advanced health care system, with organization wide central electronic medical records, both at the Community healthcare level (primary and secondary care) and in the hospitals, a major challenge for the Israeli healthcare system has been integration and continuity of care between the hospital and the community. While this is partially due to system and cultural barriers, challenges in information sharing have contributed to this. Hospitals and Community healthcare services use two different Electronic Medical Records systems and the National EHR exchange enables each side to view selected data from the other side but not to transfer it. The Israel Ministry of Health published draft regulations in 2015 on Continuity of Care to address this challenge. The draft regulations include the following requirements for both hospitals and Health Plans (responsible for operating community healthcare services and contracting with hospitals): transfer of medical information between the hospitals and the health plans, reducing hospital readmissions, appointing people responsible for liaison between community services and hospitals, appointment of positions/units responsible for continuity of care in both hospitals and Health Plans and joint discharge planning. Within this context, Assuta Ashdod Hospital, the newest public general hospital (the first to be built in 40 years) which opened in 2017 had as its vision and mission the actualization of integrated care for its region and together with Maccabi Healthcare Services, the second largest Health Plan, put a number of organizational components in place to implement this vision. These included: appointment of one of the deputy hospital directors as responsible for integrated care; setting up a Maccabi Integration Unit on the hospital premises, responsible for transitional care in the community for all patients discharged from the hospital; appointing a joint task force to address the identification and development of necessary interfaces between the EMRs of the two organizations; setting up a joint task force together with the Municipality's social services department to develop and implement processes for continuity of care not only between hospital and community healthcare services but social services as well. CONNECARE was an integral part of the plans of both the hospital and the Health Plan for the implementation of integrated care, which

is being followed very closely by the Ministry of Health and thus CONNECARE will contribute to the implementation of integrated/continuity of care at a national level.

Two new programs were put into place in Ashdod as a part of the CONNECARE project:

1. A digitally supported Pre-habilitation program for chronically ill older adults scheduled for major elective surgery in Assuta Ashdod Hospital that included a supervised and non-supervised physical activity program operated by the Hospital Physical therapy department that was approved by the surgical department heads. This program also included a nursing evaluation, emotional and psychological support for the patient and nutritional advice where necessary.
2. A digitally supported nurse case management program within the Maccabi Integration Unit to provide close monitoring and follow up for 3 months for elderly chronically ill patients discharged home after surgery.

Thus, Implementation Study 2 in Assuta Ashdod Hospital focused on Maccabi home dwelling patients 55+ with chronic conditions scheduled for an elective major surgery. These patients, due to their chronic conditions, required multiple services in the community pre and post-discharge, and could benefit from a pre-habilitation emotional and physical strengthening program. Pre-habilitation and monitoring was provided for 1-2 months prior to surgery. Post- discharge monitoring and follow up was provided for 3 months post-discharge. A case management model was used, supported by the CONNECARE digital platform comprised of a wearable (Fitbit watch), a mobile app (SMS) and a case management platform (SACM).

The coordination of the pre-surgical care was the responsibility of Assuta's Nurse Case Managers together with the physical therapy team of the hospital. The coordination of post-discharge care was the responsibility of Nurse Case Managers in the Maccabi Integrated Care Unit that is physically located in the Assuta Ashdod Hospital who coordinated with hospital medical and nursing staff and the patient's primary care doctor.

The aim of the deployment of implementation study 2 in Israel was to demonstrate the effectiveness of digitally supported integrated care for decision makers in order to facilitate its large-scale adoption across the healthcare system. Therefore, Implementation Study 2 in Israel addressed the following questions:

1. Does integrated care, as defined in the CONNECARE model (pre-habiltation plus case management) improve post-surgical outcomes including more effective post-surgery recovery as indicated by shorter length of stay, improved physical activity, improved feelings of overall health, reduced emergency room visits, and reduced readmissions to the hospital?
2. Are older adults willing and able to use digital technology (Fitbit watch and CONNECARE SMS app) as a part of the pre-habiitation preparation for surgery and as part of their recovery process post-discharge?

3. Does the close monitoring of the patient in both the pre surgery and post-surgery phases, supported by the CONNECARE digital technology, improve patient adherence to treatment plans?

The implementation of the CONNECARE platform was adapted to the specific conditions in Assuta Ashdod and Maccabi:

1. Due to the high proportion of Russian speaking elderly people within the Maccabi population, the CONNECARE app was translated into Russian as well as Hebrew.
2. The Israeli healthcare system is a National Health Insurance System with four autonomous Health Plans (of which Maccabi is the second largest) that have a contractual relationship with hospitals and each Health Plan as well as each hospital has its own Electronic Medical Record System. This posed a challenge to integration of the SACM (the case management platform) with these systems which led to two major implementation decisions:
    a. To use the SACM as a standalone system, not directly integrated with either EMR.
    b. To limit the direct use of the SACM to the physical therapy team in the hospital in addition to the Assuta and Maccabi Nurse Case managers who were responsible for integrating the relevant information between both EMR systems and the SACM.

Coordination with hospital staff on one hand and Maccabi primary care and community healthcare services on the other hand was carried out through the two EMR systems. Thus, communication between the Nurse Case Manager and the primary care physician was mediated by the Maccabi EMR, supplemented by telephone when needed.

3.3.2 Pilot Description, Inclusion Criteria and Study Design

The aim of Implementation Study 2 was to reduce undesirable post-surgical events and enhance health outcomes (i.e., length of hospital stay, re-admission rate) by a digitally supported and integrated patient-centred preventive intervention before, during and after surgery. The target group was high-risk patients undergoing an elective major surgical procedure.

All patients scheduled for elective major surgery who met the following conditions were potentially eligible for the study:

- Age 55 +
- Living at home and not in a nursing home
- Maccabi insured member
- At least one chronic diagnosis
- No Dementia/cognitive impairment
- Capable of using mobile apps
- Scheduled for orthopaedic/urology/gynaecology/general major elective surgery
- Surgery scheduled in 3-6 weeks from time of recruitment

The study design is an observational matched control group study. The intervention group (pre-habilitation + post-discharge care) was compared with a matched control group (regular care in another hospital). Comparability among intervention and control groups was addressed using a three-step propensity score matching (PSM) approach for each patient in the intervention group, 2-3 “matching” patients were identified from the Maccabi's database, using a three step matching approach. In the first step, matching between the two groups used the following variables: sex, age group (groups of 5 years), type of hospitalization and procedure code, date of hospitalization (same month, or a month before or after). In the second step, additional matching was done between the patients in the two groups based on inclusion in the same disease registries (Cardio, Diabetes, Blood pressure, Cancer, Kidney). In the third step, additional matching was done between the patients in the two groups based on total medical costs in the year prior to hospitalization (sum of 12 months) divided into 3 groups of deciles.

Main study variables and assessment tools are:

1. Patient Experience as measured by the Person-centred coordinated care experience questionnaire and the Niejmegen continuity questionnaire.
2. Staff experience as measured by ACT@Scale for staff engagement
3. Patient Engagement, use of the Digital Tools and satisfaction with the Technology including measures of actual Use of the digital tools (Fitbit and SMS app) by the patients and their satisfaction with the Technology as measured by overall satisfaction and Net Promoter Score(NPS) and the System usability scale (SUS)
4. Staff satisfaction with the technology as measured by overall satisfaction and Net Promoter Score (NPS) and the System usability scale(SUS)
5. Intervention Effectiveness for Health and Well Being (before and after intervention group only) using the Barthel Index, the Lawton index, SF12, HADS, EQ-5D, and Sweet 16
6. Intervention Effectiveness in terms of Service Utilization and Costs by comparing the intervention group to a matched control group extracted from the Maccabi database including: emergency department visits, hospitalizations, length of hospital stay, GP visits, visits to specialists, total hospital related costs, overall costs
7. Cost Benefit at two levels:

   Level 1 - By estimating the projected costs for the implementation as a routine service (based on the implementation costs for the CONNECARE project) and adding this to overall healthcare expenses for the intervention group and comparing this with the overall healthcare expenses of the control group.

   Level 2 – By assessing the benefits in health and well- being against the costs.

3.3.3 Recruitment Process and Participants

The patient recruitment period for the project in Israel was July 2018 – June 2019. During this period, Assuta's Nurse case manager (NCM) received a weekly list of patients scheduled for elective major surgery from the secretaries of orthopaedic, urology, gynaecology and general surgery departments. In order to decide whether the patient was appropriate for the study according to inclusion criteria, Assuta's NCM checked for details on each patient in the hospital's EMR. Assuta's NCM called each potential patient by phone, and explained the study, its purpose, benefits and what they would actually receive. Patients who were not available, or asked for time to think and consult with their family physician, were called again.

During the phone call with patients who agreed to participate in the study, Assuta's NCM scheduled a two hour recruitment appointment in the hospital at a time that was suitable and convenient for the patient, the NCM and one of the hospital's physical therapists.

The patient recruitment process included: (1) signature of the patient on the Consent Form; (2) preliminary assessment of the patient's health status using the assessment questionnaires, tests and indexes; (3) installing the digital applications and providing guidance on the day-to-day use of the applications; (4) preliminary physical activity assessment by the physical therapist; (5) providing a list of ways to contact the nurse and the physical therapist in case of need; and (6) building the initial pre-habilitation plan for the patient.

3.3.3.1 *Main reasons for failure to recruit and for patient drop-out*

Some of the main reasons for failure to recruit were:

- The patient lived too far from the hospital and was unwilling to come to the hospital for the recruitment and assessment process as well as the pre-habilitation sessions in physical therapy
- The patient did not speak Hebrew, Russian or English
- It was difficult to communicate with very old patients during the initial phone call
- The patient was scheduled for a long flight or family trip about a month after surgery
- The patient was not interested in participating in the study. Sometimes patients explained why they were not interested, for example:
    - The patient felt that he had no need for pre-habilitation and close monitoring and therefore would not benefit from participating in the program
    - The patient was emotionally burdened by the anticipated surgery
    - Patients who worked full-time did not have the time and were not interested in additional visits to the hospital prior to surgery or follow-up post-discharge

It should be noted that pre-habilitation was a new service in a new hospital that was not a part of regular service and was therefore not a familiar service to the patients or the surgeons, even though the surgeons viewed the idea of pre-habiltation very positively and approved the therapeutic protocols. However, it was not a part of the routine care pathway.

Some of the main reasons for patient drop-out were:

- Some patients did not comply with the program and lost interest in participating
- Discomfort with the Fitbit watch
- Postponement of the surgery

3.3.3.2 *Difficulties, problems and barriers encountered during recruitment*

During the recruitment of patients, Assuta's and Maccabi's NCMs encountered some difficulties. Problems and barriers in the process were treated and resolved during the duration of the study, for example:

- Assuta's NCM needed the help of the secretaries of the surgical departments to locate potential patients and this was not always forthcoming. During the project, a number of personal conversations by the project management team, in collaboration with department heads were held, resulting in improved cooperation.
- There was a need for real time collaboration between the Assuta's NCM and the hospital physical therapists in order to schedule patient recruitment sessions. To this end, a joint WhatsApp group was established which was very active throughout the study.

The recruitment process took much longer than expected, between 40 minutes to an hour, mainly because of the amount of time it took to go over the consent form together and to download, install and connect the two applications (Fitbit and SMS). In order to shorten and streamline the process, some of the questionnaires in the evaluation process were printed on paper and given to the patient to fill out alone (if the patient's condition permitted), so that the nurse could take care of the other stages of the process.

3.3.4 Pilot experience – A Brief Description of the Intervention

During the pre-habilitation period, the patient was scheduled for a weekly therapy session with the physiotherapist in the hospital, which included exercise on a stationary bicycle, a treadmill and reinforcement exercises according to the needs and abilities of the patient. In addition, the physiotherapist and Assuta's NCM created a treatment plan for the patient together, which included, among other things, a physical activity regimen at home. Assuta's NCM and the physical therapist monitored each patient, at least weekly, until the surgery, using the SACM system, where they could view all the automatically and manually generated data from the patient's SMS and Fitbit apps and respond with feedback or additional instructions. During the preoperative period, they could also add, delete, and change the treatment plan, as needed.

During the hospitalization for the surgery, Assuta's NCM and the physical therapist visited the patient and transferred the continuing responsibility to the Maccabi NCMs. Maccabi's NCMs created an updated treatment plan for the patient, in accordance with the medical and nursing discharge summaries from the hospital, the patient's data in the EMR, and the patient's needs. They also informed the patient's

family physician about his / her patient's involvement in the project, and asked for any specific tasks or goals that the family physician might want to add for the post-discharge recovery period.
Maccabi NCMs monitored each patient, at least weekly, for three months after the surgery, using the SACM system. Depending on patient's need and compliance with the treatment program, the nurse increased the frequency of her interventions, including phone calls and home visits. Maccabi NCMs also assisted the patient with any problems or bureaucratic hurdles in the hospital and/or Maccabi, and, when necessary referred the patient's requests to the administrative secretary for individual assistance with scheduling appointments.
Professionals' engagement in the CONNECARE program in Israel, was somewhat lacking. Other than Assuta's and Maccabi's NCMs and the hospital's physiotherapy staff, other medical or social professionals were not sufficiently involved, and treated the patient in the traditional way without significant integration that could have been created under this project. In part, the low level involvement of hospital personnel was due to the fact that the hospital was new, recently opened, and hospital staff was preoccupied with putting basic processes in place for the care of all patients. In some cases, the family physician and/or the surgeon, were aware of the patient's participation in the study, but even then did not participate in planning a personal treatment plan unless approached by the NCM with a specific question. Partial but significant integration between the hospital and the community for the benefit of the study patients was created in the field of pelvic floor physical therapy.

3.4 Groningen

3.4.1 Site Adaption of the Concept

The ambition of the University Medical Center Groningen (UMCG) as an academic and tertiary hospital in the Netherlands is to provide the right care, for the right patient, at the right time. This means that acute and complex care is centralized in the region between the hospitals, and chronic care patients are managed largely outside the walls of the hospital. With the ageing population and limited capacity in hospitals regarding medical staff and costs, there is an increasing necessity to relocate care on hospital premises to ambulant assistance at home. In order to provide such a supportive role, supplementation and innovation of care pathways by using digital tools and wearables embedded in a broad e-Health system is of vital importance. The IT systems and Electronic Medical Record (EMR) of the UMCG have recently been updated and modernized. This obviously is essential and provides conditions and opportunities for further development. In the near future, communication with integrated Personal Health Records (PHR) will become a reality, and thus a prospect of extremely rich and complex data emerges. This will foster collaborating with experts in artificial intelligence and big data and allow further personalization and tailoring of prevention and treatment. Existing research infrastructures such as Lifelines (biobank collecting data on a large-scale cohort study) and EPIC (Electronic Medical Record) may be used to expand and enrich e-Health systems and support the scaling up of activities in the

region. A central theme in the activities outlined may be support of a broad implementation of the PHR in the UMCG, as a digital system owned and managed by citizens. This PHR will comprise all relevant information on health, well-being and care utilization. In line with this ambition is the development and implementation of CONNECARE, providing a platform for the UMCG to develop and test an ICT management system and a self-management system (application; SMS) with integrated ambulant equipment (wearables) for patients. This also entails developing a smart adaptive care management system (SACM) for professionals to interact and manage patient health.

With this integrated care platform, we had the opportunity to improve perioperative care within the department of surgical oncology. Due to a general reduction in the duration of hospital stay following surgery, and limited monitoring of patients in the post-discharge phase this population is at risk of developing postoperative complications at home, which might result in unplanned readmission in the hospital. The focus of the pilot- and clinical implementation study therefore was to improve integrated care by offering remote monitoring of patients in the home setting, using the CONNECARE system and connected devices. This is intended to eventually lead to earlier detection of complications post-discharge and possibly avoid unnecessary medical consumption and hospital readmissions, which improve quality of the postoperative care after hospital discharge and improve postoperative outcome in the elderly patients. The aim of implementation study 2 in Groningen was to co-design, develop, and evaluate a novel smart, adaptive self-support integrated care system for case management of the elderly oncological patients in the postoperative period. To this end, the following questions were formulated:

- Is a novel ICT-supported integrated care management system with a mobile application and additional smart-devices for remote home monitoring in elderly cancer patients feasible?
- Under which conditions are elderly patients able and willing to use the CONNECARE IT system and connected devices?
- Does the implementation of the CONNECARE system lead to a reduction of unplanned readmission and complications in the post-operative period?
- Which parameters can be identified that predict unplanned readmission and complications?

At this moment in the UMCG, as in most European countries, postoperative monitoring is based on the need for extra care following hospital discharge. In case additional care is required, this is arranged via homecare services or by referral of the patient to a nursing home/rehabilitation centre. The patient can contact the hospital in case questions arise in the first days after hospital discharge. In addition, a follow-up consult with the surgeon is scheduled a couple of weeks following surgery. Within the current organisational model of care delivery, the general practitioner is responsible for the patient in the home setting and is the first point of contact for medical needs. In case of acute emergencies, the 911 emergency medical services can be contacted.

The CONNECARE systems, the SMS and the SACM, were introduced as stand-alone units' part of an observational study running parallel to care-as-usual clinical pathways. The coordination of the study was the responsibility of the case manager (research physician) in the hospital.

3.4.2 Pilot Description and Inclusion Criteria

The CONNECARE organisational model was introduced as an observational study with gradual implementation of the IT systems and connected devices for remote home monitoring of elderly patients after hospital discharge following oncological surgery. Patients aged over 65 years old were included from the outpatient clinic of the department of surgical oncology in the UMCG and received followed-up until 90 days (3 months) after discharge from the hospital.

Inclusion criteria were:

- Patients over 65 years of age scheduled for elective oncological surgery of a solid tumour at the Department of Surgery of the University Medical Centre Groningen
- Participants should have internet access at home
- Comprehension of the Dutch language (reading and writing)
- Willing to sign informed consent and answered the questionnaire's that are provided

Exclusion criteria were:

- Emergency surgical intervention
- Severe visual, hearing or cognitive impairment

Study variables included:

1. The actual use of the ICT tools by patients throughout the period of the study.
2. Patient satisfaction with the integrated care service as well as the digital tools using the following assessment tools: (i) Person-centred coordinated care experience questionnaire; (ii) System usability scale; (iii) Overall satisfaction and net promoter score; and, (iv) Nijmegen continuity of care questionnaire.
3. Patient outcomes including:
    - Results on clinical outcome including length of hospital stay, postoperative complications, time to detection of complications, health-related quality of life as measured by comparing patient status at baseline and after the 3-month intervention using the EQ-5D-5L questionnaire.
    - Clinical effects on physical performance (ADL, iADL, TUG, SQUASH), frailty (GFI), nutrition (MNS-SF) and mental status (HADS).
    - Service utilization of hospital services (emergency room visits, hospitalizations, other hospital services).

3.4.3 Recruitment Process and Participants

Patients were informed about the study either by telephone or a face-to-face meeting at the outpatient clinic at the department of surgical oncology, in the UMCG. Following study inclusion, a baseline assessment was carried out 1-4 week(s) prior to surgery at home or during a visit in the outpatient clinic. The case manager (research physician) provided detailed instruction on how to use the CONNECARE

system and applications, including the connected devices. A physical activity tracker (Fitbit) was used by the patients pre-operatively to determine baseline step count, continuing postoperatively at the surgical ward and at home until 3 months after surgery. During surgery or/and during postoperative stay on the Intensive Care Unit (ICU) the patients did not wear the activity tracker. Before hospital discharge, a subset of patients received additional smart-devices (thermometer, blood pressure monitor, and weight scale) with instructions on how to check their vital signs with the smart-devices during the first 14 days after hospital discharge. If the patient noticed any deviation in their recovery, he/she was instructed to contact the surgical nurse or their general practitioner. Using the SACM, the case manager tracked the postoperative recovery of the patients. In case no data was received or in case alarming parameters were observed (step count < 1000 [when average of steps is normally > 1000 steps], temperature < 36ºC or > 38ºC, blood pressure < 100/60mmHg or > 150/100mmHg, heart frequency < 50/min or > 100/min, weight < / > 5% of weight at hospital discharge), the patient was contacted by telephone for additional information. The treating physician could be contacted to discuss further actions and the monitoring with the smart-devices would be extended for 14 days. The case study began in early May 2018 and was completed at the end of October 2019.

3.4.4 Pilot Experience – Progression and Changes over Time

Patients eligible for inclusion were asked to participate, and after obtained informed consent they were enrolled in the clinical study. The ICT-system for remote home monitoring consisted of an application for patients' use (the SMS) and a professional interface for the case manager (e.g. health care professional or research physician) with the ability to test and further develop the system during implementation (the SACM). The first participating patients used an application on their mobile phone or tablet in combination with an activity tracker (Fitbit Charge 2). In a stepwise manner, new versions of the applications became available and other smart devices could be implemented in the study. These included: a smart-thermometer (Thermo by Nokia/Withings), wireless blood pressure monitor (BPM by Nokia/Withings) and weight scale (Body+ by Nokia/Withings). The patient application imported measurements from the corresponding commercial applications and provided daily insight into the progress of recovery for the patients and for the case manager in the SACM. Furthermore, patient instructions were improved prior to implementation by already providing detailed instructions to patients prior to surgery, to optimise retention of information and prepare them to self-manage and how use the CONNECARE ICT system and connected devices.

3.4.4.1 *Difficulties, problems and barriers encountered*

During all stages of development, recruitment and implementation of the CONNECARE system, barriers were encountered by either the patients/carers, care professionals, case managers, students and IT personnel. The main challenges are listed below:

- At the start of the project, a research protocol was written for the proposed clinical study. However, the functionalities of the end-product were still unknown.
- Also, in terms of the project aims, due to the highly innovative character of the CONNECARE system, at the start of the project the end functionalities were still unknown.
- In terms of study planning, a delay in the start of the clinical study necessitated a re-shuffling of the available budget in order to extend the contracts of the case managers involved in the planning and execution of the study.
- In terms of system design, we could have involved the end-user (elderly cancer patients) more in the development of the lay-out and functionalities of the SMS and related wearables.
- In terms of usability, during the developing process only releases for Android were made available. All potential participants using iOS (Apple) could not be included.
- If patients were not in possession of a smartphone, inclusion was not possible. Also, problem arose regarding mobile data, due to connection problems and the data request of the new installed apps and smart devices. The patient used all mobile data (more than the patient paid for every month). This led to extra costs from the phone company for the patient. That is why we provided an Android study tablet for all patients.

In term of system functionalities, patients had to install four separate applications on their tablet in order to use the full system.

- Also, the system was fairly complex in its use, with patients needing to keep devices connected to the system and re-connect in case connections were lost.
- In terms of system integration, delays were encountered due to an “ICT-freeze” in the UMCG due to the implementation of an organization-wide new electronic patient dossier.
- In terms of privacy and usability, due to the use of commercial products in an elderly population, product users were mailed often with commercial products of the industry (from Fitbit and from Nokia/Withings). For the elderly it was hard to distinguish between relevant information for the project and spam.
- In terms of feasibility, during the study some patients encountered connectivity issues at their place of residence. Sometimes the devices disconnected and or Wi-Fi settings were wrong. This led to a loss of data as the data was no longer shared with the SACM.

3.5 Summary – All Sites

All four sites successfully deployed their implementation studies. As mentioned in the introduction and the overall concept of Implementation Study 2, there was considerable heterogeneity among the CONNECARE implementation pilots in the four sites. This was due to the contextual differences and the commitment to implement the CONNECARE organizational model and platform in real life settings with the aim of continued deployment and scaling up after the end of the project. Barcelona focused strongly on pre-habilitation for patients undergoing major elective surgery with a purposeful overlap with Implementation Study 3. As described in this deliverable, but in much greater detail in D6.4 “Results from Case Study 3”, Barcelona implemented its pre-habilitation program in several stages – the initial stage prior to CONNECARE’s implementation was a randomized control trial from 2013-2016 in a sample of complex patients undergoing major abdominal surgery. In Implementation Study 2 this was followed by two additional studies: Protocol I – to assess sustainability of aerobic capacity and physical activity in prehabiltation three and six months post discharge, and (Protocol II) to identify factors associated with program completion, and postoperative morbidity. The next stage was the implementation of mobile technology in the prehabilitation program. Two apps were tested – the MyPathway app and an adapted CONNECARE SMS app, both with an associated activity tracker. Israel and Lleida implemented an intensive post-discharge follow-up program for all patients in the intervention group. Lleida targeted patients undergoing orthopaedic surgery whereas Israel included patients undergoing elective surgery in four areas: orthopaedics, gynaecology, urology and general surgery. In Israel, the entire intervention group had pre-habilitation in the hospital, modelled on the Barcelona pre-habilitation model, whereas in Lleida, only selected patients had pre-habilitation that took place in the community. Groningen focused on the use of the CONNECARE digital tools for vital signs and physical activity monitoring, pre- and post-surgery, for patients undergoing surgery to remove a solid tumour. All sites have had challenges in recruitment, although Barcelona had fewer challenges as its implementation took place within the context of an existing service. In Lleida, Israel, and Groningen, there were challenges to recruitment that were relatively unique to the conditions in each site. Involvement of clinicians, and particularly physicians, differed from site to site, but was an important element in the success or lack of success in recruitment. While the target population for all sites was high-risk patients, this was defined somewhat differently in each of the sites. Barcelona focused on a population of patients 70 or older and/or evaluated at ASA III/IV; Lleida’s population was 55+ with an ASA level of II/III; Israel’s study population was 55+ with one or more chronic illnesses (assumed ASA II/III, since the anaesthesiology evaluation was not available at the time of recruitment) and Groningen’s population was 65+ years of age scheduled for elective oncological surgery of a solid tumour. In all cases, a basic capability for using a smartphone or tablet was required by the patient and/or his/her carer, and all of the patients were living at home. The design of the implementation in all sites was a non-randomized matched intervention-control group design.

The process in all of the sites was supported by digital technologies that included a wearable and an app in either the pre-surgical period, the post-surgical period or both. Lleida, Israel, and Groningen used the CONNECARE SMS for all intervention group patients whereas Barcelona used the OMRON pedometer in the pre-CONNECARE trial, the Fitbit in Phase 1, and Lifevit with the MyPathways App in Phase 2 and a modification of the CONNECARE SMS with LifeVit in Phase 3. The clinician's case management platform (SACM) was used in Lleida and Groningen as a standalone system with attempts at some level of integration with existing hospital IT systems whereas Israel used it completely as a standalone system. Barcelona opted for a direct integration of the mobile app with existing hospital IT systems. In all sites, there was an intervention group receiving integrated care supported by ICT and a control group for comparison in order to assess usability, user satisfaction, improved patient outcomes and cost-effectiveness.

4. Implementation Study 2 Results

The final results of the implementation studies are presented in this section including:

1. Recruitment Process results and Final Recruitment Numbers
2. Patient and Staff Assessment of the Integrated Care Service and organizational lessons learned
4. Use of the Digital Tools and Patient and Staff Satisfaction with the Digital tools
5. Intervention Effectiveness – Patients' Health and Well-being
6. Intervention Effectiveness – Resource Utilization and Costs

4.1 Barcelona

4.1.1 Protocol I – Post-discharge impact of pre-habilitation

In Protocol I, 56 patients were included in the usual care group and 54 subjects in the pre-habilitation group and they were followed-up after discharge. The original RCT on pre-hablitation[10] was powered for postoperative complications. Therefore, the variables described were planned as secondary outcome variables. Endurance time (ET) measured using a cycling constant-rate exercise testing protocol at 80% of peak oxygen uptake, was assessed at baseline, pre-surgery (end of pre-habilitation programme), and at 3 months after surgery. Physical activity by the Yale Physical Activity Survey (YPAS)[11], self-perceived health status by the Short Form Health Survey (SF-36)[12], and psychological status by the Hospital Anxiety and Depression Scale (HADS)[13] were assessed at baseline, pre-surgery (end of pre-habilitation programme), 3 and 6 months after surgery. Moreover, all-cause mortality and use of healthcare resources at 30 days, and 3 and 6 months after surgery were also registered.

Statistical analysis – Data are presented as mean (standard deviation, SD) o mean (95% confidence interval (CI) when indicated. Comparisons were done using Student's t-test or Mann-Whitney test for numerical variables depending on their distribution, and X^2 or Fisher's exact tests for categorical variables, respectively. A p-value < 0.05 was considered statistically significant.

[10] Barberan-Garcia A, Ubré M, Roca J, Lacy AM, Burgos F, Risco R, Momblán D, Balust J, Blanco I, Martínez-Pallí G. Personalised Prehabilitation in High-risk Patients Undergoing Elective Major Abdominal Surgery: A Randomized Blinded Controlled Trial. Ann Surg. 2018 Jan;267(1):50-56

[11] Donaire-Gonzalez D, Gimeno-Santos E, Serra I, Roca J, Balcells E, Rodríguez E, et al. [Validation of the Yale Physical Activity Survey in chronic obstructive pulmonary disease patients]. Arch Bronconeumol [Internet]. 2011;47(11):552–60.

[12] Alonso J, Prieto L, Anto JM. The Spanish version of the SF-36 Health Survey (the SF-36 health questionnaire): an instrument for measuring clinical results. *Med Clin (Barc)*. 1995;104:771–776.

[13] Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand*. 1983;67:361–370.

Summary results of the study on sustainability of pre-habilitation-induced effects are displayed in the two figures below, indicating changes in endurance time (aerobic capacity) and changes in daily-physical activity:

Sustainability of prehabilitation-induced effects

As displayed in Figure 1, first block of columns, pre-habilitation induced a significant enhancement of aerobic capacity, expressed by the increase in exercise endurance time. The second block of columns indicates the changes in exercise endurance time between the end of the pre-habilitation programme and 3 months after hospital discharge. As expected, aerobic capacity decreased in both groups due to the functional effects of surgery. However, the decrease was relatively higher in the intervention group than in the control group. These are expected results due to the recent acute increase of endurance time in the intervention group because of the pre-habilitation programme. However, if we analyse the aerobic capacity at 3 months after discharge expressed as changes against baseline (before pre-habilitation), we observe that the intervention group shows significant preservation of training-induced enhancement of aerobic capacity.

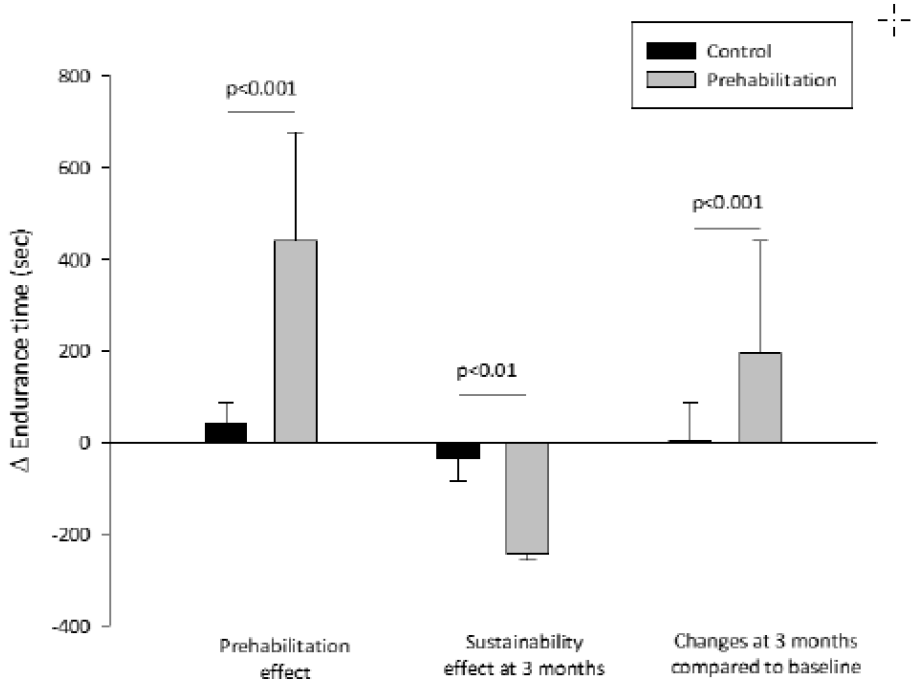

Figure 1 - Pre-habilitation-induced effects on endurance time. Pre-habilitation effect on endurance time (first pair of columns) = [Pre-surgery endurance time] – [Baseline endurance time]; Sustainability effect of pre-habilitation at 3 months (second pair of columns) = [Endurance time at 3 months] - [Pre-surgery endurance time]; Changes of endurance time at 3 months compared to baseline (third pair of columns) = [Endurance time at 3 months] - [Baseline endurance time].

Likewise, the results of daily physical activity (YPAS) as changes against post-pre-habilitation and compared with baseline (before pre-habilitation) showed a similar pattern as aerobic capacity. The pre-habilitation group had better postoperative functional recovery showing higher daily physical activity than the control group at 6 month after discharge.

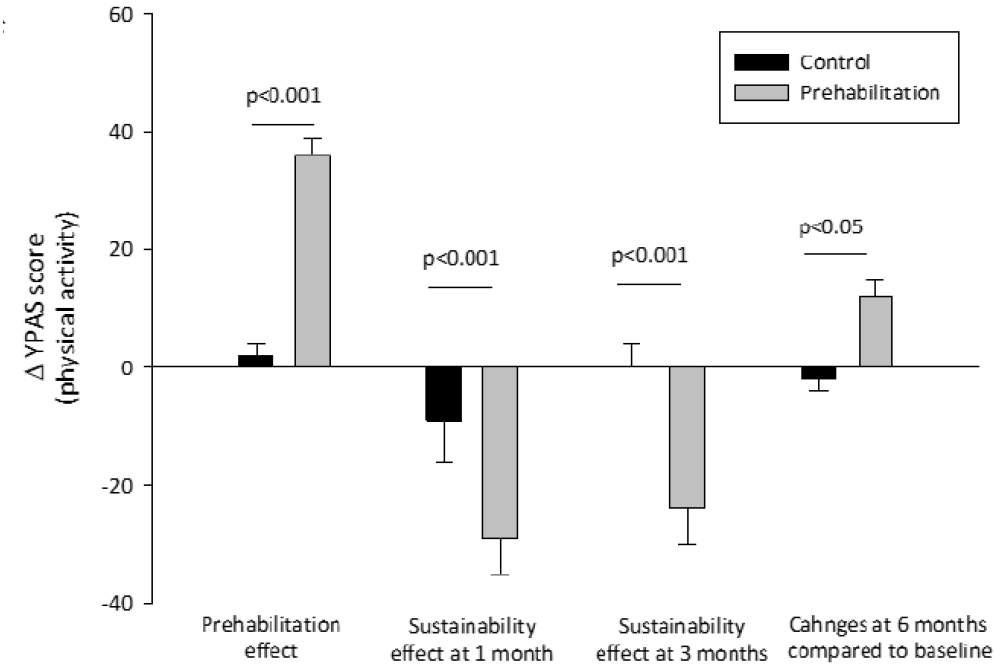

Figure 2 - Pre-habilitation-induced effects on physical activity. YPAS: Yale physical activity survey; Pre-habilitation effect on physical activity (first pair of columns) = [Pre-surgery physical activity] – [Baseline physical activity]; Sustainability effect of pre-habilitation at 1 month (second pair of columns) = [Physical activity at 1 month] - [Pre-surgery physical activity]; Sustainability effect of pre-habilitation at 3 months (third pair of columns) = [Physical activity at 3 months] - [Pre-surgery physical activity]; º (fourth pair of columns) = [Physical activity at 6 months] - [Baseline physical activity].

Very interestingly, pre-habilitation showed as a protective factor for 30-day hospital readmission (18 vs. 3%) of 30-day hospital readmissions rate for usual care and pre-habilitation groups, respectively; p-value=0.009) with a relative risk of 6.4 (95% CI 1.4-30.0).

Overall, the study showed a positive mid-term impact of pre-habilitation on functional recovery and decreased the use of healthcare resources after hospital discharge. These results encouraged the rationale for the current protocol aiming at exploring cost-effective synergies between pre-habilitation and postoperative short-term care.

Further information on Protocol I can be seen in British Journal of Anaesthesia. 2019 Oct;123(4):450-456 (see **D6.4 -** ANNEX IV).

4.1.2 Protocol II – Determinants of program completion and postoperative morbidity in patients undergoing pre-habilitation

See ***APPENDIX I.1*** for complete information on the manuscript submitted for publication.

As demonstrated in Protocol 1 Above, Prehabilitation has been shown to be an effective intervention to improve postoperative outcomes in patients undergoing major surgery. However, customization of the prehabilitation services to patients' characteristics is an unmet need. The protocol for study aimed to identify factors associated to program completion, and to postoperative morbidity, in patients undergoing to digestive, gynaecologic and urologic major surgeries.

This was a cohort study including patients enrolled in the pre-habilitation unit of Hospital Clinic de Barcelona, from June 2017 to December 2018. The pre-habilitation program included 5 main interventions: i) motivational interviewing; ii) supervised exercise training; iii) promotion of physical activity; iv) nutritional optimization; and, v) psychological support. Pre-habilitation completion was defined as attending ≥ 80% of appointments.

Of a total sample of 200 patients, 120 (60%) completed the program. Among completers, 62 did not suffer from postoperative complications (52%). Undergoing oncologic surgery (24.5 [3.9-153.8]; p= 0.001), suffering from endocrine and metabolic diseases (3.8 [1.2-12.3]; p= 0.025) and willingness to participate in mindfulness sessions (OR [95% CI] 3.1 [1.03-9.15]; p= 0.044) were associated with program completion, while being older (0.93 [0.88-0.97]; p= 0.002) was related to lower probability of completion. Among completers, higher baseline fitness (Duke Activity Status Index) (0.95 [0.91-0.999]; p= 0.019) and higher risk of malnutrition (Malnutrition Universal Screening Tool) (1.8 [1.1-3.1]; p=0.023) were related to reduced postoperative morbidity.

The study identified actionable factors useful to personalize pre-habilitation programs which may facilitate effectiveness and sustainability of the service.

4.1.3 Protocol III – Evaluation of digital tools enabling perioperative care

4.1.3.1 *Adaptation of MyPathway® to Study Cases 2 and 3*

The pre-habilitation program deployed in Hospital Clínic for patients with high surgical risk that are candidates for major elective surgery has been described in Section 3.1 of this document as well as in the above paragraphs. An existing digital tool called MyPathway® was adapted as a supporting tool for the pre-habilitation program in order to promote self-management of the patients, enabling remote off-line control and efficient interactions between patients and professionals[14].

[14] Zurita Celia. Interventions for self-management and healthy lifestyle promotion: Assessment of technological tools for self-management in the Prehabilitation service at Hospital Clínic de Barcelona and strategy for regional

The aim of this study was to assess the digital tool MyPathway®, used in the service of pre-habilitation at Hospital Clínic de Barcelona and to assess its potential to foster community-based activities of the service and facilitate its regional deployment.

A checklist version of the Model for Assessment of Telemedicine (MAST) was used as the framework for the assessment of the tool. Two simultaneous studies assessing performance of local adaptations of MyPathway® to support specific healthcare services (pre-habilitation and Home-based non-invasive ventilation) were conducted. The commonalities of both studies are reported jointly, and the results section has been structured as a mini-MAST report. (See APPENDIX I -1.2.2 for the complete report).

The results of the implementation of MyPathway® show that patients' average satisfaction and usability of the App are considered positive. The prehabilitation service is showing cost-effectiveness and technology of the app is mature, but integration with Catalan health systems is needed for regional deployment. Moreover, there were delays in the delivery of the iOS version and there are reasonable doubts on the potential of the tool to evolve covering identified needs.

The technology of MyPathway® needs improvement to cover all identified requirements, but shows potential to efficiently support the prehabilitation services. However, limitations shown by the vendor in terms of ensuring further evolution of the App strongly support the exploration of alternative solutions in order to ensure the success of regional deployment of the service.

4.1.3.2 *Adaptation of CONNECARE SMS*

The CONNECARE SMS suitably adapted to the pre-habilitation case study consists of an adaptation of the functionalities of overall CONNECARE SMS to the requirements of the multimodal pre-habilitation service currently deployed at HCB, including changes modularity of the technical solution and adaptation to the interface level. The system has been developed by EURECAT with close and continuous iterations with the pre-habilitation team at HCB-IDIBAPS (see description of the application in **D6.4, ANNEX I**).

Since the adapted version of the CONNECARE SMS has been decoupled from the CONNECARE SACM, a new web backend was developed by EURECAT to allow healthcare professionals to prescribe and monitor available tasks for patient self-management: physical activity goals, nutritional advices, mindfulness exercises and predefined data collection instruments.

Robustness of the application to be used in a real clinical scenario was achieved in October 2019. Since then it has been tested in small group of 16 candidates to pre-habilitation at HCB. All of them were evaluated at baseline and after one-month follow-up. From the methodological standpoint the study protocol was equivalent to the one adopted in MyPathway® (see results in ***APPENDIX I.2***).

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deployment. Celia Zurita conducted the current research as part of her final report to get the MD degree at the School of Medicine. University of Barcelona, June 2019.

4.2 Lleida

At the end of July 2019, the recruitment of patients for Implementation Study 2 was completed. From July 2018 to July 2019, a total of 82 patients were found to be eligible according to the EMRs. Of them, 43 patients could not be recruited: 40 patients did not pass the technological test and 3 patients did not agree to participate in the study. On the other hand, 39 patients were recruited. An overview of the recruitment of CONNECARE recruitment and patient participation is provided below. Up to 29 patients in Implementation Study 2 completed the 3-month post-discharge follow up and were discharged from the. The losses of follow-up corresponded to 10 drop-outs caused because the patients felt already recovered and did not perceive the need in continuing in the project. Similarly, up to 31 control patients were recruited out of the 35 initially planned, all of them completing the follow-up.

4.2.1 Recruitment Results

The main characteristics of the patients recruited in the CONNECARE arm (n=39) were: 15 (39%) men, mean (SD) age of 72.3 (8.9) years, and mean (SD) Charlson score of 4.1 (1.5). The main characteristics of the patients recruited in the control arm (n=31) were: 8 (26%) men, mean (SD) age of 73.4 (7.7) years, and mean (SD) Charlson score of 4.2 (1.7). None of the differences between CONNECARE and control patients were statistically significant.

Figure 2 - IRBLL CS2 - identification and recruitment of patients over time

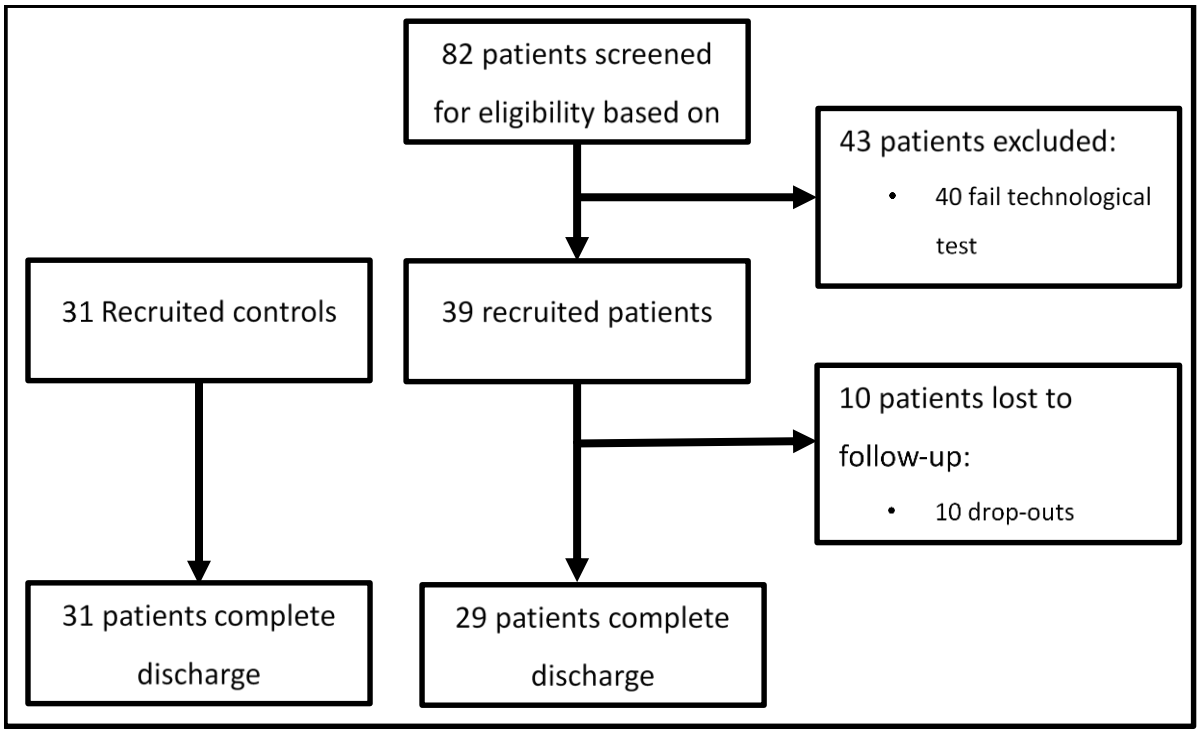

Figure 4 - IRBLL CS2 – CONSORT chart

4.2.2 Implementation of the Integrated Care Service and model

4.2.2.1 *Patients rating of the Integrated Care Service and Model*

Person Centred Coordinated Care Experiences Questionnaire (P3CEQ)

At discharge, patients were asked to assess the patient-centeredness of the CONNECARE system by means of the P3CEQ. This questionnaire consists of six questions, with a scale of 0 – 3, (0 - Not at all, 3 - Always). The mean (SD) P3CEQ from a total maximum score of 18, was 15.7 (3.5) for CONNECARE patients and 16.0 (2.4) for control patients. This rates the patient-centeredness of the CONNECARE system as excellent, but not different to the experienced among controls. Detailed results on P3CEQ are in Appendix II, Table 4.

Items G1-G5 from the Nijmegen Continuity Questionnaire (NCQ)

At discharge, patients were asked to assess the perceived continuity of care from hospital to primary care of the CONNECARE system by means of items G1-G5 from the NCQ. The mean (SD) score of G1-G5 NCQ was 3.5 (1.2) from a total maximum score of 5. This, rates the perceived continuity of care of the CONNECARE system as good. Detailed results on NCQ can be found in APPENDIX II, Table 5.

4.2.3 Issues reported in the Implementation Log – Organization and Process Issues

- Direct communications between the patient and the professionals enabled via SACM/SMS are part of CONNECARE's core features. However, the feature was not implemented on day one but in a subsequent update. While waiting for the messaging feature professionals had to contact patients using standard phone calls and had no option for sharing images.
- The recruitment of patients into the CONNECARE system was slower than expected mainly because of the limitations on patients'/carers' technological abilities and outdated technological equipment (smartphones with non-supported android versions and limited internal memory).

4.2.4 Evaluation of the Implementation Process

4.2.4.1 *Description of the processes that worked well and successfully*

- The messages and the possibility of sending images from the patients allowed a better control of local complications of the surgical wound.
- Through the implementation of the pain tests and messages, a better control of the pain degree in the sub-acute phase of the surgical process has been possible.
- A tight monitoring of blood pressure in hypertensive patients has been possible avoiding related complications.
- Problems related with the compatibility of usual medication of the patient with the new medication related with the surgical process have been avoided.
- A wide monitoring of the recovery of the physical activity has been possible.
- In some cases, a collaborative health care with the primary care team has been carried out avoiding emergency room visits.
- The detection of acute complications related with the surgery enabled the possibility of scheduling hospital visits that could solve the problems without the need for emergency room visits.
- Infections related with the surgical process have been diagnosed in advance enabling early action.

4.2.4.2 *Description of the processes that did not work*

- The patients that dropped out usually do that because they feel fully recovered and in their opinion the don´t need any further monitoring. This suggests the need to be flexible on the monitoring times and consider shorter monitoring periods.

4.2.5 Patients Engagement and Actual Usage of the ICT Tools and Devices

4.2.5.1 *Using the pedometer (Fitbit)*

Use of the Fitbit was measured by the number of days that the Fitbit of each patient transmitted to the SMS app. The mean (SD) number of prescribed Fitbit use was 86 (23) days, and the mean (SD) number of active Fitbit usage days was 66 (32). The majority of the patients were compliant in their use of the Fitbit, with 67% of patients using the Fitbit for more than 60 days and 30% of patients using it every day during the post discharge follow-up period. Women had a lower mean number of days transmitted than men, with this difference being borderline significant (T test p-value=0.090). Age was associated to lower number of transmitted days (Linear regression model adjusted by sex and Charlson p-value= 0.049). Detailed results on Fitbit use are in APPENDIX II, Table 1.

4.2.5.2 *Using the messaging function of the SMS app*

The mean (SD) number of messages sent by the patients was 18 (23). All patients sent at least 1 message and up to 66% of patients sent six or more messages. Women tended to use more this feature, although a Negative binomial regression model including age, sex and Charlson showed that neither sex (p-value= 0.852) or age (p-value= 0.348) were associated to the number of messages sent. It must be noted that the messaging function was not implemented from the beginning of the project, and this limited the engagement of the very first participants in the use of this feature. Once implemented, the patients perceived the feature as very useful and used it a lot. Detailed results on the use of the messaging function can be found on APPENDIX II, Table 2.

4.2.5.3 *Responding to questionnaires*

Patients in CS2 were asked to answer questionnaires concerning aspects on their recovery after surgery (i.e. pain). The median (p25-p75) number of successfully submitted questionnaires out of all requested questionnaires were 46% (14% - 79%) for the post-surgical questionnaire and 72% (39% - 81%) for the EQND. This shows that patients replied to the requested questionnaires on a regular basis.

4.2.5.4 *Monitoring vital signs*

- **Monitoring blood pressure –** Patients were asked to measure their blood pressure (BP) frequently and at different times of the day in accordance with their medical status. The report for BP using the SMS app, was done either manually (by typing the results after using a standard BP cuff) or automatically (by using an electronic device linked with the SMS app). The mean (SD) percentage of measures reported out of times prescribed was 35% (24%). Thus, most patients succeeded in monitor BP on a daily basis, but were reluctant to measure BP more than once a day.
- **Monitoring body temperature –** Patients were asked to record their body temperature especially during the first weeks after surgery. The recording of body temperature using the

SMS app was done manually (by typing the results into the SMS after using a standard thermometer). The mean (SD) percentage of measures reported out of times prescribed was 38% (14%). Thus, patients measured their temperature approximately one third of the times they were asked to do so.

Detailed results on the use of monitoring devices can be found in APPENDIX II Table 3.

4.2.6 Patients Satisfaction with the Technology

4.2.6.1 *Satisfaction with the CONNECARE system – Likert scales and Net Promoter Score (NPS)*

At discharge, patients were asked to assess their experience with the CONNECARE system (including the SMS app and linked devices). The overall satisfaction with the CONNECARE system was outstanding, with scores in overall satisfaction, easiness of use, and ability to use without help having medians of 8/10 to 10/10. The answer to the question "How likely is it that you recommend the CONNECARE system to a family member or friend?" was used to calculate the NPS, subtracting the percentage of Detractors from the percentage of Promoters. The NPS ranges between −100 and +100, a positive score is considered good, a NPS of +50 is generally deemed excellent, and anything over +70 is exceptional. The NPS score was +43% in patients using SMS app + Fitbit and +45% in patients using only SMS app. These rates are good, and close to reaching the excellent threshold (+50%). Detailed results on the Likert scales and NPS can be found in APPENDIX II Tables 6-8.

4.2.6.2 *Satisfaction with the CONNECARE system – System Usability Scale (SUS)*

At discharge, patients were asked to assess the usability of the CONNECARE system (including the SMS app and linked devices) by means of the SUS. Based on research, a SUS score above a 68 would be considered above average and anything below 68 is below average. The mean (SD) SUS was 68.2 (24.4), with 55% of patients scoring ≥ 68, which rates the product as good. Detailed results on the Likert scales and SUS can be found in APPENDIX II, Table 9.

4.2.6.3 *Changes in Satisfaction Over Time*

The Implementation studies were the final step in the PDSA cycle and were intended to be a major part of the co-design process. In particular, the SMS underwent significant refinements and improvements during the course of the pilot studies. Technical bugs were fixed, functions were altered or added and usability was improved considerably. Lleida performed a time-series analysis of satisfaction and usability ratings by patients according to date of recruitment, paralleling the increasing maturity of the SMS and found that, indeed, there is a clear trend of increasing satisfaction and usability ratings over time. Overall satisfaction, easiness of use and ability to use without help ratings increased from 6.2 to 9.3, 5.5 to 9.3 and 8.3-9.5 respectively. The NPS score increased from 37.5% to

80% and the SUS score went from 64.7 to 83. This can be clearly seen in the following graph:

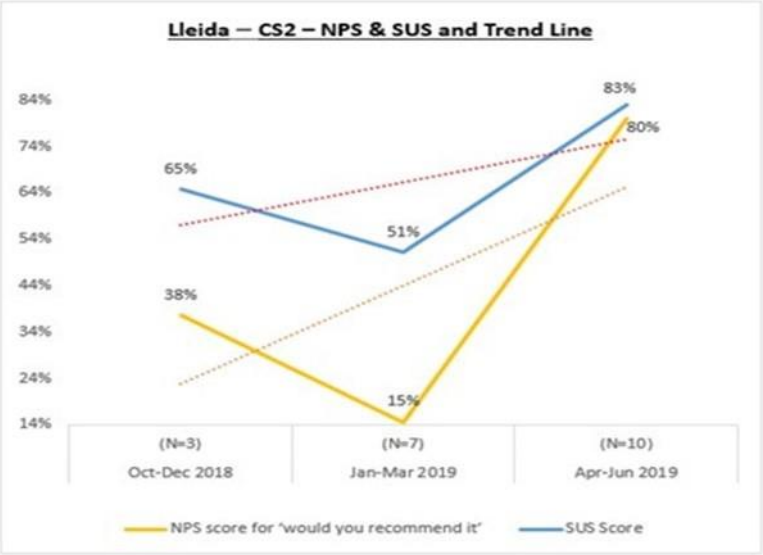

Figure 5 - IRBLL CS2 - Satisfaction with the SMS over Time

This is a clear indication of the success of the pilot in achieving its objective of producing a more mature product as a direct result of patient and staff feedback over the course of the study.

4.2.6.4 *Staff Satisfaction with the Technology*

A total of 30 professionals involved in CS1 and/or CS2 were asked to assess the SACM platform using Likert scales, NPS and SUS between April and May 2019: 1 hospital case-manager, 3 hospital physicians, 1 hospital surgeon, 1 hospital anaesthesiologist, 3 primary care case-managers, 12 primary care physicians, and 9 primary care nurses. As opposed to patients, the overall satisfaction with the CONNECARE system was poor, with scores in overall satisfaction, easiness of use, and ability to use without help having medians of 6/10 or 6.5/10. The NPS score was -35%, and most probably reflecting the difficulties experienced in using a tool being under development and not fully integrated with existing systems. Similarly, the SUS score was average, with a mean (SD) of 61.7 (19.0) and 43% of staff scoring ≥ 68. Detailed results on the staff satisfaction with the technology can be found in APPENDIX II, Tables 10-12.

4.2.7 Issues with the Digital Tools Recorded in the Implementation Log

4.2.7.1 *SACM & SMS usability problems*

- Most of the day to day problems reported by the case manager were related to patients' accessibility issues (password recovery) and missing data (human or technological errors on the input of data that resulted in missing data, data recorded with errors, or duplicated data or

tasks). This fostered the addition of correction features to be used by either the patient or professionals. Furthermore, it implies the need for a permanent user support team while the CONNECARE system is implemented and ongoing.

- Another set of issues had a direct relationship with usability and user friendliness of the system, and leaded to improvements on the front end of the SACM and/or SMS (i.e. improvements in the graphical visualization of repeated measurements over time). These issues were solved throughout the refinement and fine-tuning phase of the project.

4.2.7.2 *Technical problems with SACM & SMS*

- Most of the technical issues reported in the implementation log were bugs that needed to be reported, prioritized and solved on a regular basis. These bugs included tasks that were tagged as completed at the time of prescription; issues with decimal values introduced to the SACM/SMS; messages not reaching all the involved professionals; desynchronization between the SACM and SMS when changing prescriptions, team members or other key aspects of a given patient care plan; issues in the time registry of when a given action was performed; etc. All these issues were solved promptly but generated some occasional discomfort with the system among its users. This implies the need for a permanent technological support team while the CONNECARE system is implemented and ongoing.

4.2.7.3 *Integration with other Information Systems*

- The achieve degree of integration with the hospital and primary care electronic medical records (SAP & eCAP, respectively) was very low. This reduced the overall potential of the CONNECARE system and halted the use of past recorded episodes of the patient as an automated assist to professionals in terms of risk assessment.

4.2.8 Intervention Effectiveness

4.2.8.1 *Health & wellbeing questionnaires (SF-12)*

The intervention effectiveness was measured by the comparison of a health-related quality of life measure, the SF-12 questionnaire, at baseline and after the 3-month intervention period, both in CONNECARE patients and in the control group. The intervention generated significant changes in the physical dimension of SF-12 (mean (SD) change: +15.4 (11.7); p-value<0.001) and the total SF-12 score (mean (SD) change: +16.2 (14.3); p-value<0.001). However, similar changes were seen in the control group: physical dimension of SF-12 (mean (SD) change: +14.1 (9.0); p-value<0.001) and the total SF-12 score (mean (SD) change: +16.1 (14.8); p-value<0.001). Therefore, crude and adjusted (sex, age, and Charlson) linear regression models did not find statistically significant differences in the changes experimented by patients in the CONNECARE program or control patients. The logical conclusion is that the huge improvement in quality of life experienced after a hip or knee replacement surgery

overwhelms any specific improvement directly attributable to the CONNECARE program. Detailed results on the effectiveness as measured by the SF-12 can be found on APPENDIX II, Table 13.

4.2.8.2 *Service utilization during the follow-up*

The number of unplanned hospital or primary care visits, as well as hospital admissions, either related or unrelated to the surgery procedure of the patients, were recorded during the 3-month follow-up. Being in the CONNECARE program significantly reduced the total number of unplanned visits (mean (SD) among controls: 1.48 (1.52); mean (SD) among CONNECARE: 0.69 (0.97); adjusted p-value=0.003). Analyses based on hospital admissions were not possible as only one hospital admission was recorded during the follow-up period (1 control patient). No mortalities were registered during the follow-up among CS2 patients. Overall, the main benefit of the CONNECARE system in terms of service utilization was the avoidance of unplanned visits. Detailed results on the effectiveness as measured by service utilization can be found on APPENDIX II, Table 14.

4.2.8.3 *Intervention costs*

Estimating the overall cost per patient of implementing the CONNECARE program is not trivial. For the purpose of the current study, a hospital-based nurse case-manger was recruited for the duration of the study (Jul 2018 – Oct 2019), with a total cost per month of 3500€. During the whole study period, she recruited and managed 91 patients in the CONNECARE program (52 CS1 + 39 CS2), taking responsibilities in the management of the patients as well as providing technical support and assistance, collecting research-related data and participating in the overall development of the CONNECARE H2020 project. Therefore, in a real-life non-research scenario, it is estimated that a single hospital-based nurse case-manger could manage up to 500 simultaneous patients, resulting in a cost of 7€ per patient and month. During the study, the rest of involved medical staff either in the hospital or in the primary care assumed any potential increase in workload related to the use of the CONNECARE platform at no additional cost. In this sense, it must be noted that, on one hand, a fully implemented CONNECARE program would imply a higher number of CONNECARE patients and thus an increase in workload; on the other hand, a fully mature and integrated platform would be much less demanding for involved professionals. In any case, the re-structuring of staff's time to include the new tasks would be fully assumed by the health system and no additional personnel would be required, thus no additional cost would be generated. The cost of licensing and running the CONNECARE platform as well as the costs to maintain, evolve and support it cannot be easily established. In this sense, the costs of other health services like Home-based oxygen therapy, where a supplier covers the role of providing devices, licenses and technical support, have been used to generate a per year per patient estimation of 200€. Therefore, a total cost of 23.67€ /patient and month has been estimated as direct costs of the CONNECARE program for the purpose of the current analyses. Given that the duration of the intervention was 3 months, the final costs of the CONNECARE program was 71.01€. Additionally, 2

sensitivity scenarios were also analysed were CONNECARE program costs were incremented by +50% and +100%. No indirect costs were considered.

Cost of unplanned visits and hospital admissions

According to the official data of 2013 (CVE-DOGC-A-13051031-2013), the overall cost of unplanned medical visits in the health region of Lleida is 62€. The cost of hospital admissions is 555€ per day. The average total cost of unplanned visits during the 3-month study period was 93€ among control patients and 42.76€ among CONNECARE patients. Similarly, the cost of hospital admissions was 148€ and 0€, respectively. Therefore, patients in the CONNECARE program generated an average saving of 198.24€.

Overall costs

When considering both the cost of the CONNECARE program and the cost of unplanned visits and hospital admissions, patients in the CONNECARE program generated an average saving of 127.23€. When considering scenarios with +50% and +100% CONNECARE program costs the CONNECARE program still generated savings: 91.72€ and 56.22€, respectively.

Cost-benefit

The cost-effectiveness of the CONNECARE program was assessed by means of the incremental cost-effectiveness ratio (ICER). Effectiveness was measured by the comparison of the change in SF-12 total score, at baseline and after the 3-month intervention period. Costs were measured considering overall costs in the 3 CONNECARE program scenarios (100%, 150%, and 200%). All three scenarios reported a negative ICER, thus demonstrating a negative incremental cost associated with 1 additional point gain in SF12 (100% CONNECARE program costs: -1590.38; 150% CONNECARE program costs: -1146.5; and, 200% CONNECARE program costs: -702.75). This means that the CONNECARE program was more cost-effective than standard care, even when considering scenarios with increased costs of the program.

Detailed results on the costs and cost-effectiveness can be found in APPENDIX II, Tables 15 and 16.

4.3 Israel

4.3.1 Recruitment Results

From July 2018 until the end of June 2019, Assuta's Nurse Case Manager (NCM) received names of 388 candidates for major elective surgery who were Maccabi members 55 years or older. 270 (70%) were found to be potentially eligible according to the medical record. Of them: 74 patients (27%) were found unsuitable after a conversation with the patient, 93 patients (34%) said explicitly that they were not interested, and 35 patients (13%) were recruited.

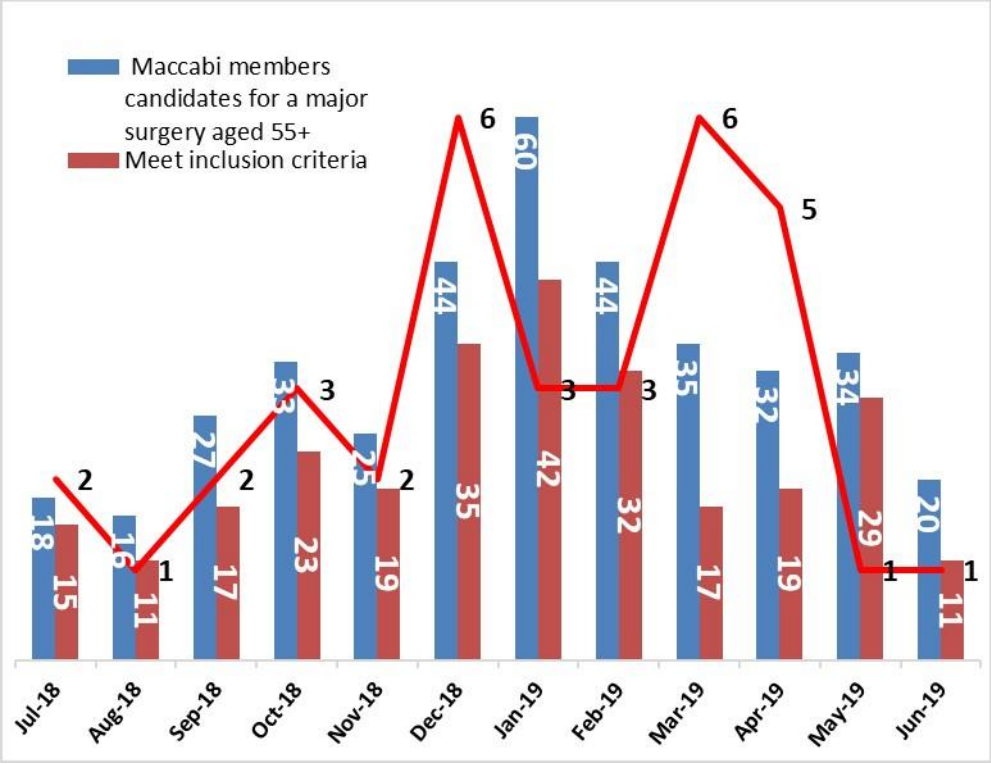

Figure 6 - Assuta CS2 - identification and recruitment of patients over time

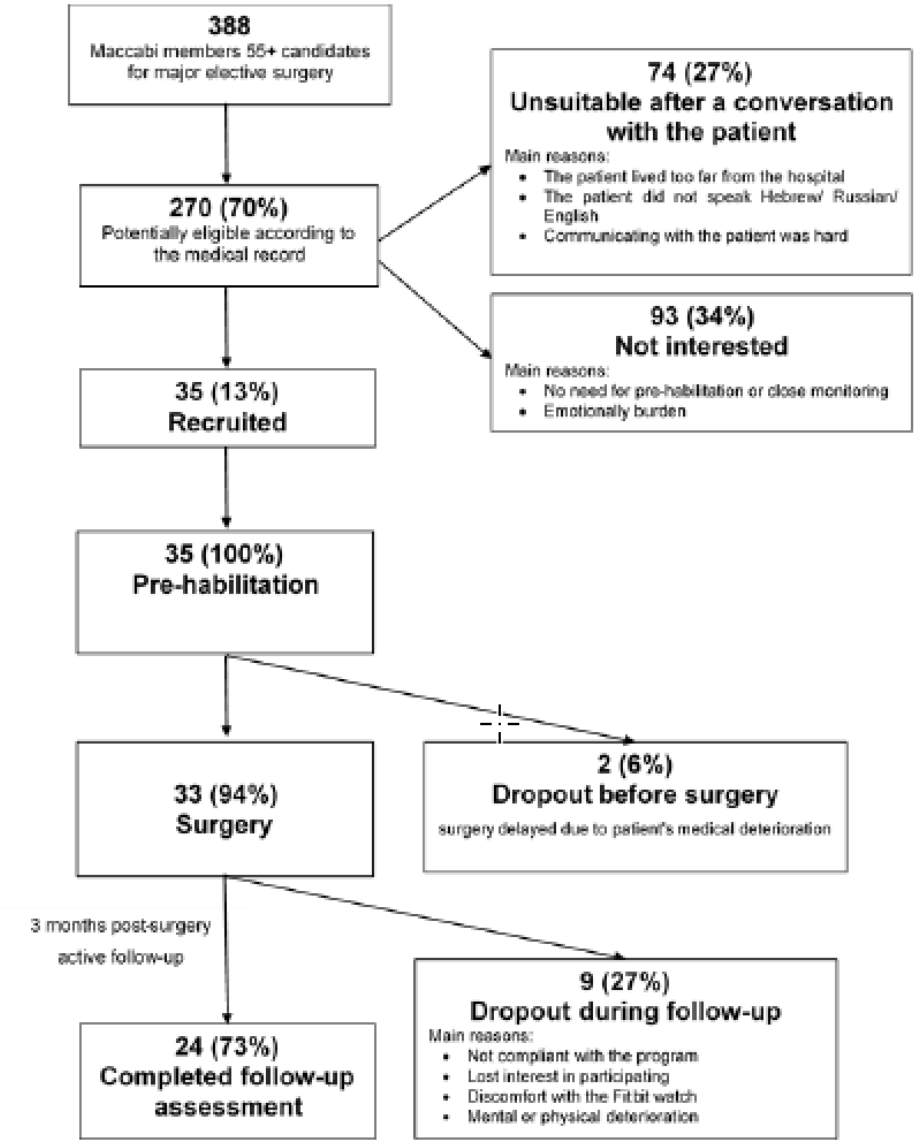

Figure 7 - Assuta CS2 - CONSORT chart

As of the end of September 2019, of the 35 patients recruited, 24 patients (69%) did pre-habilitation, completed the three months follow-up and were discharged from the project after completing the feedback questionnaires. Some patients have continued the follow up for an additional month at their request. 11 patients (31%) dropped out of the project prior to completing the entire course of follow-up. The patients who chose to leave the study early were not different from the whole group in sex and age distribution and Charlson score average.

Of the 35 patients recruited 18 (51%) were males and 17 were females ranging from ages 58-78 with an average age of 64.9 and median of 63. Average Charlson score was 3.37 (median 3). Most of the patients were living with a spouse (89%), defined themselves as having middle socioeconomic status (76%), and just over half had university education (57%).

4.3.2 Implementation of the Integrated Care Service

The integrated care service in Israel for implementation Study 2 consisted primarily of two services:

1. A multidisciplinary pre-habilitation service 3-6 weeks prior to major elective surgery and included supervised physical activity and endurance training in the Assuta Ashdod hospital physical therapy department and “unsupervised” physical activity at home in accordance with a care plan and a prescribed number of daily steps as well as other prescribed physical exercises. It also included emotional and motivational support by the Assuta Case manager and the Physical therapists and nutritional advice when needed. The “unsupervised” physical activity at home was measured by the Fitbit (steps, intensity) and reporting of activities performed by the patient in the SMS app. These were transmitted to the Clinicians dashboard (the SACM) and enabled both the Nurse Case manager and the physical therapists to monitor the patient’s activity.
2. Intensive post-discharge monitoring, follow up and care management by the assigned Nurse Case managers in the Maccabi Integration unit. This included an integrated care plan coordinated with the relevant professionals in the community (via the Maccabi EMR), and a personal patient care plan with prescribed activities including blood pressure monitoring, medication monitoring, physical activity (including steps), as well as reminders to eat and drink. A designated Maccabi secretary supported patients in making follow up appointments with their doctors in the community as well as with Maccabi services. In addition, where needed, the Nurse Case managers involved other professionals such as social workers

4.3.3 Patients Assessment of the Integrated Care Service and Model

4.3.3.1 *Person Centred Coordinated Care Experiences Questionnaire (P3CEQ), N=28*

In order to assess the patient's perceptions of patient-centeredness during the project, patients were asked to complete the Person Centred Coordinated Care Experiences Questionnaire (P3CEQ). This questionnaire consists of six questions, with a scale of 0 – 3, (0 - Not at all, 3 - Always). The median (p25-p75) P3CEQ was 13.5(9.8-16) from a total maximum score of 18, which rates the patient-centeredness of the CONNECARE system as good.

0 - Not at all 3 - Always	% of patients answered "Always"
F1. Did you discuss what was most important for YOU in managing your own health and wellbeing?	32%
F2. Were you involved as much as you wanted to be in decisions about your care?	68%
F3. Were you considered as a ‘whole person’ rather than just a disease/condition in relation to your care?	79%
F4. Did your care-team / providers involve your family/friends/carers as much as you wanted them to be in decisions about your care?	39%

F5. Have you had enough support from your care team / providers to help YOU to manage your own health and wellbeing?	68%
F6. To what extent do you receive useful information at the time you need it to help you manage your health and wellbeing?	75%

The results for F3 and F6 are relatively high, suggesting perceived patient-centeredness in the CONNECARE system for the patients completing the whole pre-habilitation and post discharge follow-up period, as very good. However, questions F1 and 2 regarding family/friends/carers involvement and issues important to the patient, received a low rating. These results need to be analysed in greater depth, as both issues were supposed to be part of the CONNECARE patient empowerment agenda.
The overall positive results are exemplified by patient comments in the open questions at the end of the satisfaction questionnaire:

- "I was very stressed before the operation, the conversations with the nurse and the physiotherapist reassured me and I felt that I arrived much calmer for the surgery"
- "There was always a response from the staff"
- "I see great importance in the project, it can greatly help people who are discharged from hospital"
- Only praises, excellent personal communication and excellent instruction
- Worthwhile project, contributed a lot to my return to fitness after orthopaedic surgery

4.3.3.2 *Items G1-G4 from the Nijmegen Continuity Questionnaire (NCQ), N=25*

In order to assess the patient's perceptions about the continuity of care during the project, patients were asked to respond to items G1-G4 from the Nijmegen Continuity Questionnaire (NCQ). This questionnaire consists of five questions, with a scale of 0 – 5, (0- NA, 1-Strongly disagree, 5- Strongly agree). The median (p25-p75) score of G1-G4 NCQ was 10.0 (9-11) from a total maximum score of 20.

1- Strongly agree 5- Strongly disagree	**% of patients answered "Agree" or "Strongly agree"**
G1. My care providers transfer information very well to one-another	92%
G2. My care providers work together very well	88%
G3. My care providers are very well connected	84%
G4. My care providers always know what one-another is doing	80%
G5. I have to wait too long to obtain a service/appointment	20%

The results show high patient satisfaction with their treatment and continuity of care among the different physicians and caregivers during the study period, suggesting the perceived continuity of care of the CONNECARE system for the patients completing the whole pre-habilitation and post discharge follow-up period, was very good. The main hypothesis for this result is the availability and high level of service

of Assuta's and Maccabi's case manager nurses and physical therapists, as well as the support of a medical secretary who helped the patients deal with bureaucracy and coordination.
These results are reflected in the patient's comments in the open questions at the end of the satisfaction questionnaire:

- "The team (the nurses and the physiotherapist) worked well together"
- I have only praise for the team, excellent Interpersonal communication capabilities, and excellent training capabilities"
- "the objective of the project is very important- help and follow up of patients post discharge is very important".

4.3.3.3 *Staff Assessment of the integrated care service and its implementation*

Staff engagement and assessment of the integrated care service and its implementation was measured using the ACT@Scale – a series of statements to which staff were asked to indicate their level of agreement. The detailed results for each question are in APPENDIX III Table 14. Overall, the entire staff – nurse care managers and physical therapists, had a clear understanding of what the project was trying to achieve and strongly believed that patients were benefitting from it. They also agreed strongly that their involvement in the project positively changed their views on integrated care. However, the Nurse Care Managers and physical therapists differed significantly on other issues. The physical therapists felt that they had little influence on how the project was managed, and they felt that they did not receive adequate training and there was not sufficient time available to support their training, whereas the Nurse Case Managers rated these aspects much more positively. A fairly obvious explanation for these differences is, that the Nurse Case Managers were staff recruited for and dedicated to the project at the level of about 50% FTE. The Maccabi Case Managers intensively followed the patients for 3 months post—discharge, whereas the physical therapists were involved only in the prehabilitation phase of the project and none of them were dedicated to the project but inserted the CONNECARE patients into their regular schedule. They were therefore much less available for training and overall involvement.

Overall, the staff felt they were actively involved and encouraged to provide feedback on the development of the CONNECARE integrated care model.
The team considered a number of factors in the integrated care model as most important:

- The multi-professional team communication efficiency, when all clinicians are involved and updated on the patient situation and needs
- Ongoing follow-up and monitoring of the patient tailored to the patient's need
- First meeting with the patient and his/her family in the hospital, either during hospitalization and / or before surgery, or before discharge to the community
- Active participation of the patient in improving his or her health
- Raising awareness and education for physical activity

As barriers to implementing the model, the team noted the following:

- Lack of cooperation from the Assuta staff in the inpatient wards and outpatient clinics
- Technical difficulties for the patient in using the app
- Lack of sufficient interaction between the hospital and community

The staff made the following suggestions for improving staff engagement:

- Stronger involvement of hospital management
- More work meetings with regular updates and feedback
- Direct contact with a technical assistance person who can respond quickly and efficiently to patients as well as staff
- Sufficient working space to enable all project staff to sit together
- More comprehensive training for every team member who enters the project on the app and the SACM
- Regular periodic sessions of the multi-professional team to briefly discuss each patient

4.3.4 Organization and Process Issues Reported in the Implementation Log

- Most of the day-to-day problems reported by the case managers under Organization and Process issues in the log were related to workflow problems and patient adherence.
- Regarding workflow, tips for improving recruitment were reported, such as reducing the minimal age of patients eligible for study inclusion, and taking into account during recruitment the patients' ability to respond to the study and the treatment plan for 3-4 months,
- Regarding patient adherence, some positive patient comments were reported, but mainly patient usability problems were reported such as forgetting the app's password, discomfort with using the Fitbit, etc.
- Other implementation log reports addressed problems with collaboration between members of the study's staff and changes in the study protocol.

4.3.5 Evaluation of the Implementation Process

4.3.5.1 *Lessons learned from processes that worked well and successfully*

The following are descriptions of examples of implementation processes that worked well and may be worth replicating in expanding the integrated care service in the future:

- Characteristics of case manager nurses - Recruitment of nurses that have another half-time position in the hospital enabled flexibility to accommodate patients' needs by enabling her, for example, to see patients at times not dedicated exclusively to the study. The recruitment of Russian speaking nurses (for both pre and post discharge period) was very important due to the size of the Russian-speaking population in Ashdod.

- In order to add value for patients in the study, a part-time medical secretary from Maccabi Healthcare Services was added to the project team to assist patients in scheduling appointments for specialists and imaging tests in the community and reducing bureaucratic obstacles (for both pre and post discharge period). The secretary assisted the nurse case managers in integration and coordination when needed and was perceived by patients as making the program more attractive.
- Enabling multiple options for the patients to meet the nurses/physiotherapists for assessment, physiotherapy sessions in the pre-habilitation period, re-training on the app and Fitbit use and in cases where there was a problem with the Fitbit or the App was very important. Maccabi's NCMs were given the option of home visits with patients, (which was not in the original protocol), and this option was used extensively by the nurses to the high satisfaction of the patients. In addition, in order to encourage patients to come to the hospital when needed (for pre-habilitation or additional training in the use of the digital tools) the project provided entry tickets to hospital parking as needed.
- Engaging more active involvement of the family physician was challenging but rewarding when successful. When the nurses encountered a patient suitable for the study who expressed interest in the study but had doubts, the nurses turned to the personal secretary of the patient's family physician and the family physician encouraged the patient to participate in the study.
- Strengthening the communication among the clinical staff was very critical. Following several cases of errors and problems with information transmission, a joint WhatsApp group was created enabling all staff members to communicate quickly and in real time. In addition, weekly routines were created, mainly by using Outlook reminders, to remind the staff regarding scheduled time of patients' surgery, when to visit patients in the hospital or patients discharge from the study.
- The transfer of responsibility for the patient from Assuta's NCM to Maccabi's NCMs was not ideal through the SACM system. In the beginning of the study, Maccabi's NCMs lacked data on patients recruited by Assuta's NCM. In order to address this problem, an email reporting template was developed for Assuta's NCM to report to Maccabi's NCMs about each patient recruited, accompanied with an Outlook calendar reminder for each patient's day of surgery.
- Distribution of a step-by-step clear printed guide with screenshots on the use of the application and the Fitbit watch for patients at their first meeting with the nurses was essential to the training process for the patients in the use of the CONNECARE digital tools.
- Another important implementation factor was the recognition that some patients had a mobile phone that did not support the app and therefore needed to receive a tablet in order to access the CONNECARE app. The tablets that were provided had SIM cards in order to avoid potential WIFI problems in the patient's home.

4.3.5.2 *Lessons learned from processes that did not work*

Learning from failure is at least as important as learning from success. Some of problems encountered in implementing the CONNECARE digitally enabled integrated care service were:

- The nurses chosen for the role of Case Manager had high interpersonal abilities, but low technological abilities which proved to be a real hindrance in providing the necessary technological support and guidance to patients in using the SMS, as well as creating challenges for their own use of the SACM
- The process of obtaining weekly updated lists of patients scheduled for surgery from the Surgical Clinics as a basis for identifying potentially eligible patients for recruitment was complicated and did not work and flow well, despite several attempts to improve the process
- The cooperation of the patient's family physician was not ideal, the family physicians were informed of the patient's participation in the study, but a deeper relationship and integration was only created in a few cases
- Engaging hospital staff with the project (head nurses, department heads, hospital management) was difficult and very time consuming. This was partially due to the fact that the project started at the same time as the new hospital opened its doors for the first time and consequently, hospital staff was very preoccupied with putting the day-to-day processes of running a hospital and treating patients in place. The hospital vision of implementing integrated care was often overshadowed by the pressure of the day-to-day challenges.
- The use of the SACM system was cumbersome. The consequence of the decision to use the SACM as a standalone system was that all data that needed to be shared was double entered - once into the SACM and a second time via organizational emails or the Hospital and Maccabi EMRs.
- The post discharge Nurse Case managers were initially managed by a senior nurse. During the course of the project, management of the case managers was shifted to a physician, the medical director of the integration unit. This resulted in a lack of close nursing supervision and affected the Case Managers' performance.

4.3.6 Patient and Staff Use and Satisfaction with the CONNECARE Digital Tools

4.3.6.1 *Patients engagement and actual usage of the ICT tools and devices*

As CONNECARE is a digitally enabled integrated care project, the degree of success in the actual use of digital tools developed and implemented in the project, was a key outcome and addresses one of the key study questions.

Patient adherence in the use of the Pedometer (Fitbit). Use of the Fitbit was measured by the number of days that the Fitbit of each patient transmitted to the SMS app and the number of steps transmitted by the Fitbit through the app to the SACM. There was very high compliance in the use of the Fitbit,

during the pre-habilitation period (between 3-5 weeks (21-35 days) the average number of days transmitted by the Fitbit was 33 and for the 3 month period following discharge the average number of days transmitted per patient was 24 days during months 1 and 2 and 23 in the third month. It should be noted that many of the patients were Sabbath observant – meaning that according to Jewish Law – they were not permitted to use either the app or the Fitbit from Friday sundown until Saturday night - so an average of 24 days out of a possible 26 is quite impressive. More significant was the change in the average daily number of steps. The average during the prehabilitation period was over 7000 steps per day and 70% of the patient walked between 5000-10000 steps daily. As anticipated, the number of daily steps went down post-surgery but increased significantly in months 2 and 3. Neither age nor sex was a significant factor. As an interesting addendum, 14 patients continued to report steps after being discharged from the study, with 6,087 average daily number of steps. All data and detailed statistical analysis can be found in APPENDIX III Tables 1 and 2.

Patient adherence in the use of the Self-Management System (SMS) app. Overall, patient adherence in the use of non-Fitbit related functions of the app was relatively low. It should be noted, however, that the app was a "work in progress" throughout the pilot and thus, patients recruited earlier encountered many more difficulties in using the app that were then corrected so that the app became more user friendly over time. This is clearly evidenced by the messaging function of the app, which was introduced after the start of the pilot. The average number of messages per patient was 4.7. Just under a third of the patients sent more than 6 messages and only 15% of the patients sent more than 10 messages. However, a time-series analysis shows that patients recruited later tended to make much more use of the app as illustrated in figure 8 below. Two time-series analyses were computed with the ratio messages/patient as the dependent variable and month as the independent one. The analyses also included predicted values for 5 months post study. As can be seen, the messages per patient ratio increased along the study period.

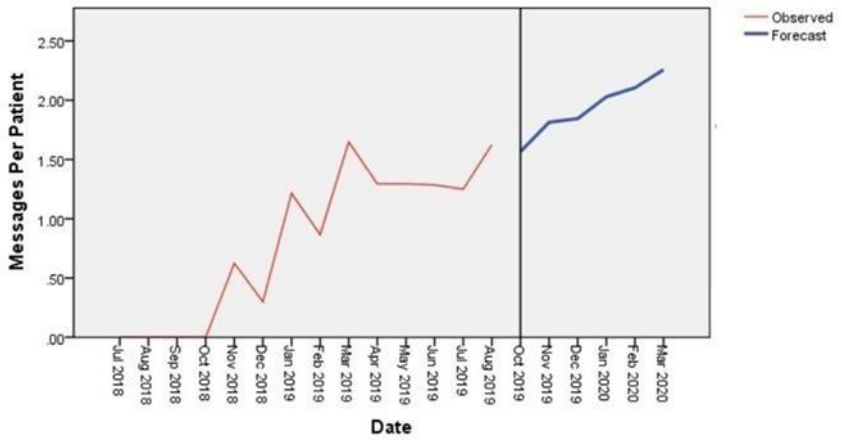

Figure 8 Use of the Messaging Function Over Time

Patients were asked to complete the EQ5D questionnaire weekly on the SMS app, in order to follow their self-reported quality of life during the follow up period. Eight patients reported 1-5 times, and only 3 patients reported more than 5 times. Although it was initially planned that the recommender system would provide "real" feedback to patients responding to the questionnaire – this was never implemented, so that there was not a strong incentive for patients to fill out the questionnaire.

Only six patients were required by their clinicians to monitor their blood pressure. Patients in the study did not have blood pressure cuffs with Bluetooth for automatic transmission to the app, and therefore they were required to enter their blood pressure values manually. All of the patients reported, but not as frequently as prescribed.

Patients scheduled for elective surgery were also required to perform and report additional tasks to improve their fitness such as bending their knees, walking up and down stairs. Patients may have performed these tasks but they did not report them. During the pre-habilitation stage, patients reported performance of 25% of the number of tasks prescribed whereas they only reported 15% post-surgery. Based upon patient comments on the satisfaction questionnaires and the high compliance in step reporting, it is reasonable to assume that the actual performance of these tasks was significantly higher than the reporting of the tasks through the app.

The detailed figures and analysis regarding patient adherence in the use of the SMS app can be found in APPENDIX III Table 3.

Patient satisfaction with the CONNECARE digital tools. At discharge, patients were asked to assess their experience with the CONNECARE system, including the SMS app and the Fitbit watch, using the Net Promoter Score (NPS) tool, consisting of four questions, each of which with a Likert scale score of 0 – 10, (0 = poor, 10 = good), 25 patients responded.

Likert scale score (0 = poor TO 10 = good)	SMS App		Fitbit	
	median	p25-p75	median	p25-p75
1. Overall satisfaction	6.4	3.5-9.5	8.9	8-10
2. Easiness of use	6.7	4.5-10	9.4	9-10
3. Ability to be used without help	6.7	1.5-10	9.1	9-10
4. Would you recommend it?	6.1	0.75-10	8.6	8-10

The answer to the question “How likely is it that you would recommend the CONNECARE system to a family member or friend?” was used to calculate the NPS. The NPS ranges between −100 and +100, a positive score is considered good.

NPS – Fitbit

Score ‘would you recommend it’	# patients	% patients
0-6 (detractors)	3	12%
7-8 (passives)	5	20%
9-10 (promotors)	17	68%

NPS – SMS App

Score 'would you recommend it'	# patients	% patients
0-6 (detractors)	10	40%
7-8 (passives)	7	28%
9-10 (promotors)	8	32%

The NPS score was 56% for the Fitbit which rates it as great (>50% - 70%) and -8% for the SMS which is a low rating.

Another tool to evaluate and assess the usability of the CONNECARE app, was the System Usability Scale (SUS) tool, consisting of eight questions, with a Likert scale score of 1 – 5, (1.0 = strongly disagree, 5.0 = strongly agree).

The median (p25-p75) SUS score was 62.2 (48.8-77.5), which rates the product as good.

Overall, we can see that the patients in implementation study 2 rated the Fitbit watch as easy to use and would recommend it to their friends. However, the CONNECARE app was evaluated by the patients as less easy and attractive. These results are also supported by patients' comments in the open questions at the end of the satisfaction questionnaire:

- "The Fitbit watch was very comfortable. The use of the watch gave me motivation to walk and move"
- "I loved the Fitbit watch very much, thanks to it I started walking every morning"
- "The application was complicated; there were many problems that were difficult to deal with. I think that for an older person it will be very difficult"
- "It was very hard for me to use the app, I needed a lot of help"
- "I suggest connecting the project app to the Maccabi Online app. If the application would allow scheduling appointments with doctors, it would be more effective for me"

Essentially, the comments provide an explanation and a better understanding of the quantitative results of the actual use of both the Fitbit and the SMS App. The Fitbit was simple and easy to use and required very little effort on the part of the patient. They could also view the number of steps they walked on the watch itself without going into the app. The SMS app required much more effort, logging in and entering the various functions in order to use them.

Nonetheless, it is important to remember that the development of the CONNECARE SMS was a work in progress that continued to evolve throughout the course of the implementation study based on feedback from patients and staff. Therefore, a time-series analysis was done to address the level of satisfaction with both the Fitbit and the SMS by month of patient recruitment. Satisfaction with the Fitbit was high regardless of when patients entered the study in terms of overall satisfaction, NPS and SUS. However, there was a real difference in satisfaction with the SMS between patients who entered early, and patients who entered later when the technology was more mature. Overall satisfaction increased from 3.5 to 6.1, ease of use increased from 3.5 to 6.6, ability to use without help increased from 5 to 6.5, and the response to "would you recommend it?" increased from 3.5 t0 9.5. The NPS improved and the

SUS Score increased from 53.75 to 63.33. Detailed Results are in Appendix III – 2E. The following graph illustrates this evolution:

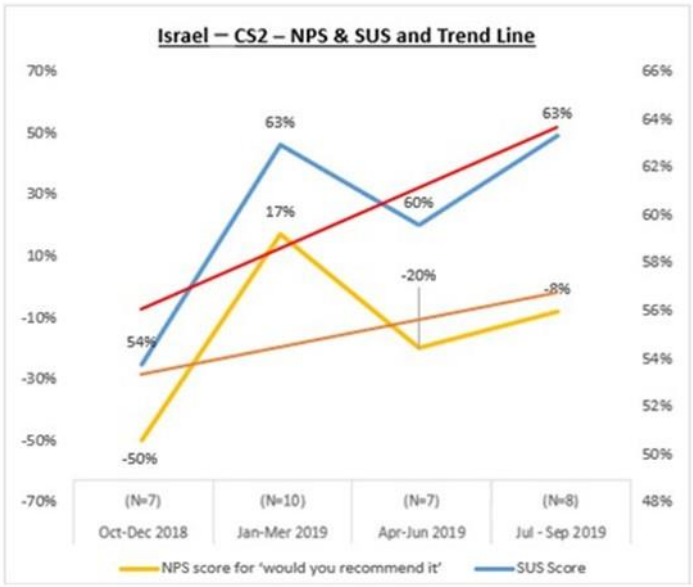

Figure 9 – Israel CS2 – Patient Satisfaction with the SMS Over Time

4.3.6.2 *Staff Assessment of and satisfaction with the digital tools (Fitbit, SMS and SACM)*

Staff satisfaction with all of the digital tools was measured using two assessment tools: The Net Promoter Score (NPS) tool, and the System Usability Scale(SUS). The NPS tool uses a Likert scale of 0= poor – 10 =good for four questions. The fourth question - How likely is it that you recommend the CONNECARE system to a family member or friend?" is used to calculate the Net promoter Score (NPS) by subtracting the percentage of Detractors from the percentage of Promoters. The NPS ranges between −100 and +100, a positive score is considered good.

The team was asked to answer the questionnaires anonymously three times during the study period - November 2018, March-May 2019 and at the end of the study. Six staff members answered the questionnaire, three CM nurses and three physiotherapists. The level of satisfaction was significantly different for the nurse case managers and the physical therapists and the results changed over the course of the study. The overall satisfaction of the nurse case managers increased significantly during the course of the study, although clearly, like the patients, they were much more satisfied with the Fitbit than the SMS app, and they were clearly not enthralled by the SACM. The level of satisfaction of the physical therapists with the Fitbit was similar to that of the nurse case managers although satisfaction declined during the course of the study. They were much less satisfied with both the SMS and the SACM and their satisfaction declined during the course of the study. The other measure of satisfaction was the System Usability Scale (SUS). The scores for both the SMS and the SACM for both groups of staff was

below average, although the SUS score increased for both groups by the end of the pilot. The detailed results can be found in the APPENDIX III Tables 12 and 13.

4.3.7 Issues with the digital tools as reported in the Implementation Log

4.3.7.1 *SACM & SMS usability problems*

- Since the technical staff did not enter the implementation log very frequently, many day-to-day urgent usability issues were reported directly to the technical staff via email or phone and were not reported in the log. Usability problems that were reported in the log were those of low or medium priority.
- Most of the problems reported by the case managers were regarding the SMS installation process and specific problems in the SACM use.

4.3.7.2 *Technical problems with SACM & SMS*

- Most of the technical issues reported under technical problems in the implementation log were bugs that needed to be prioritized and solved on a regular basis. Similar to usability issues, day-to-day urgent bugs were reported to the technical staff via email or phone and not reported in the log as they needed to be resolved immediately.
- Most of the problems reported in the implementation logs were suggestions for improving the usability and use of both the SMS and the SACM. For example:
    - Patients requested the ability to create their own tasks
    - Patients requested that the pop-up alerts make a sound and not just appear on the screen
    - The nurses proposed to change the graphs presenting the simple task's reports in the SACM.
    - The nurses proposed to change the order of graphs for physical activity in the SACM.

4.3.7.3 *Other Digital Health Tools*

- Most of the problems reported in this category in the implementation log related to the Fitbit and the Tablets given to patients
- Some were technical problems in using the devices, and some were more administrative problems, such as a patient who lost his watch or charger.
- Most technical issues were related to connectivity problems between the Fitbit watch and the app.

4.3.7.4 *Integration with other Information Systems*

There was no digital integration with other information systems although the possibilities were explored with the ICT departments of both Assuta Ashdod and Maccabi, which will lay the foundation for integration in the future.

4.3.8 Clinical Outcomes and Cost Effectiveness

4.3.8.1 *Intervention effectiveness - Health & wellbeing questionnaires (only intervention Before VS After)*

Health and Well-being were assessed in the intervention group only as the control group was extracted from the Maccabi database and had no contact with the project. The intervention group was assessed using the following instruments at the time of recruitment and at the point of discharge from the study:

- Barthel Index (Activities of Daily Living)
- Lawton Index (Instrumental Activities of Daily Living)
- SF12
- HADS
- EQ-5D
- Sweet 16

There was a positive improvement in patient status in all of the scales at discharge. However, there was a statistically significant decrease in pain discomfort and an increase in feeling of health as measured by EQ-5D-5L and significantly reduced levels of anxiety as measured by HADS. The full quantitative results for all scales can be found in APPENDIX III Table 15.

4.3.8.2 *Intervention effectiveness - Service utilization and costs (Intervention vs Control, Before vs After the Intervention)*

All of the service utilization and cost results were assessed by comparing the intervention group with the matched control group. In the Israeli intervention, the major objective was improved post-surgical outcomes including more effective post-surgery recovery as indicated by shorter length of stay, improved physical activity, improved feelings of overall health, reduced emergency room visits, and reduced readmissions to the hospital.

There was no difference between the intervention group and control group in number of emergency room visits both before, and after surgery and in fact, the number of ER visits was exceedingly low in both groups. Likewise, there was no difference between the two groups in number of hospitalizations per capita both prior to surgery and 30 days post-discharge, which was also very low for both groups. This is perhaps not surprising as both groups consisted of patients, albeit with multiple chronic conditions, who were hospitalized for an elective surgical procedure.

There were no mortalities in the intervention group and 3 deaths in the control group but this was not significant.

There were more visits to the GP in the intervention group than the control group both before and after surgery although not statistically significant, and virtually no difference in the number of visits to specialists. The intervention group also had higher pharmacy costs and higher "private institute" costs

(significantly including home rehabilitation, which is outsourced to selected "private providers" by Maccabi)

Total hospital costs and thus overall costs were higher for the intervention group during the intervention but lower for the period after the intervention. After analysis, the conclusion was that the costs **during the intervention** that included pre-habilitation, the hospitalization for the surgery itself and the post-discharge follow-up were due to three factors:

- Hospital costs as obtained from the Maccabi database included not only inpatient hospitalization but also visits to hospital out-patient departments, diagnostic tests etc. not necessarily related to the elective surgical procedure. There was no way to distinguish costs related to the surgery from other hospital related costs with no bearing at all. In fact, however, the difference between hospital related costs for the intervention group and control group was small - only €104.
- There is also the peculiarity of the Israeli reimbursement system. Most elective surgical procedures are paid by DRG – that is a flat rate per surgery regardless of length of stay. Therefore, length of stay is not reflected in hospital costs or overall costs.
- We hypothesized that intervention costs would be higher during the intervention due to higher patient adherence with the care plan. This is reflected most predominantly in higher pharmacy costs and higher "private institute" costs (including provision of home rehabilitation). Nurse Case Managers closely monitored patient adherence to medication regimens and assisted patients in more rapid access to other services.

However, the costs post intervention may be relevant as they are not affected by the above factors and therefore may indicate the potential sustainability of the effect of the integrated care intervention.

While due to small sample size, the results are not statistically significant, the differences in costs between the intervention group and the control group after the intervention are striking. The mean for total hospital-related costs in the intervention group was 48 Euros per capita as opposed to 369 Euros per capita in the control group and thus the mean overall costs post intervention were 332 Euro per capita for the intervention group compared to 551 Euros per capita in the control group.

Another relevant measure that is also masked by the Israeli reimbursement system is average length of stay for the surgical procedure. Overall Average length of stay for the intervention group was lower (2.48 days) than the control group (2.74 days) mainly due to orthopaedic surgery (2.56 days in the intervention group as opposed to 3.67 days in the control group) and general surgery (2.33 days in the intervention group as compared to 3.75 days in the control group. See APPENDIX III Tables 16-26 for detailed analysis.

4.3.8.3 *Cost effectiveness*

The cost of the intervention was calculated by estimating the costs of the implementation of the intervention as a routine service in Assuta Ashdod Hospital and Maccabi, based on relevant costs as we saw them in the study. The relevant costs in the study that we took into account were the costs of the nurse case managers in Maccabi that were hired specifically for the CONNECARE study, the hours reported by the physical therapists and the costs of the Fitbit (assuming that the Fitbits would be provided to patients free of charge as part of the service). In calculating the cost per capita for the nurse case managers, the assumption was that a full time nurse could handle a caseload of 200 patients (based on a similar program for remote monitoring already operating in Maccabi). For each patient in the intervention group the projected cost of the intervention was calculated by adding the estimated cost for implementation (248 Euro) to the average overall health costs for the intervention group, which than was compared with the average cost of the matched patients from the control group. The additional costs of the intervention itself as estimated made the intervention group more expensive during the intervention but less expensive during the post intervention period as noted above. In order to properly assess cost-effectiveness, this comparison needs to occur on a longitudinal basis and the costs of the two groups should be measured after 3 months, 6 months and a year. If the difference in the comparative costs of the two groups one month after the intervention persists over time, this may well affect the cost-effectiveness ratio. The detailed analysis can be found in APPENDIX III Table 27.

4.3.8.4 *Cost benefit*

While the cost of the intervention itself was relatively high, the benefits were also significant. The statistically significant decrease in pain discomfort and increase in feeling of health as measured by EQ-5D-5L and as well as the significantly reduced levels of anxiety are significant benefits and have potential implications for the sustainability of the intervention's effect long term. The comments of the patients, as well as the fact that almost 50% of the patients continued to use the Fitbit to monitor and improve their physical fitness after their discharge from the study may support the potential for long- term sustainability of the integrated care program.

4.4 Groningen

4.4.1 Recruitment Results

A total of one hundred and two patients were found eligible between May 2018 until October 2019. Fifty patients were recruited, and thirty-seven patients completed the 3 months study follow-up after surgery. The flow-chart demonstrates reasons for drop-out. We present the results of implementation study 2 of patients monitored with different tools and devices of the CONNECARE system.

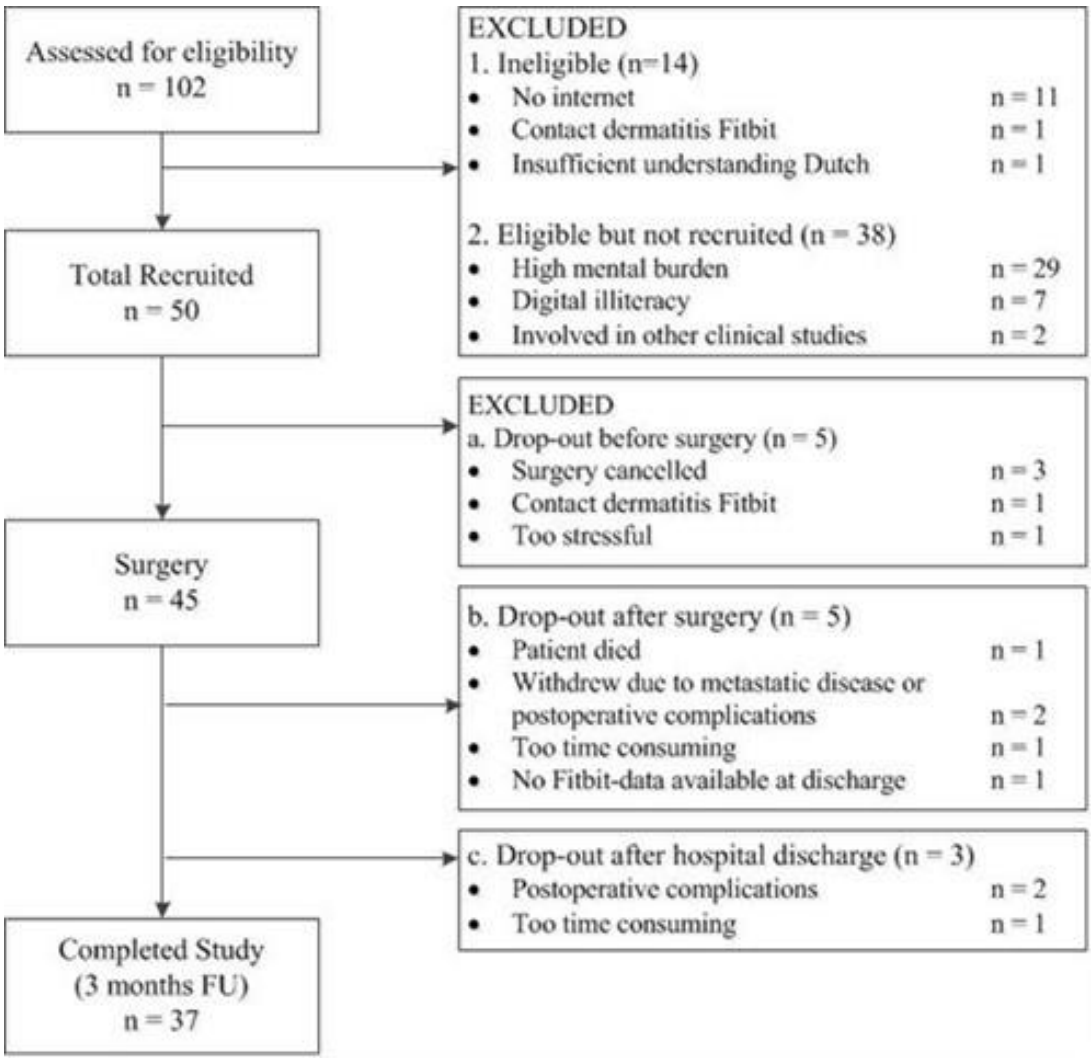

Figure 10 – Groningen CS2 – CONSORT Chart

4.4.1.1 *Main reasons for failure to recruit and for patient drop-out*

Difficulties in patient recruitment had several causes:

- At the start recruitment rates were low because screening of patients was based on the waiting list for surgery, and were approached by telephone

- Initially, recruitment of patients happened at one surgical department
- Reasons to decline study participation included: high mental burden, no internet access, digital illiteracy, insufficient understanding of the Dutch language and previous negative experience with research.
- Reasons for patient drop-out included: cancellation of surgery, postoperative decease, study withdrawal because of incurable disease, complications or contact dermatitis (Fitbit).

4.4.2 Implementation of the Integrated Care Service and model

In the implementation study the CONNECARE system was not integrated in existing care but ran in parallel to care-as-usual. Therefore, patients were not asked to complete questionnaires regarding collaboration and integration.

4.4.3 Issues reported in the Implementation Log – Organization and Process issues

- In terms of the project aims, due to the highly innovative character of the CONNECARE system, at the start of the project the end functionalities were still unknown.
- In terms of study planning, a delay in the start of the clinical study necessitated a re-shuffling of the available budget in order to extend the contracts of the case managers involved in the planning and execution of the study.
- In terms of system integration, delays were encountered due to an 'ICT-freeze' in the UMCG due to the implementation of an organization-wide new electronic patient dossier.
- Also, at the start of the project a research protocol was written for the proposed clinical study. However, the functionalities of the end-product were still unknown.

4.4.4 Evaluation of the implementation process

4.4.4.1 *Lessons learned from processes that worked well and successfully*

- During the first months of the study the participation rate was low. To solve this, eligible patients were mostly contacted face-to-face at the out-patient clinic instead of approached by telephone. The change in approach resulted in an increase in participation rate.
- Patients experienced usability problems (e.g. font size of text and icons too small) and rapid mobile data loss due to continuous synchronization of steps to the application when using the application on their own smartphone. In addition, a number of patients had an old smartphone not suitable to run the application. Finally, some participants who were interested in participating did not use a smartphone yet. To solve these issues, we provided all patients with study tablets.
- Login into the patient application with existing patients email addresses and own password appeared to be time consuming at installation and hard to remember for patients. Therefore, we

preinstalled all applications on the tablets and created usernames and passwords for study purposes.

- Some participants encountered difficulties connecting new devices to their home Wi-Fi-connection and reproducing instructions given at baseline. To solve this, baseline testing, instruction, and connecting to Wi-Fi preferably took place at home of the patients instead of in the hospital.
- Patients had more difficulty opening the Fitbit-application to synchronize the step count than was expected, which resulted in a considerably amount of telephone calls to the casemanager. To solve this, an instruction pamphlet with basic information about how to use the tablet and how to open applications was added to the instruction at baseline. The instructions were adjusted with perceived understanding of specific usability problems of patients already using smart-devices and applications. The first days of using the smart-devices, a part of the patients still called the casemanager with questions, but the explanation proved to be more effective when patients were referred to the paper instruction pamphlet at the same time.
- Some of the usability issues were due to slow Wi-Fi/Bluetooth connections. Especially the automated transfer of information of the weight scale to the application on the tablet showed considerable delays. To solve this issue, patients observed that it was easier to enter their weight manually, directly into the CONNECARE application without using the smart-weight scale.
- To improve the recruitment rate, collaboration with other surgical departments in the UMCG was arranged.
- To improve patient inclusion, collaboration with research nurses of the department of surgery was arranged. The research nurses saw new patients and screened the inclusion criteria before patients were approached for participation in the study.
- The case manager functioned also as helpdesk for the participating patients.

4.4.4.2 *Lessons learned from processes that did not work*

- In terms of privacy, due to the use of commercial products in an elderly population, product users were mailed often with commercial products of the industry (from Fitbit, From Nokia etc.). For the elderly it was hard to distinguish between relevant information for the project and spam.
- In term of system functionalities, in early versions of the deployment patients had to install 4 separate applications on their device in order to use to full system.
- Also, the system was fairly complex in its use, with patients being able to keep devices connected to the system and re-connect in case connections were lost.

4.4.5 Patient Engagement and Actual Usage of the ICT Tools and Devices

When the inclusion started, the home monitoring system was still under development. Therefore, ICT tools were step-wise added to the implementation study. Monitoring physical activity with the Fitbit started before surgery, until 3 months after surgery. Extended home monitoring for 2 weeks after hospital discharge following surgery, was performed with digital questionnaires and additional smart-devices (temperature, blood pressure, weight). Table 4.4.1.in APPENDIX IV demonstrates the number of patients that were prescribed monitoring with different tools and devices of the CONNECARE system, and their compliance to the measurements.

4.4.5.1 *Using the Pedometer (Fitbit) after surgery*

Use of the Fitbit was measured by the number of days that the Fitbit of each patient transmitted to the SMS app. Four patients dropped-out before completing 3-months follow-up. For the 37 patients completed follow-up of 90 days, the median (p25-p75) number of prescribed Fitbit use was 90 days, and the median (p25-p75) number of active Fitbit usage days was 86 (76.5-89.5). All patients were highly compliant in their use of the Fitbit and used it on a daily basis. Median (p25 – p75) compliance (% of prescribed days that Step Count was > 0 and transferred to SACM) was 95.6% (85% - 99.4%). Results are presented in Table 4.4.2.in APPENDIX IV.

4.4.5.2 *Using the messaging function of the SMS app*

The messaging function was not implemented from the beginning of the project, and when available it was decided not to use it in this implementation study. If contact with participants was necessary, it was mostly due to technical issues or alarming parameters, and telephone contact was preferred to messaging function.

4.4.5.3 *Responding to questionnaires*

The electronic questionnaires required for postoperative home monitoring for implementation study 2 in Groningen became available in the newest version of the SMS end 2018. From January 2019 two questionnaires were prescribed for 17 patients, who were asked to complete both questionnaires every day for 14 days after hospital discharge. Results on prescription and compliance are shown in table 4.4.1. in APPENDIX IV

Of the six patients who completed less than 50% of the questionnaires, four patients had a post-surgical complication or re-admission and three of the patients with complications decided to withdraw from the study. One patient thought it was too much time to invest, and decided to withdraw from the study. The last patient who had a low compliance reported he had internet problems during the first 2 weeks after discharge, and could not complete the 2-weeks intensive home-monitoring.

4.4.5.4 *Monitoring Vital Signs*

The detailed results for monitoring all of the vital signs can be found in APPENDIX IV Table 4.4.1.

- **Monitoring blood pressure.** The recording of blood pressure using the SMS app was with a smart-blood pressure monitor, the Nokia BPM, and was automatically transmitted from the Nokia Health Mate Application to the SMS. The first patients who used a Nokia blood pressure (BP) monitor were discharged from the hospital following surgery, in December 2018. Blood pressure monitoring was prescribed for 14 days. 27% of the patients monitored their Blood Pressure between 8-12 days and 40% of the patients monitored their blood pressure for more than 13 days.
- **Monitoring heart rate.** Although patients were not specifically asked to record their heart rate (HR), the tensiometer used (Nokia) provided this information in beats/minute (b.p.m.) automatically to the system when being used.
- **Monitoring body temperature.** Patients were asked to record their body temperature daily during the two weeks after surgery. The recording of body temperature using the SMS app was with a smart-thermometer, the Nokia Thermo, and was transmitted from the Nokia Thermo application to the SMS. Body temperature was measured by 33% of the patients between 8-12 days and by 30% of the patients for more than 13 days.
- **Monitoring body weight.** Patients were asked to record their body weight daily during the two weeks after surgery. The recording of body weight using the SMS app was first with the Nokia Body +, but this appeared difficult to use for patients. The three patients who had used the Nokia Body + suggested themselves to use the option to enter their weight manually into the SMS, and we asked the other patients to enter it manually into the SMS as well. 40% of the patients entered their weight into the SMS for 8-12 days and 20% (5 patients out of 25) entered their weight for more than 13 days.

4.4.6 Patient Satisfaction with the Technology

4.4.6.1 *Satisfaction with the CONNECARE system - Likert scales and Net Promoter Score (NPS)*

Satisfaction Likert scales at discharge (n = 36)

At discharge, patients were asked to assess their experience with the CONNECARE system (including the SMS app and linked Fitbit device).

Questions	Likert scale score (0 to 10)	
	Mean	SD
1. Overall satisfaction	7.4	1.2
2. Easiness of use	7.6	1.3
3. Ability to be used without help	7.1	1.8
4. Would you recommend it?	7.9	1.4

Net Promotor Score at discharge (n=36)

The answer to the question "How likely is it that you recommend the CONNECARE system to a family member or friend?" was used to calculate the NPS. The NPS score was +16.7%.

Score 'would you recommend it'	# patients (n=36)	% patients
0-6 (detractors)	5	13.9%
7-8 (passives)	20	55.6 %
9-10 (promotors)	11	30.6%

Satisfaction Likert scales at 3 months follow-up (n = 37)

At 3 months follow-up, patients were again asked to assess their experience with the CONNECARE system, now including SMS with questionnaires, Fitbit and additional smart-devices. Patient satisfaction was higher at 3 months follow-up that at the time of discharge.

Questions	Likert scale score (0 to 10)	
	Mean	SD
1. Overall satisfaction	7.8	1.5
2. Easiness of use	7.8	1.6
3. Ability to be used without help	7.6	1.8
4. Would you recommend it?	8.0	1.7

Net Promotor Score at 3 months follow-up (n = 37)

Score 'would you recommend it'	# patients (n=37)	% patients
0-6 (detractors)	5	13.5%
7-8 (passives)	16	43.2%
9-10 (promotors)	16	43.2%

The NPS score at 3 months follow-up was +29.7%.

4.4.6.2 *Satisfaction with the CONNECARE system – System Usability Scale (SUS)*

System Usability Score at discharge (n = 36)

At discharge, patients were asked to assess the usability of the CONNECARE system (including the SMS app and Fitbit devices) by means of the SUS. The median (p25-p75) SUS was 71.3 (53.8-83.8).

System Usability Score at 3 months follow-up (n = 37)

At discharge, patients were asked to assess the usability of the CONNECARE system (including the SMS app and Fitbit devices) by means of the SUS. The median (p25-p75) SUS was 80.0 (56.3-93.8).

4.4.7 Staff Satisfaction with the Technology

Implementation study 2 in Groningen was performed with the case manager (research nurse/ researcher) in control for all aspects of patients' identification, recruitment, data collection and follow-up. As such, treating physicians were not primarily involved, as the CONNECARE implementation study was performed as a research study, running in parallel with care-as-usual. Therefore, as other care personnel were not primarily involved in the CONNECARE study they were not asked whether they were satisfied with the technology. At the moment, a qualitative study in underway at the department of surgery to investigate what the needs and belief are of care professionals with regards to the concept of CONNECARE.

4.4.8 Issues with the digital tools as reported in the Implementation Log

4.4.8.1 *SACM & SMS usability problems*

- Problems arose regarding mobile data; due to connection problems and the data request of the new installed apps and smart devices. The patient used all mobile data (more than the patient paid for every month). This led to extra costs from the phone company for the patient.
- In terms of usability, during the developing process only releases for Android were made available. All potential inclusions using iOS (Apple) could not be included. Besides, if patients were not in possession of a smartphone inclusion was not possible.

4.4.8.2 *Technical problems with SACM & SMS*

- During the study some patients encountered connectivity issues at their place of residence. Sometimes the devices disconnected and or Wi-Fi settings were wrong. Leading to a loss of data as the data was no longer shared with the SACM and therefore with the hospital.

4.4.9 Patient Outcomes

Patients were a median of 7 days (IQR 4-14.5) admitted to the hospital and a total of forty-seven postoperative complications were scored. An overview of postoperative complications is presented in the following Table.

Postoperative complications (n=47), n (%)	
Complications < 90 days?	30 (63.8)
Clavien Dindo Grade 1	13 (27.7)
Clavien Dindo Grade 2	7 (14.9)
Clavien Dindo Grade 3A	1 (2.1)

Clavien Dindo Grade 3B	7 (14.9)
Clavien Dindo Grade 4A	1 (2.1)
Clavien Dindo Grade 5	1 (2.1)
Complications at home	18 (38.3)
Hospital readmissions < POD 90	9 (17.6)
Median time for readmission hospital discharge (days, range)	6 (range 3 – 81)

4.4.10 Intervention Effectiveness

Health and Well-being questionnaires

We do not have results on the effectiveness of the eHealth intervention as such, as we have not compared the results of health and well-being questionnaires with a control group without eHealth intervention. We do have results on health and well-being questionnaires before and after surgery of all patients, as shown in the Table 4.4.3 in APPENDIX IV. There was a slight but significant decrease in ADL, and a decrease in depressive symptoms over time. Frailty, IADL, anxiety and quality of life did not significantly differ before and after surgery.

Service Utilization

A total of nine hospital readmissions were scored, 17.6% of the total number of patients recruited. The median time from hospital discharge until readmission was 6 days (range 3 - 81 days). Of all postoperative complications detected, eighteen (38.3%) occurred at home. Information on visits to the general practitioner could not be collected. These results confirmed our hypothesis at the start of the implementation study that complications at home and hospital readmission did occur frequently after cancer surgery in elderly patients (age 65 or older). Of the nine hospital admissions observed, one could have been predicted by the mobile devices connected to the SACM, but could not have been prevented. More patient data is required in order to establish more firm correlations between remote monitoring and early identification of complications. Therefore, we will continue patient inclusion using the CONNECARE study protocol and ICT system until we reach approximately 80 patients next year, on which the observational study was originally powered statistically.

Costs and Cost Effectiveness

Due to the lack of a suitable control group available for analyses, an analysis of cost-effectiveness could not be performed in our site. Direct and indirect costs of the intervention were all covered by the project budget allocated to us as clinical site. The majority of the costs constituted hiring research personnel to

act as case managers for both implementation studies. A more comprehensive and in-depth analyses should be performed in future studies, with a rigorous set-up of the control group to enable comparative analyses.

Physical Activity

Data from the first 50 patients were used in a sub-study to investigate recovery of physical activity after surgery in elderly cancer patients. To better inform patients on the possible postoperative course, the aim of this sub-study was to quantify physical activity by accelerometer-based activity wearables preoperatively, during hospital admission until discharge and three months after surgery. Of all patients, Fitbit data of 40 patients was analysed at hospital discharge, and of 37 patients at three months follow-up. Median step count at baseline, before hospital discharge and three months follow-up was 5974 (IQR 4250 – 7922), 1619 (IQR 920-2839; 27% of baseline) and 4674 (IQR 3047 – 7592; 85% of baseline), respectively (Figure 11-A and B). Two of the 40 patients (5%) and fifteen of 37 patients (41%) achieved recovery of physical activity at ≥ 90% of baseline step count at hospital discharge and on three months postoperative, respectively (Figure 12). Further analysis is being performed to identify patient characteristics that are predictive to enhance complete recovery of physical activity at 3 months after surgery.

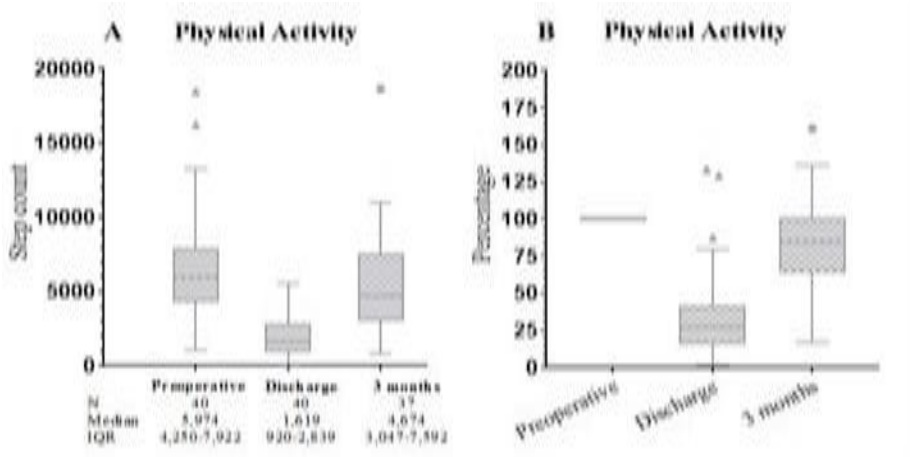

Figure 11 – Groningen CS2 – Absolute and relative step count for all patients

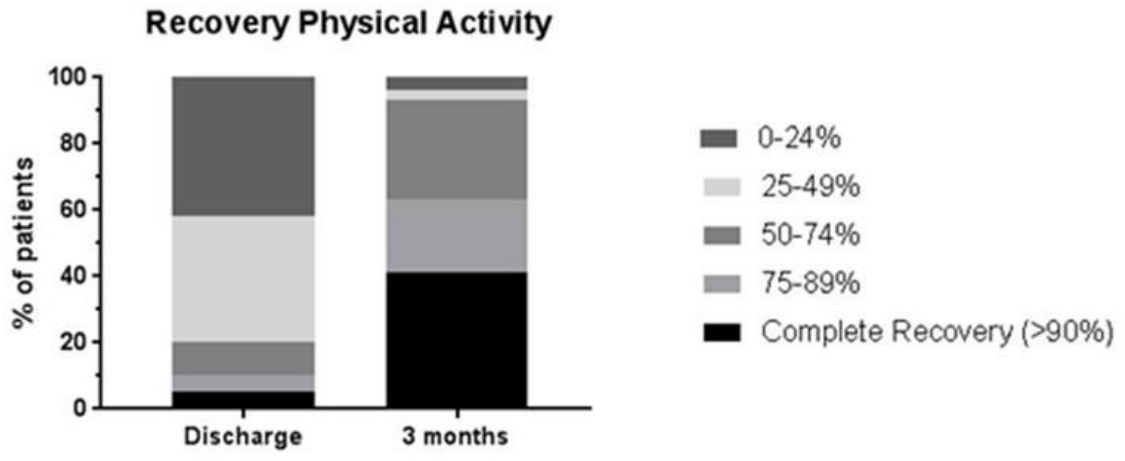

Figure 12 – Groningen CS2 – Overview of patient recovery over time

4.5 Summary of All Sites

4.5.1 Satisfaction with the CONNECARE Integrated Care Service

Overall, the patient satisfaction with both the service and the technology was positive although there were some significant differences among the sites. While different measures were used to assess the service itself as opposed to the technology, it is fairly clear, particularly from patient comments, that the two were very intertwined in the eyes of the patient. As CONNECARE is an integrated care project, the assessment of the service focused on to what extent patients perceived the service as being patient cantered and meeting their needs and to what extent they perceived the care they received as "integrated" i.e. that there was coordination and continuity of care among healthcare professionals. This was explicitly measured by Lleida and Israel, using the P3CEQ and the NCQ for all of the patients in the intervention group. In Barcelona, this was measured only for the sub-sample of patients who used MyPathways@ for pre-habilitation and not for the entire intervention group receiving pre-habilitation, as pre-habilitation was already an existing service in Hospital Clinic. Responses were very positive for both measures in Lleida and Israel. In Israel, two areas were perceived as particularly problematic for patients: the lack of sufficient involvement of family members and insufficient attention to issues they perceived as important in managing their own care. In Barcelona, there were positive results for both P3CEO and NCQ measures.

Staff engagement and satisfaction with the service was addressed by all of the sites as is indicated in the sections addressing processes that did and didn't work and in the deliverables on PDSA in WP2. In Barcelona and Lleida there were regular staff meetings but only a limited number of staff members were directly involved in all aspects of the CONNECARE Project. In Israel, there were also regular staff meeting among direct project staff. In Groningen, only the Case manager hired for the project was

directly involved, but Groningen is performing a qualitative study among surgery department staff. Barcelona addressed some of the staff issues in the mini-Mast evaluation of the use of digital tools. In Israel, staff engagement and satisfaction with the integrated care service was explicitly measured using the ACT@Scale. The results of this assessment showed that CONNECARE program staff had a clear understanding of what the project was trying to achieve and firmly believed that patients were benefiting from it. Major issues that surfaced from all sites were the need for intensive staff training, both from a service perspective and in the use of the digital tools. Staff needs to be involved in the design of the organizational processes and their modification as time progresses based on experience. The need for full integration of new digital tools with the existing ICT systems that staff are used to working with (EMR in the hospital and in primary care) is essential for success and ultimate integration into routine care. The need for broader professional staff involvement both in the hospital and the community as well upper level management involvement and support was also highlighted as being very important to successful implementation.

4.5.2 Compliance and Satisfaction with the Digital Tools

With regard to the supporting technology, there was high compliance in Lleida, Israel and Groningen in the use of the Fitbit but lower compliance in the use of the SMS app. The messaging function only became available very late in the process and was underutilized. This was particularly evident in Israel although a time-series analysis showed that patients recruited after the function became available, used it more frequently than patients who began without it. Lleida's population used this function frequently, but it should be noted that the SMS was used primarily by the patients' carers, whereas in Israel it was used exclusively by the patients themselves. Answering the questionnaires through the SMS app was variable among the sites ranging from good to fair when prescribed in Lleida and Groningen and poor in Israel where patients did not perceive the value. Vital signs monitoring, where prescribed, was carried out with a high degree of compliance although not necessarily at the frequency prescribed, particularly when the patients were asked to measure more than once a day. Overall, the satisfaction with the technology as measured by Likert Scales/NPS score and SUS was relatively high, despite a significant number of problems along the way. Israel measured satisfaction with the Fitbit and the SMS app separately and there was significantly higher satisfaction with the Fitbit than the SMS. Both Lleida and Israel performed a time- series analysis of satisfaction with the SMS that clearly shows that the maturity of the app had a strong influence on satisfaction levels. Patients recruited later, after many bugs had been resolved and usability significantly improved, showed much higher satisfaction than patients recruited earlier. This is an important finding as the major objective of the implementation pilots was to further refine and improve the technology based on input from patients and staff during the course of the pilots, resulting in a more mature product at the end of the project. Barcelona implemented the digital tools as part of pre-habilitation with a small number of patients with a moderate degree of patient satisfaction.

Staff satisfaction with the technology was much lower in all sites. There was low satisfaction with the SACM in Lleida, Israel and Groningen (Barcelona did not even attempt to use it except in one very limited trial). This was partially because the SACM was a work in progress throughout the project and staff members had significant frustration, particularly in the early stages, with bugs and technical issues. However, the fact that it was used as a stand-alone and the lack of integration with existing systems was a major problem. Staff was often required to double enter (into the SACM and the regular EMR) and although Lleida successfully used the SACM for intra- staff coordinations, Israel found WhatsApp a much more user-friendly tool for communication among the staff.

4.5.3 Effectiveness of the Interventions

Implementation Study 2 focused on preventive patient-centred interventions in complex chronic patients undergoing elective major surgical procedures. The aim of the intervention was to reduce undesirable post-surgical events and enhance health outcomes by a digitally supported and integrated patient-centred preventive intervention in the peri-surgical period - before, during and after the surgery. The CONNECARE model consisted of two major components: an organizational model for integrated care and a technological platform to support the integrated care organizational processes. The four pilot sites focused their attention on different aspects of the organizational model, with some variation in the implementation of the digital tools focusing on somewhat different target populations (age and surgical procedures), although all were high-risk elderly patients undergoing an elective surgical procedure. The differences among the sites serve to highlight the value of different aspects of the process, which, taken as a composite, increase the breadth of the findings.

Barcelona focused primarily on pre-habilitation as a significant part of the integrated care service for reducing post-operative morbidity and improving post-surgery health outcomes with very positive results. The original RCT demonstrated lower post-operative complications for patients undergoing pre-habilitation. The secondary outcomes analysis performed within the context of CONNECARE showed significantly increased aerobic capacity in pre-habilitation patients at 3 months post-surgery compared to baseline and better post-operative functional recovery with higher daily physical activity compared to baseline than the control group at 6 months post-surgery. In addition, there was a significant difference in 30-day hospital readmission – 3% in the pre-habilitation group as opposed to 18% in the control group who received usual care. A further study identified the characteristics of patients with a higher likelihood of completing the pre-habilitation program. For Israel, the Barcelona pre-habilitation model was a key component of the integrated care service, with the addition of a 3 month post-discharge monitoring and follow-up. Patients showed improvement in all health and well-being measures at discharge from the program compared with pre-surgery baseline but most significantly in decrease in pain discomfort, increased feelings of overall health and reduction of anxiety. Length of stay was lower in the intervention group than in the control group. Healthcare costs were higher in the intervention group during the intervention, which was anticipated as patients were more adherent to their post discharge care plan

including more GP visits and adherence to medication regimes resulting in higher pharmacy costs among others. Also, the lower length of stay was not reflected in hospital related costs due to the Israeli flat-rate for procedure reimbursement system. However, post intervention, the costs for the intervention group were strikingly lower than the control group and this remained true even when the cost of the intervention was added to the healthcare expenditures. In Lleida, pre-habilitation was only prescribed for selected patients and monitored by primary care, but, like Israel, patients received 3 months of close post-discharge monitoring and follow-up. The Lleida intervention group showed improvement on all health and well-being measures, but not significantly greater than the control group. However, being in the CONNECARE program significantly reduced the total number of unplanned hospital visits and the cost-effectiveness analysis indicated that the CONNECARE program was more cost effective than standard care even when considering scenarios with increased costs of the program. Groningnen targeted cancer patients undergoing surgery to remove a solid tumour and therefore anticipated a relatively higher rate of post-operative complications and readmissions. Groningen focused on monitoring vital signs and encouraging physical activity using the CONNECARE platform (Fitbit + SMS with SACM used by the case manager for monitoring) and was able to show a significant post-operative physical activity recovery at 3 months follow up post-surgery.

In summary, the results of Implementation study 2 would seem to indicate that the CONNECARE digitally supported integrated perioperative care model seems to be cost effective as well as cost-beneficial. It is important to add that, due to the limitations in terms of sample size, heterogeneity of the interventions and some of the outcome measures, these results need to be validated, both by comparing intervention and control groups over time (at 6 months and a year post-discharge), and in larger scaled up programs, using more mature technology, and more rigorous evaluation, before drawing final conclusions.

5. Roadmap toward perioperative care

The results reported in D6.3 and D6.4 provide a strong rationale for perioperative care in all of the sites. In HCB, the results support expanding the ongoing programs addressing scalability with a portfolio of modular and personalized services with a population-based orientation. In this regard, Barcelona faces two major challenges: the consolidation of robust technological tools supporting ACM and collaborative work that generate added value to the clinical services enhancing accessibility and decreasing costs; and improving risk assessment and service selection through dynamic multilevel predictive modelling. Progress achieved in these two areas: technology and risk prediction should provide the basis for formulation of proposals toward personalized preventive services supporting perioperative care that should result in citizens' empowerment for self-management and cost-efficient healthcare. Moreover, these interventions show high potential for transferability to cardiovascular rehabilitation of chronic patients.

The above is also relevant for the other sites. Both Lleida and Israel agree that the results reported in this deliverable will form a strong basis for expanding the deployment of digitally supported and integrated perioperative care at both regional and national levels and Groningen sees potential for moving from a relatively stand-alone project to subsequent integration in regular care. Patient satisfaction with the integrated perioperative care and its perceived benefits in the preparation for and recovery from surgery, as well the healthcare outcomes and resource utilization results indicate that this approach has significant potential for accelerating the shift toward integrated, patient-centred care.

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8. Appendices

Barcelona Appendices

Lleida Appendices

Israel Appendices

Groningen Appendices

APPENDIX I

Barcelona – Implementation Study 2

Determinants of program completion and postoperative morbidity in patients undergoing prehabilitation (Protocol II)

(Manuscript to be submitted for publication)

Determinants of PROGRAM completion and postoperative morbidity in patients undergoing multimodal prehabilitation: A cohort study

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ABSTRACT

Introduction: Prehabilitation has shown to be an effective intervention to improve postoperative outcomes in patients undergoing major surgery. However, customization of the prehabilitation services to patients' characteristics is an unmet need. The current study aims to identify factors associated to program completion, and to postoperative morbidity, in patients undergoing to digestive, gynaecologic and urologic major surgeries.

Methods: This was a cohort study including patients enrolled in the prehabilitation unit of Hospital Clinic de Barcelona, from June 2017 to December 2018. The prehabilitation program included 5 main interventions: i) motivational interviewing; ii) supervised exercise training; iii) promotion of physical activity; iv) nutritional optimization; and, v) psychological support. Prehabilitation completion was defined as attending ≥ 80% of appointments.

Results: Of a total sample of 200 patients, 120 (60%) completed the program. Among completers, 62 did not suffer from postoperative complications (52%). Undergoing oncologic surgery (24.5 [3.9-153.8]; p= 0.001), suffering from endocrine and metabolic diseases (3.8 [1.2-12.3]; p= 0.025) and willingness to participate in mindfulness sessions (OR [95% CI] 3.1 [1.03-9.15]; p= 0.044) were associated with program completion, while being older (0.93 [0.88-0.97]; p= 0.002) was related to lower probability of completion. Among completers, higher baseline fitness (Duke Activity Status Index) (0.95 [0.91-0.999]; p= 0.019) and higher risk of malnutrition (Malnutrition Universal Screening Tool) (1.8 [1.1-3.1]; p=0.023) were related to postoperative morbidity.

Discussion: The current study identifies actionable factors useful to personalize prehabilitation programs which may facilitate effectiveness and sustainability of the service.

Key words: prehabilitation; adherence; exercise training; nutritional optimization; mindfulness.

INTRODUCTION

Surgery represents a major metabolic stress associated with a significant reduction in both physiological and functional capacity[1]. This acute situation places patients at risk of postoperative morbi-mortality and may complicate the recovery phase[2]. It is well-accepted that successful surgery outcomes are not only conditioned by the magnitude of the operation, but also by the patient's physical and psychological status[3,4].

During the last years, multimodal prehabilitation has been postulated as an effective intervention to improve postoperative patient outcomes after surgery by means of a bundle of preoperative actions including exercise training, nutritional optimization and psychological support, among others[4–9]. However, considerable non-completion rates have been reported, which may be blunting the effects of the intervention. Given the short time span of prehabilitation programs, determined by the length of the period between candidates' detection and surgery, it is critical to ascertain the factors conditioning patients' adherence and response in order to refine the service and optimize its outcomes.

To our knowledge, only one study[10] has assessed factors influencing adherence to prehabilitation by means of a survey gathering patients' perspectives on the program. In this descriptive study, by Ferreira V and colleagues[10], patients reported transportation issues as the biggest barrier for prehabilitation sessions attendance. However, prospective studies on this topic, combining qualitative and quantitative data from different domains, are required.

The current investigation was focused on a twofold aim using a multilevel approach. We firstly explored the determinants of prehabilitation completion and, among prehabilitation completers, we additionally analysed the factors associated to postoperative morbidity. The final objective was to identify key factors to take into account in order to redesign the current perioperative care unit at Hospital Clínic de Barcelona.

METHODS

Study design and subjects

This investigation assessed the cohort of patients included in the prehabilitation unit at Hospital Clínic de Barcelona. Briefly, all eligible patients fulfilled the following criteria: i) Undergoing to elective digestive, gynaecologic and urologic major surgeries; ii) high-risk for surgical complications defined by age > 70 and/or American Society of Anesthesiologists (ASA) risk classification 3-4[11]; and/or ii) unfit subjects (defined by Duke activity status index (DASI)[12] < 46) undergoing highly aggressive surgeries; iii) estimated preoperative schedule allowing for at least 4 weeks of prehabilitation; and, iv) agreement to participate in the program. For the present investigation, we included patients whom have attended at least to the visit for prehabilitation baseline assessment. Undergoing non-elective surgery was an exclusion criterion. The informed

consent was approved by the Ethics Committee for Medical Research of Hospital Clínic de Barcelona (HCB/2016/0883; Approval date April 18, 2017) and all subjects included understood, accepted, and signed it.

Interventions

For logistic reasons (capacity of the training facilities) we conducted two different types of multimodal prehabilitation programs (programs A and B) aiming to enhance patients' clinical status. Program A included: i) a motivational interview; ii) a physical activity promotion plan; iii) nutritional management; and, iv) psychological support. Program B included, in addition to all the elements of program A, a hospital-based supervised high-intensity exercise training intervention. The later was done only in patients with relevant comorbidities conditioning physical fitness and/or undergoing to highly aggressive surgeries (e.g. esophagectomy, total gastrectomy, pelvic exenteration).

The main aims of the motivational interview were to co-design the characteristics of the physical activity plan while reinforcing patients' motivation and to raise the compromise with the behaviour change regarding the program objectives.

The program promoting physical activity consisted on increasing patients' daily steps based measured by a pedometer and/or optimization of walking intensity, assessed by the modified Borg scale[13]. International recommendations on step-based physical activity[14] were used as a theoretical framework to set up the objectives. Patients were scheduled for a weekly visit at the prehabilitation unit to follow-up and refine physical activity objectives.

Patients received personalized dietary counselling from a registered dietician. Based on the initial evaluation, patients received recommendations of a healthy balanced diet or a diet adapted to their digestive symptoms, as appropriate. The daily amount of protein intake capable of producing a positive nitrogen balance in these patients is estimated to be close to 2 $gr \cdot Kg^{-1} \cdot day^{-1}$. This protein intake (1.5-2 $gr \cdot Kg^{-1} \cdot day^{-1}$) was assured in patients with adequate kidney function, distributed in three main daily meals, by means of food enrichment, and/or nutritional supplementation such as whey protein powder or casein. Sufficient caloric supply was assured as a mean to guarantee proper protein utilization.

All patients were invited to attend weekly mindfulness group sessions. This intervention was specially recommended to those patients showing higher signs of anxiety/depression (defined by hospital anxiety and depression (HAD) scale[15] > 8) . The sessions (90 minutes of duration each) included breathing and relaxation exercises conducted by an expert psychiatrist or psychologist. The final aim was to reduce the levels of stress, anxiety, and depression of the patients.

The supervised exercise training sessions consisted of a high-intensity endurance training performed on a stationary cycle-ergometer (*Technogym® Excite Bike; Cesena; Italy*) and strength muscular training (*Technogym® Plurima Multistation Wall; Cesena; Italy*). Patients' underwent 2 to 3 sessions per week. Each endurance training session included 5 minutes of warm-up, 37 minutes of interval training, and 5 minutes of cool down. The interval training combined 3 minutes of high-intensity pedalling and 3 minutes of active rest. Work-rate progress during the program was tailored on an individual basis, according to patients' symptoms (modified Borg scale)[13], to maximize the training effect. The strength training session consisted in 3 series of 15 repetitions for each of the following exercises: i) horizontal rowing; ii) pectoral press; and, iii) quadriceps bench. Weight progress during the program was adapted to patients' tolerance with the final aim of maximizing the training effect.

Procedures

Briefly, we obtained baseline data from all patients included in the multimodal prehabilitation program: i) sociodemographic variables: age, sex and smoking status; ii) environmental variables: area of residence; iii) clinical variables: haemoglobin, body mass index (BMI), Canadian study on health and ageing (CSHA) clinical frailty scale[16], steps per day, willingness to participate in mindfulness sessions, type of surgery, neoadjuvancy, age-adjusted Charlson index[17], comorbidities, malnutrition universal screening tool (MUST) score[18], DASI[12], six-minute walk distance (6MWD)[19], hand-grip and Yale physical activity survey (YPAS) score[20]; and, iv) psychological variables: HAD scale[15].

Study outcomes

To explore factors associated to adherence to the prehabilitation program, we defined program completion as attendance to at least 80% of the program appointments. Among patients who completed the program, we stratified patients in two groups, namely: patients suffering postoperative complications and patients not suffering postoperative complications. Severity of postoperative complications was assessed using the Dindo-Clavien criteria[21].

Statistical analysis

We performed a sensitivity analysis, to deal with the possibility of bias due to missing data, using a multiple imputation with the method of chained equations assuming the hypothesis of missing-at-random[22,23]. The available sample size was fixed by the current number of patients attended in the prehabilitation unit of our hospital. To analyse the determinants of study completion and response to intervention, we first compared the individual characteristics (sociodemographic, clinical and psychological) at baseline between non-completers and completers, and between patients suffering postoperative complications and patients not suffering postoperative complications using unpaired Student's t-test, Wilcoxon rank-sum, Chi-square or Fisher's tests,

depending on the variable distribution. Second, we built two multivariable logistic regression models (one for study completion and one for response to the program) including as exposures all variables that showed statistically significant differences in the bivariate analysis between non-completers and completers, and between patients suffering postoperative complications and patients not suffering postoperative complications, respectively. We used backward and forward strategies considering clinical as well as statistical criteria to decide the final variables to be included in the models. A p-value <0.05 was considered statistically significant.

RESULTS

Between June 12th, 2017 and December 31st, 2018 a total of 224 patients undergoing the target surgeries were included in the multimodal prehabilitation program. Twenty-four (11%) out of the 224 patients did not receive surgery and, thus, were excluded from all analysis (**Figure 1**). **Table 1** depicts the characteristics of the overall study group (n=200) and, separately, patients undergoing physical activity promotion (group A, n= 81), as well as those additionally following exercise training (group B, n=119).

Overall, patients had a mean (SD) age of 70 (11) years and were mostly male (73%). 88% of them underwent oncologic surgery and 23% received neoadjuvant treatment. Patients had a large prevalence of comorbidities with an age-adjusted Charlson index of 5.4 (2.1).

Patients enrolled in program B showed higher frailty level (measured by the CSHA clinical frailty scale) higher ASA index, higher comorbidities prevalence, and lower functional status (measured by the DASI) than those who were included in program A (**Table 1**).

Determinants of prehabilitation program completion

Overall, a total of 80 patients (40%) attended to less than 80% of the scheduled program sessions. From the total range of baseline variables, age, willingness to participate in mindfulness sessions, undergoing oncologic surgery, neoadjuvance therapy, ASA index, endocrine and metabolic diseases, renal disease, hepatic disease, neurologic disease, 6MWD and hand grip strength were significantly different between completers and non-completers (**Table 2**). In the multivariate analysis, undergoing to oncologic surgery (24.5 [3.9-153.8]; p= 0.001), suffering from endocrine and metabolic diseases (3.8 [1.2-12.3]; p= 0.025) and willingness to participate in mindfulness sessions (OR [95% CI] 3.1 [1.03-9.15]; p= 0.044) were related to higher probability to complete the program, while being older (0.93 [0.88-0.97]; p= 0.002) was related to lower adherence.

Determinants of postoperative morbidity

Among completers (n=120), 62 patients (52%) showed no complications during the postoperative period. Mean (IQR) number of postoperative complications per patient was 0.95 (0-1.5), ranging from 0 to 6 complications (mode=0), following a non-parametric distribution. The Dindo-Clavien distribution of the complications was as follows: 73% minor (40 % type 1; 33% type 2); and 27% major (10% type 3a; 10% type 3b; 5% type 4a; and, 2% type 5). No significant differences in postoperative complications were found between completers and non-completers.

The type of surgery, MUST score, DASI score and depression score of the HAD questionnaire at baseline were different between patients suffering and not suffering postoperative complications (**Table 3**). The multivariate analysis showed that lower fitness level, as measured by the DASI (0.95 [0.91-0.999]; p= 0.019), and higher risk of malnutrition, measured by the MUST (1.8 [1.1-3.1]; p=0.023), are independent factors associated to high postoperative morbidity.

DISCUSSION

This is the first study assessing the determinants of completion to prehabilitation on perioperative morbidity in patients undergoing major surgery.

Main findings of the investigation of factors associated with adherence to prehabilitation are: i) Undergoing oncologic surgery, suffering from endocrine and metabolic diseases and willingness to participate in mindfulness sessions are factors positively related to a higher probability to complete the prehabilitation program; while, (ii) being older is related to lower adherence. The study also shows that postoperative morbidity is independently associated to low physical fitness, measured by DASI, and to risk for malnutrition, assessed using MUST.

Regarding the impact of oncologic surgery on adherence, we hypothesize a potential relationship between self-perceived health status and motivation for prehabilitation. The newly diagnosed malignancy might contribute to make the patient more receptive to lifestyle changes (teachable moment) and, therefore, increases patients' eagerness to participate in the program. In this line, patients expressing willingness to participate in the mindfulness sessions at baseline were also more likely to complete the program. These findings underline the important role of motivation towards prehabilitation, which has been previously showed as an important factor for physical activity in chronic patients[24,25] and elderly subjects[26]. Therefore, we believe that the present study reinforces the role of the motivational interviewing, among other behavioural interventions, as one of the key actions to be included in a prehabilitation program. In that sense, the use of information and communication technologies to promote lifestyle changes (i.e. mHealth, eHealth) is a potential effective tool to be tested in this scenario[27]. Consequently, assessments on motivation and self-efficacy [28,29] should be performed to monitor these type of interventions.

The literature shows controversial results about the effect of diabetes on self-management and cardiopulmonary rehabilitation adherence[30–32]. In the current investigation, we found endocrine and metabolic diseases (including diabetes, dyslipidaemia and overweight/obesity) as independent factors positively associated to prehabilitation program completion. We consider, however, that further research is needed in order to clarify if adherence shows disease specific relationships or it can be mostly influenced by patients' perception of disease severity. Interestingly, unlike the literature on cardiopulmonary rehabilitation and self-care in chronic conditions[33–36], our study has not found anxiety and depression levels as being predictors of poor attendance to prehabilitation. One could argue that while chronic patients have been adapting gradually to their conditions over the years, in prehabilitation patients, the impact of the recent diagnosis and the implications of a major surgery generate a favourable momentum to raise adherence to the program, irrespective of the impact of the chronic process on anxiety and depression status.

We hypothesize that a moderate negative impact of age on adherence can be mostly associated to low performance status leading to transport difficulties to the prehabilitation centre, previously reported as a barrier in both rehabilitation[35,37] and prehabilitation[10] services.

Proper cardiopulmonary and lean body mass reserves[38,39] are required to meet the demands of surgical stress response, namely: increased both oxygen uptake[40] and whole body catabolism[41], among others. Consistently with the existing literature[42,43], our study found that simple tools to assess baseline both fitness and nutritional status (DASI and MUST scores, respectively) reliably predict surgical outcomes in the context of a prehabilitation program. These findings highlight the need to identify patients who may require intensified prehabilitation programs, with special attention on nutritional optimization and exercise training.

Conversely, supervised high-intensity exercise training was not showed as a factor related to lower risk of suffering postoperative complications. However, it is worth noting that our unit, due to capacity reasons, prioritise multimorbid patients at higher risk for surgery and patients with lower fitness status to be included in this supervised training program, as stated in the methods section of the current manuscript and showed in **table 1**. Therefore, equal efficacy for prevention of postoperative complications of a high intensity exercise training program and a plan promoting walking-based physical activity cannot be concluded from the current investigation due to group differences.

Study limitations

The current research shows some study limitations such as lack of data of patients rejecting to be included in prehabilitation and absence of control group. However, while fully acknowledging these shortcomings, a major strength of the study relies in the fact that prehabilitation was

administered to consecutive patients from three different types of surgery (digestive, gynaecologic and urologic), as a mainstream service of our hospital. Therefore, the results can be qualified as "real life" novel findings showing advantages over other reports based on research-oriented study designs.

Conclusions

We can conclude that enhanced adherence to prehabilitation will require implementation of modular and decentralised programs, including personalized behavioural interventions, using resources and facilities at community level. Moreover, postoperative morbidity may be reduced by optimizing exercise training and nutritional interventions in terms of both intensity and duration.

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AB-G wrote the first draft of the manuscript and did the statistical analysis. AB-G also contributed to perform the intervention, to the study design, data collection and interpretation and contributed to and approved the final version of the manuscript. AH, EG-S, BR, BC, PH, ST contributed to perform the intervention, to the study design, data collection and interpretation and contributed to and approved the final version of the manuscript. DC, FD, RR, ML-B, AL, MMM, BT, FV, MC-M, RN-R, MU, MJA and GM-P contributed to the study design, data collection and interpretation and contributed to and approved the final version of the manuscript. JR contributed to the study design, data interpretation and contributed to and approved the final version of the manuscript. We would like to acknowledge Dr Raquel Sebio, Ms Victoria Alcaraz and Technogym for their collaboration to the achievement of this work.

COMPETING INTERESTS

The authors declare that they have no conflict of interests.

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APPENDIX

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	All patients n=200	Program A n=81	Program B n=119	p-value
Sociodemographic variables				
Age (years), m (SD)	70 (11)	71 (11)	70 (11)	0.764
Sex: male, n (%)	145 (73)	55 (67)	90 (76)	0.093
Smoking status, never smoker, n (%)	72 (36)	35 (43)	37 (31)	0.222
Environmental variables				
Area of residence				
Reference area of the hospital, n (%)	121 (61)	50 (62)	70 (59)	0.202
Rest of Barcelona city, n (%)	28 (14)	7 (9)	21 (15)	
Barcelona metropolitan area, n (%)	31 (16)	13 (16)	18 (15)	
Rest of Catalonia, n (%)	20 (10)	9 (8)	11 (14)	
Clinical variables				
Haemoglobin, ($g \cdot dL^{-1}$)	13.0 (3.8)	13.2 (3.4)	13.0 (4.4)	0.700
BMI (kg/m^2), m (SD)	27 (5)	27 (5)	27 (6)	0.512
CSHA clinical frailty scale, m (SD)	2.4 (1.1)	2.2 (1.0)	2.6 (1.2)	0.040
Willingness to participate in mindfulness sessions, n (%)	85 (43)	39 (49)	45 (39)	0.187
Type of surgery,				
Digestive surgery, n (%)	152 (76)	59 (73)	92 (78)	0.050
Urologic surgery, n (%)	44 (22)	18 (22)	26 (22)	
Gynaecologic surgery, n (%)	4 (2)	4 (5)	0 (0)	
Oncologic surgery, n (%)	176 (88)	75 (91)	101 (86)	0.368
Neoadjuvance, n (%)	42 (23)	14 (18)	28 (24)	0.692
ASA classification				
ASA 1	86 (43)	54 (68)	32 (27)	<0.001
ASA 2	72 (36)	26 (31)	46 (39)	
ASA 3	41 (21)	2 (3)	39 (33)	
ASA 4	1 (1)	0 (0)	1 (1)	
Charlson index, n (SD)	5.4 (2.1)	5.0 (2.1)	6.0 (2.2)	0.002
Comorbidities				
Endocrine and metabolic diseases, n (%)	87 (44)	27 (33)	60 (51)	0.020
Respiratory diseases, n (%)	70 (35)	21 (26)	49 (42)	0.025
Cardiac diseases, n (%)	74 (37)	26 (32)	48 (41)	0.235
Vascular diseases, n (%)	99 (50)	28 (35)	71 (60)	0.001
Renal diseases, n (%)	95 (48)	25 (31)	70 (59)	<0.001
Hepatic diseases, n (%)	100 (51)	20 (25)	80 (68)	<0.001
Neurologic diseases, n (%)	103 (52)	22 (27)	81 (67)	<0.001
MUST score, m (SD)	1.1 (1.2)	0.9 (1.1)	1.3 (1.3)	0.062
DASI score, m (SD)	29 (13)	32 (15)	27 (12)	0.010
6MWD (m), m (SD)	456 (108)	458 (112)	453 (106)	0.808
Hand grip (kg) (dominant hand), m (SD)	29 (10)	28 (11)	29 (9)	0.305
YPAS index, m (SD)	36 (19)	39 (20)	34 (19)	0.111
Psychological variables				
HAD total score, m (SD)	9.8 (6.6)	9.7 (6.8)	10.0 (6.4)	0.828
HAD-A, m (SD)	5.5 (3.8)	5.7 (4.2)	5.5 (3.5)	0.707
HAD-D, m (SD)	4.3 (3.4)	4.0 (3.1)	4.5 (3.5)	0.391

Table 1 - Table 1. Baseline characteristics of patients stratified by type of program. Values are mean (SD) or number (proportion) when indicated.

"Program A" program included: motivational interviewing, physical activity plan, nutritional optimization and psychological support; "Program B" program included: motivational interviewing, physical activity plan, nutritional optimization, psychological support and supervised exercise training; BMI: Body mass index; CSHA: Canadian study of health and aging; ASA: American society of anesthesiologists; MUST: malnutrition universal scale tool; DASI: Duke activity status index. 6MWD: Six-minute walk distance; YPAS: Yale physical activity survey; HAD: Hospital anxiety and depression scale; HAD-A: Hospital anxiety and depression scale-anxiety; HAD-D: Hospital anxiety and depression scale-depression

Barcelona metropolitan area, n (%)	9 (11)	22 (18)	
Rest of Catalonia, n (%)	12 (15)	8 (7)	
Clinical variables			
Haemoglobin, ($g \cdot dL^{-1}$)	13.0 (4.5)	13.1 (3.7)	0.936
BMI (kg/m^2), m (SD)	27 (6)	27 (5)	0.562
CSHA clinical frailty scale, m (SD)	2.2 (0.9)	2.5 (1.2)	0.075
Supervised exercise training, n (%)	54 (68)	64 (54)	0.057
Willingness to participate in mindfulness sessions, n (%)	21 (27)	64 (53)	<0.001
Type of surgery,			
Digestive surgery, n (%)	66 (83)	86 (72)	0.099
Urologic surgery, n (%)	14 (18)	30 (25)	
Gynaecologic surgery, n (%)	0 (0)	4 (3)	
Oncologic surgery, n (%)	61 (77)	115 (96)	<0.001
Neoadjuvance , n (%)*	18 (15)	24 (32)	0.013
ASA classification			
ASA 1	28 (35)	58 (48)	0.003
ASA 2	25 (31)	47 (39)	
ASA 3	26 (33)	15 (13)	
ASA 4	1 (1)	0 (0)	
Charlson index, n (SD)	5.6 (2.4)	5.6 (2.1)	0.938
Comorbidities			
Endocrine and metabolic diseases, n (%)	46 (58)	42 (35)	0.002
Respiratory diseases, n (%)	32 (40)	38 (32)	0.231
Cardiac diseases, n (%)	35 (44)	39 (33)	0.135
Vascular diseases, n (%)	47 (59)	53 (44)	0.060
Renal diseases, n (%)	51 (63)	45 (38)	<0.001
Hepatic diseases, n (%)	51 (64)	50 (42)	0.002
Neurologic diseases, n (%)	56 (70)	48 (40)	<0.001
MUST score, m (SD)	1.4 (1.2)	1.0 (1.2)	0.055
DASI score, m (SD)	30 (13)	28 (13)	0.234
6MWD (m), m (SD)	479 (107)	441 (107)	0.022
Hand grip (kg) (dominant hand), m (SD)	32 (12)	28 (10)	0.042
YPAS index, m (SD)	39 (21)	34 (18)	0.133
Psychological variables			
HAD total score, m (SD)	9.3 (6.2)	10.1 (6.8)	0.460
HAD-A, m (SD)	5.4 (3.6)	5.6 (3.9)	0.744
HAD-D, m (SD)	3.9 (3.1)	4.5 (3.5)	0.278

Table 2 - Table 2. Baseline variables related to completion in patients participating in a multimodal prehabilitation program. Values are mean (SD) and number (proportion) when indicated.

Non-completers: Those patients attending less than 80% of the program appointments; Completers: Patients attending at least 80% of program appointments; BMI: Body mass index; CSHA: Canadian study of health and aging; ASA: American society of anesthesiologists; DASI: Duke activity status index; 6MWD: Six-minute walking distance; YPAS: Yale physical activity survey; HAD: Hospital anxiety and depression scale; HAD-A: Hospital anxiety and depression scale-anxiety; HAD-D: Hospital anxiety and depression scale-depression.

	Patients suffering postoperative complications n=58	Patients not suffering postoperative complications n=62	p-value
Sociodemographic variables			
Age (years), m (SD)	72 (9)	74 (10)	0.206
Sex: male, n (%)	45 (78)	40 (65)	0.159
Smoking status, never smoker, n (%)	19 (32)	30 (48)	0.180
Environmental variables			
Area of residence			
Reference area of the hospital, n (%)	33 (57)	40 (65)	0.427
Rest of Barcelona city, n (%)	9 (16)	8 (13)	
Barcelona metropolitan area, n (%)	10 (17)	12 (19)	
Rest of Catalonia, n (%)	6 (10)	2 (3)	
Clinical variables			
Haemoglobin, ($g \cdot dL^{-1}$)	12.4 (2.0)	13.6 (4.7)	0.072
BMI (kg/m^2), m (SD)	27 (4)	28 (6)	0.380
CSHA clinical frailty scale, m (SD)	2.7 (1.2)	2.3 (1.1)	0.128
Supervised exercise training, n (%)	32 (55)	32 (53)	0.855
Willingness to participate in mindfulness sessions, n (%)	36 (62)	28 (45)	0.070
Type of surgery			
Digestive surgery, n (%)	34 (59)	52 (84)	0.001
Urologic surgery, n (%)	23 (40)	7 (11)	
Gynaecologic surgery, n (%)	1 (1)	3 (5)	
Oncologic surgery, n (%)	57 (98)	58 (94)	0.366
Neoadjuvance , n (%)*	12 (22)	6 (10)	0.063
ASA classification			
ASA 1	28 (48)	30 (48)	0.988
ASA 2	23 (40)	24 (39)	
ASA 3	8 (13)	7 (12)	
Steps per day first week of program, m (SD)	7920 (3604)	6737 (3790)	0.150
Charlson index, n (SD)	5.5 (2.2)	5.6 (2.0)	0.671
Comorbidities			
Endocrine and metabolic diseases, n (%)	22 (38)	20 (32)	0.568
Respiratory diseases, n (%)	20 (35)	18 (29)	0.560
Cardiac diseases, n (%)	17 (29)	22 (36)	0.560
Vascular diseases, n (%)	24 (41)	29 (47)	0.275
Renal diseases, n (%)	23 (39)	22 (36)	0.707
Hepatic diseases, n (%)	25 (43)	25 (40)	0.853
Neurologic diseases, n (%)	25 (43)	23 (37)	0.577
MUST score, m (SD)	1.3 (1.4)	0.7 (1.0)	0.006
DASI score, m (SD)	25 (15)	31 (14)	0.017
6MWD (m), m (SD)	432 (105)	450 (109)	0.387
Hand grip (kg) (dominant hand), m (SD)	28 (8)	28 (11)	0.737
YPAS index, m (SD)	31 (17)	37 (18)	0.116
Psychological variables			
HAD total score, m (SD)	11.5 (7.5)	8.9 (5.9)	0.061
HAD-A, m (SD)	6.1 (4.0)	5.2 (4.0)	0.233
HAD-D, m (SD)	5.4 (4.2)	3.7 (2.5)	0.022

Table 3 - Table 3. Baseline variables related to postoperative morbidity in patients participating in a multimodal prehabilitation program. Values are mean (SD) and number (proportion).

Evaluation of the adaptation of MyPathway® to CS2/CS3 in Barcelona (Protocol III)

Patients' usage of the ICT tools and devices

Within the prehabiliation program, 7 patients tested MyPathway® App and LifeVit® pedometer. Six of those patients completed (alone or with help) the study questionnaires.

There was detected poor comfortability of the patients with the LifeVit® system that holds the pedometer. It proved not to be secure enough leading to rather frequent patients' loss of the equipment. The problem is not attributable to MyPathway, but due to the type of LifeVit® design chosen. Some patients also reported differences between the register of steps in the app and pedometer, as well as incidences with the connectivity via Bluetooth® between the two.

Person-centered coordinated care experience questionnaire (P3CEQ)

P3CEQ questionnaire's median score was 15.5 (score range from 0 to 20), which can be considered as a good result. In general, patients always felt treated as persons rather than illnesses. They also have been given enough important information about their health situation and have felt supported by the health care team. Most of the time, patients felt involved in the decision making, as well as their family. However, we cannot compare with previous P3CEQ, so it is difficult to establish if the intervention and use of the App has had an impact to this regard. Moreover, according to some annotations written on the surveys, some patients might understand the questions as if they are about their general health care experience and others might have been thinking about the intervention specifically.

Median (0.5 percentile)	Mean	StDev
15.5	15.83	1.94

Nijmegen Continuity Questionnaire (NCQ)

Patients' perspective of continuity of care measured by the NCQ it gives a median score of 3.6 (score range 0 to 5). This result should be interpreted in order to assess the perspective of patients about communication and coordination among health care providers. Moreover, according to some annotations written on the surveys, some patients might understand the questions as if they are about their general health care experience and others might have been thinking about the intervention specifically.

Median (0.5 percentile)	Mean	StDev
3.60	3.53	1.14

Patients' satisfaction with the technology – NPS

The Net Promoter Score is a known questionnaire used to assess satisfaction with a product, which includes a key question: "How likely is it that you would recommend our system CONNECARE to a family member or friend?". Patients can give an answer ranging from 0 ("not at all likely") to 10 ("extremely likely"). Individuals scoring a 9 or a 10 are called "promoters", individuals scoring 7 or 8 are called "passives" (or neutrals) and individuals scoring 0 to 6 are labelled as "detractors". The results of the questionnaires are displayed in **Table 1**.

Table 1 - Rating of satisfaction by means of Net Promoter Score for patients.

	N patients	% patients
0-6 (detractors)	1	17%
7-8 (passives)	4	67%
9-10 (promotors)	1	17%
Net Promoter Score (Promoters-Detractors)		**0%**

The general questions about satisfaction had the same distribution as the NPS [from 0 ("not at all likely") to 10 ("Extremely likely)]. We conducted the median of the answers, and they are as follow.

	Median	Mean	StDev
General impression	**5.5**	5.5	3.14
Easy to use	**8**	7.33	3.4
Ability to use without help	**8.5**	6.83	3.67

One patient scored 0 in all of three general satisfaction questions, although he rated as very positive all the other questionnaires and he rated the probability of recommending the system (NPS) with a 7 (out of 10). Answers from these questionnaires were included, although we found it to be inconsistent. This explains such a high standard deviation in these results.

Patients' satisfaction with the technology – SUS

A system or product receiving a score of 68 and above in the SUS (ranging from 0 to 100) is considered to have good usability. The mean score in the current pilot study was 72.1, as detailed in **Table 2**.

Table 2 – System Usability Scale for patients of the adaptation of MyPathway to CS2/CS3 in Barcelona.

	SUS score
N	6
Mean (SD)	72.1 (23.21)
Score ≥ 68, n(%)	3 (50%)

According to these results, MyPathway® is considered to have good usability. A deeper analysis of this result should be considered (see **D6.4, ANNEX I** for further analysis).

Implementation log

Log 1. One patient could not connect LifeVit® to MyPathway® App. He introduced the number of steps registered by LifeVit manually, which was tedious for the patient. He sometimes introduced it after 00.00h, which counted as another day and generated messages that didn't match with the reality.
Log 2. One patient had technical problems connecting LifeVit® to MyPathway®, which were solved spontaneously after a few days. However, MyPathway® always registered 1000 steps less (approximately) than LifeVit® at the same time.
Log 3. Two patients did not make us of the App but received the sms with the daily target number of steps (via sms) and monitored their activity with the pedometer. One of these patients had the App installed, but after some time it showed an error with the following message: "The service is temporary unavailable".
Log 4. Two patients had punctual connection problems between the App and LifeVit®, but they both were able to complete the program. One of these patients introduced the number of steps manually during the days with connection problems.
Log 5. One patient had a non-compatible Android version, so the App couldn't be installed.
Log 6. One patient didn't have enough space in his dispositive and couldn't liberate it.
Log 7. Some patients complained about the securing system of the pedometer, which sometimes got open. Patients were worried about losing it and some of them did not wear it for this reason.
Log 8. Ona patient tested the pedometer walking the same distance a series of times and reported that the pedometer registered different number of steps and km (up to 400 steps of difference).

Professionals experience with the system

Ten healthcare professionals involved in the prehabilitation program at HCB assessed the digital tool. Technical reliability of MyPathway® regarding: (i) quality of communication with the pedometer (LifeVit®) and reporting in the web portal; (ii) delays in the delivery of the iOS version; and, (iii) rather poor response of the vendor indicate poor potential for use of the target digital tool at HCB, as well as regarding regional scalability.

Assessment of MyPathway® App and LifeVit® pedometer using a Mini-Mast Approach

OVERVIEW

1. State the name or title of the telemedicine service.

MyPathway® as supporting digital tool for the PreHab service

2. Describe the purpose of implementing the telemedicine service. (Include descriptions of the patients/citizens, current technology and outcome measures).

The aim of the current study was to assess usability and acceptability of MyPathway® by patients and health professionals involved in the PreHab service at HCB in order to plan scalability of the service at regional level.

Assessment of the digital tool was carried out by ten professionals (GM, AB, EG, JR, IC, EA, MJA, CH, EB and FB) involved in the PreHab service at HCB, eight patients undertaking the PreHab program during at least two weeks, and thirty-four patients from the intervention arm of the RCT on Home-based NIV.

MyPathway® was interoperable with the health information system (SAP system) at HCB using the setting specifically prepared in the Nextcare project.

Main objectives of the current study were to assess acceptability by patients and professionals, as well as robustness of the digital tool for regional scalability of the PreHab service.

3. Write a short summary of the expected outcomes of the telemedicine service.

Acceptability and usability of the digital tool, as well as robustness for regional deployment.

4. Describe the evidence base for the assessment – e.g. a pilot study or a systematic literature review.

Pilot study for the PreHab service
Preliminary data from RCT on Home-based NIV

5. Describe the evidence level of your current knowledge of the outcomes of the telemedicine service.

Evidence Level:	1	2	3	4	5
Clinical effectiveness				x	
Patients'/citizens' perspective				x	
Economic aspects				x	

Organisational aspects				x	

6. Describe the degree to which the outcomes described in the current evidence base can be transferred to the patients/citizens affected by the telemedicine service.

We hypothesize that a digital tool showing proper performance can contribute to enhance patient empowerment for self-management of PreHab such that the intervention can gain in effectiveness while being partially transferred from a hospital-based approach to a community-based approach. Such results would greatly facilitate large scale regional deployment of the PreHab service.

TECHNOLOGY

7. Which IT-technologies and equipment are included in the telemedicine service?

A personal health system supporting the patient to manage his/her condition: (i) monitoring daily steps prescription; (ii) receiving motivational messages; (iii) providing access to educational material; and, (iv) generating patient reported outcomes (PROMs) and patient reported experiences (PREMs).

A professional web portal for remote monitoring and interactions with patients.

8. Describe the requirements on the technical infrastructure at the hospital, in the municipality, at the general practitioner's office and in the patients' or citizens' homes.

Patients need to own or have access to a mobile phone or tablet with compatible OS and Internet connection.

At hospital (HCB) level, it is needed an integration of the hospital's health system SAP with the personal health system via Order Entry message or ORM. The ORM message is securely bypassed between SAP and MyPathway® with a Fast Healthcare Interoperable Resource platform (HAPI FHIR) deployed in the intranet of hospital information systems. Such bypass consists on sending an invitation letter to the e-mail and SMS of the patient (if already informed in the Hospital SAP) with instructions on how to access the browser and app-based version of the personal health system and how to setup their password for the first time.

Similar strategies would be needed in different hospital or health systems.

9. Describe the degree of planned integration into other IT-systems.

If the results of the testing are positive, integration with the regional personal health folder (La Meva Salut, LMS), and consequently with the regional shared health care record (HC3) is planned.

10. Are there alternative vendors or other applicable telemedicine solutions available?

Yes, the technology tested is not complex. The challenges are mostly related to usability/acceptability of the App and response-time of the vendor to requests for enhancement of the digital tool. The clinical research team is currently working on the adaption of an alternative App (X-care) generated from the EU project CONNECARE.

SAFETY

11. Describe the experiences concerning the technical reliability e.g. number of patients'/citizens who can be reached by the IT-solution.

Technical reliability of MyPathway® regarding: (i) quality of communication with the pedometer (LifeVit®) and reporting in the web portal; (ii) delays in the delivery of the IOS version; and, (iii) rather poor response of the vendor indicate poor potential for use of the target digital tool at HCB, as well as regarding regional scalability.

12. Describe the risks for patients/citizens when using the telemedicine service, e.g. health care errors/clinical incidents.

No significant health risks have been detected. The interactions supported by the digital system are not critical in terms of health impact. However, it has been detected poor comfortability of the patients with the LifeVit® system that holds the pedometer. It proved not to be secure enough leading to rather frequent patients' loss of the equipment. The problem is not attributable to MyPathway, but due to the type of LifeVit® design chosen.

Some patients also reported differences between the register of steps in the app and pedometer, as well as incidences with the connectivity via Bluetooth® between the two.

CLINICAL EFFECTIVENESS

13. Describe the impact of the telemedicine service on the patients'/citizens' health (e.g. mortality, morbidity, functionality, health related quality of life, pain).

As indicated in the Introduction, the PreHab service is showing cost-effectiveness. The use of digital tools on top of the service aims to foster scalability. The assessment of impact of telemedicine was not the purpose of the current research. The current report targets assessment of usability/acceptability and robustness of MyPathway®

14. Describe the impact of the telemedicine service on the patients´/citizens' use of other health services. (e.g. hospitalisation, outpatient visits, visits to general practitioners, home nursing, assistance, rehabilitation)

Not addressed in the current study.

PATIENT PERSPECTIVES

15. How does the telemedicine service affect the patients´ perception of satisfaction and safety during treatment?

5 out of 8 patients tested in the PreHab service had completed two weeks of use of the digital tool at the time of this assessment. They completed the questionnaires designated previously.

Net Promotor Score for Satisfaction was 6. Scores above 0 are considered as a positive result regarding customer loyalty.

Safety parameters where addressed within the System Usability Score (SUS), which was punctuated with a total SUS score of 68. This score corresponds to a 50th percentile.

Similar results regarding satisfaction and usability were found in the Home-based NIV study (see D6.2).

16. Estimate the percentage of patients complying with the inclusion criteria, who are expected to accept the telemedicine service.

The unique limiting factor is availability of smart phone. The digital tools is simple to manage. Limitations regarding usability are not an issue. However, robustness of the equipment and fluent/quick response of the vendor to requests are major factors limiting use of the digital tool to foster scalability of the service.

17. Describe the impact of the telemedicine service on the patients'/citizens' self-care.

This was not a target objective of the current study

ECONOMIC ASPECTS

18. How many patients/citizens are expected to use the telemedicine service each year?

All high-risk candidates to major surgery at HCB. The estimation is approximately 1200 patients per year. The PreHab service may benefit from personalization and modularity becoming a general service preventing complications of surgery. In that case regionalization would be compulsory and the use of the App should be extended to all surgical candidates

19. Describe increases and decreases in staff cost per year.

If the App works properly it would significantly decrease costs of PreHab. It is of note that in its current form, the service is already cost-effective.

20. Describe investment costs for equipment, adjustment of the physical environment, training, etc.

The investment costs are minor and easily paid by current saving of the PreHab service, provided that the telemedicine solution is robust and really supports regionalization of the service.

21. Describe additional increases or decreases in cost per year (e.g. equipment, service agreements, support, integration, maintenance, transport).

Calculations have not been done, but it is estimated that the current costs of the PreHab program would decrease by >20% and, most importantly, would increase the capacity of the system to include new candidates, as well as would enhance adherence and results of the program by transferring part of the activities to the community.

22. Describe expected changes in reimbursement per year for the institution offering the telemedicine service (e.g. DRG payment, municipal co-financing, payment for services).

No need for changes in the reimbursement because healthcare providers generate efficiencies with the program. We can envisage transient initial financial incentives to set the program in new hospitals.

23. Calculate total cost and changes in reimbursement per year by inserting the information from questions 19-22 in the table below.

Not relevant. As explained above savings generated by a robust digital tool are clear and its detailed calculation is beyond the aims of the current study. Details on costs of the PreHab program have been reported in a recent study assessing cost-effectiveness (see D6.4).

24. Describe uncertainties in the above calculations.

No relevant, as described above.

25. Describe the economic effects to be expected by other hospitals, municipalities, general practitioners, patients/citizens, relatives, etc.

Regional scalability of the service would generate healthcare efficiencies both at provider level as well as at health system level. Moreover, citizens' satisfaction is expected.

ORGANIZATIONAL ASPECTS

26. Describe the consequences for the staff of the telemedicine service, e.g. workflow, staff training and work environment.

There is a need for staff training in using the app and professional portal, as well as technological support in case of malfunction. For now, the prescription of the telehealth system is done in the preanesthetic consultation, and the on-boarding process is done within some of the scheduled activities of PreHab programme (Mindfulness or training sessions), so professionals providing the telemedicine service need to schedule their own timetable according to it and go to the patient's location during the activities.

The main effect of telemedicine-supported PreHab is the partial transfer of the program to the community through either home-based or health clubs-based activities

27. Describe the need for changes in the physical environment when using the telemedicine service.

No additional facilities are needed to use this telemedicine service, as it can be provided within existing locations in the hospital, and patients use it outside healthcare facilities (on the street, at home, etc.).

28. Describe the consequences of the telemedicine service on other departments, support functions, hospitals, municipalities, general practitioners etc., concerning task shifts between professions and sectors.

It would imply a more active role of community-based stakeholders without significant overload which, at the end of the day, will result in enhanced continuity of care.

SOCIO-CULTURAL, ETHICAL AND LEGAL ASPECTS

29. Has the telemedicine equipment been CE marked – and if so in which class?

Yes. In its original design is being used in Sheffield on regular basis. The current adaptations done in Barcelona are not CE marked.

30. Has the legal basis for the telemedicine service been clarified, e.g. concerning patients' rights or responsibilities?

Not currently. This is a step to be taken when adopting a final decision regarding implementation of MyPathway®.

31. Which ethical or psychological considerations are raised by the telemedicine service, e.g. access to treatment, equality in treatment or waiting time for treatment?

Adoption of MyPathway® in real life settings may require formal testing using a RCT, but this situation it is still far from this stage of implementation. Prescription of the eHealth application is restricted to those patients that have access to a smartphone or tablet, so it is subjected to economic and lifestyle characteristics of patients.

32.How is the patients'/citizens' social or employment-related situation affected by the telemedicine service?

The telemedicine service doesn't require a substantial amount of time of use, compared to undergoing the program without it, so it shouldn't represent an impediment to social and work-life

Evaluation of the adaptation of the CONNECARE's SMS to CS2/CS3 in Barcelona (Protocol III)

Patient use of eHealth

Most patients (87%) have reported to have email address and 12 out of the 16 patients (75%) have smart-phone with internet connection. So that, most popular used devices are computer and smart-phones with connection, an only 1 patient informed to be using health devices.

8 out of 15 patients (53%) are familiar to health apps but only 2 patients (29%) really use them on a regular basis and would be willing to share the info coming from the app with their doctor or nurse. Those apps used are related to physical exercise, nutrition and health centre information. Additionally, these 2 patients feel more comfortable when using this kind of apps and they perceived this could help to improve or even prevent health problems. However, at the same time, both stated that the use of the app makes them feel more worried or stressed. Finally, one patient stated that the use of the app could not really avoid unnecessary visits to hospitals or health care centres.

Patient experience

A total of 16 patients used the adaptation of the CONNECARE SMS to CS2/CS3 in Barcelona with the LifeVit® physical activity tracker within the perioperative care context. The satisfaction with the technological solution was assessed by the NPS and the SUS. Median scoring of the each of the questions of the NPS is reported below in the **Table 3**. Overall, the reported good scorings and usability with the app [median (IQR) scoring for the 4 questions was 8.1 (7.1 – 9.0)].

The percentage of promoters was of 37.5%, being 63% of them were rated as detractors or passives.

Table 3 - Rating of satisfaction by means of Net Promoter Score for patients.

	1. Overall satisfaction	2. Is the system easy to use?	3. Do you need help to use it?	4. Would you recommend it?
Skewness (Se)	-0.5 (0.56)	-0.92 (0.56)	-0.26 (0.56)	-1.0 (0.56)
Median (IQR)	8.0 (8.0 - 9.8)	8.0 (7.0 – 10.0)	7.5 (5.3 – 9.8)	8.0 (7.3 – 10.0)

Score for 'would you recommend it'	N patients	% patients
0-6 (detractors)	1	6.3
7-8 (passives)	9	56.25
9-10 (promotors)	6	37.5
Net Promoter Score (Promoters-Detractors)		**31.25**

However, taking into account that a system or product that received SUS score of 68 and above is considered to have a good usability, for 56% of the patients (**Table 4**) the adaptation of the CONNECARE SMS to CS2/CS3 in Barcelona was considered to have a good usability.

Table 4 –System Usability Scale for patients of the adaptation of the CONNECARE SMS to CS2/CS3 in Barcelona.

	n=16	
Mean (SD)	67 (21)	
Skewness	-0.52	
	N	**%**
Score above 68	9	56%

Patient usage

Although all patients were given a wristband pedometer (LifeVit®) during the follow up period, patients were adherent to report daily physical activity 36% of the period, which correspond to 11 days on average. With respect to mindfulness exercises, patients performed 3 exercises on average during the follow up period.

Professionals' experience

The NPS score for professionals is negative (**Table 5**). However, since the median of overall satisfaction is 5, we could consider that professionals had neutral experience using the backend of the adaptation of the CONNECARE SMS.

Table 5 - Rating of satisfaction of the backend by means of Net Promoter Score for professionals.

Net Promoter Score (N = 3)			
Likert scale score (0 = poor TO 10 = good)	**1. Overall satisfaction**	**2. Would you recommend it?**	
Skewness	0,00	-1.73	
Median	5	5	
25th Pct	3.5	3.5	
75th Pct	6.5	7	
Score for 'would you recommend it'		N professionals	% Professionals
0-6 (detractors)		2	66.7
7-8 (passives)		1	33.3
9-10 (promotors)		0	0,0
Net Promoter Score (Promoters-Detractors)			-66.7

In terms of perceived usability, none of the healthcare professionals (n=3) reported a SUS score higher than 68, as depicted in **Table 6**.

Table 6 – System Usability Scale of the backend for professionals.

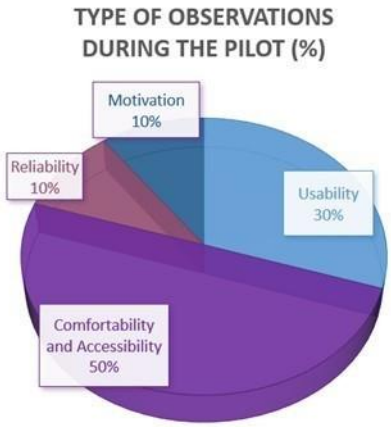
	n=3	
Mean (SD)	51.67(15.07)	
Skewness	0.49	
	N	**%**
Score above 68	0	0%

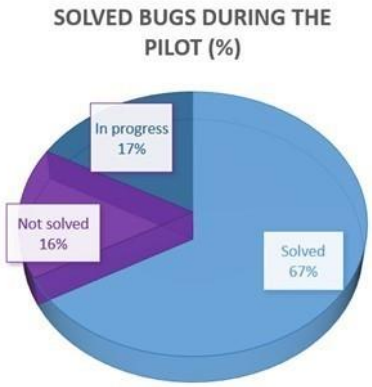
Professional usage

During the follow up period, 2 physiotherapists were in charge of creating the patients into the system, supporting the patients to set their own password, downloading the app into their smartphones, login into the app for the first time, prescribing the tri-modal prehabilitation (i.e., daily physical activity, nutritional tips and mindfulness exercises) to the patient and finally following the patient adherence to the prehabilitation program. In addition, both physiotherapists were providing first-level support to any technical issues patients might encounter with the use of the app and/or the wristband pedometer.

Implementation log

Most of the bugs reported during the pilot (N=6) were either solved or an alternative solution was given. Only 1 bug was not solved (the user cannot set his own password when requiring password recovery). All issues were reported from users of Android devices.





With respect to the type of observations during the pilot, 50% were due to comfortability and accessibility (system forces to use random password when the user resets it) and usability (30%, mostly due to lack of technology robustness.

APPENDIX II

Lleida - Data analyses Implementation Study 2

General description of the statistical analyses:

Statistical analyses were conducted using Stata (Ver. 12.1). Statistical level of significance was set to $\alpha = 0.05$.

1. Patients' usage of the ICT tools and devices

1A. Use of the Pedometer (Fitbit)

Table 1: Days Fitbit transmitted – CS2

Days Fitbit transmitted	all	men	women
N	33	13	20
Mean (SD)	66.4 (32.0)	76.9 (22.2)	59.7 (35.9)
	N (%)	**N (%)**	**N (%)**
Less than 30 days	7 (21%)	1 (8%)	6 (30%)
30-59 days	4 (12%)	2 (15%)	2 (10%)
60-89 days	12 (37%)	5 (38.5%)	7 (35%)
90 days	10 (30%)	5 (38.5%)	5 (25%)

Women had a lower mean number of days transmitted than men, with this difference being borderline significant (T test p-value= 0.090).
Age was associated to lower number of transmitted days (Linear regression model adjusted by sex and Charlson p-value= 0.049).

1B. Use of the messaging function in the app

Table 2: Number of messages sent using the app – CS2

	All	Men	Women
N of messages	30	13	17
Mean (SD)	17.8 (23.2)	17.2 (26.8)	18.2 (21.0)
	N (%)	**N (%)**	**N (%)**
0 messages	0 (0%)	0 (0%)	0 (0%)
1-2 messages	3 (10%)	2 (15%)	1 (6%)
3-5 messages	7 (23.3%)	3 (23%)	4 (23%)

6-10 messages	7 (23.3%)	4 (31%)	3 (18%)
> 10 messages	13 (43.3%)	4 (31%)	9 (53%)

A Negative binomial regression model including age, sex and Charlson showed that either sex (p-value= 0.852) or age (p-value= 0.348) were not associated to the number of messages sent.

1C. Response to questionnaires in the SMS app

Patients in CS2 could be asked to answer questionnaires concerning aspects on their recovery after surgery (i.e. pain). The median (p25-p75) number of successfully submitted questionnaires out of all requested questionnaires were 46% (14% - 79%) for the post-surgical questionnaire and 72% (39% - 81%) for the EQND. This shows that patients replied to the requested questionnaires on a regular basis.

1D. Use of monitoring devices

Table 3: Percentage of measures reported out of times prescribed

Use of monitoring devices – CS2		
Prescribed measure	**N**	**Mean (SD)**
Blood pressure	39	35% (24%)
Body temperature	33	38% (14%)

Overall patients in CS2 were willing to report all the requested measures on a daily basis. However, when measures were prescribed more than once a day, patients tended to do it just once a day.

2. Patient's Experience

2A. Person-centered coordinated care experience questionnaire (P3CEQ)

Table 4: Answers to P3CEQ – CS2

	Controls (n=31)	CONNECARE (n=29)	
P3CEQ questions	**% answering "always"**		**p-value***
1. Did you discuss what was most important for YOU in managing your own health and wellbeing?	65%	62%	0.306
2. Were you involved as much as you wanted to be in decisions about your care?	65%	59%	0.438
3. Were you considered as a 'whole person' rather than just a disease/condition in relation to your care?	77%	79%	0.359
4. Did your care-team / providers involve your family/friends/carers as much as you wanted them to be in decisions about your care?	68%	62%	0.428
5. Have you had enough support from your care team / providers to help YOU to manage your own health and wellbeing?	71%	69%	0.518
6. To what extent do you receive useful information at the time you need it to help you manage your health and wellbeing?	77%	79%	0.266
P3CEQ total score: mean (SD)	15.7 (3.5)	16.0 (2.4)	0.684

* Chi^2 test (considering all the response options) or T test as appropriate.

2B. Nijmegen Continuity Questionnaire (NCQ)

Table 5: Answers to NCQ

Nijmegen Continuity Questionnaire (NCQ) – CS2 (n=27)	
NCQ G1-G5 statements	**N (%) answering "Agree" or "Strongly agree" ***
G1. My care providers transfer information very well to one-another	8 (67%)
G2. My care providers work together very well	7 (58%)
G3. My care providers are very well connected	7 (58%)
G4. My care providers always know what one-another is doing	7 (70%)
G5. I have to wait too long to obtain a service/appointment	22 (82%)
NCQ total G1-G4 score: mean (SD)	3.5 (1.2)

* Excluding patients answering N/A.

2C. Patients satisfaction with the technology – NPS

Table 6: Rating of satisfaction in patients using SMS + Fitbit app – CS2

SMS+FITBIT NPS (N=21)				
Likert scale score **(0 = poor to 10 = good)**	**1. Overall satisfaction**	**2. Easiness of use**	**3. Ability to be used without help**	**4. Would you recommend it?**

Median (p25-p75)	10 (7-10)	8 (5-10)	8 (3-10)	9 (7-10)

Table 7: Rating of satisfaction in patients using SMS app – CS2

SMS App NPS (N =29)				
Likert scale score **(0 = poor to 10 = good)**	**1. Overall satisfaction**	**2. Easiness of use**	**3. Ability to be used without help**	**4. Would you recommend it?**
Median (p25-p75)	10 (8-10)	8 (5-10)	8 (5-10)	9 (8-10)

The NPS:

The answer to the question "How likely is it that you recommend the CONNECARE system to a family member or friend?" was used to calculate the NPS. Subtracting the percentage of Detractors from the percentage of Promoters. The NPS ranges between −100 and +100, a positive score is considered good, a NPS of +50 is generally deemed excellent, and anything over +70 is exceptional.

Table 8: NPS score in CS2

CS2 - NPS SCORE				
	SMS + Fitbit		**SMS**	
Score for **'would you recommend it'**	N patients	% patients	N patients	% patients
0-6 (detractors)	3	14%	4	14%
7-8 (passives)	6	29%	8	27%
9-10 (promotors)	12	57%	17	59%

The NPS score was +43% in patients using SMS app + Fitbit and +45% in patients using only SMS app. These rates are good, and close to reaching the excellent threshold (+50%).

2D. Patients satisfaction with the technology – SUS

Based on research, a SUS score above a 68 would be considered above average and anything below 68 is below average.

Table 9: SUS score in CS2

SUS total score for the SMS App in CS2	
N	**29**
Mean (SD)	68.19 (24.38)
Score ≥68, n (%)	16 (55%)

3. Staff's Experience

A total of 30 professionals involved in CS1 and/or CS2 were asked to assess the SACM platform between April and May 2019: 1 hospital case-manager, 3 hospital physicians, 1 hospital surgeon, 1 hospital anaesthesiologist, 3 primary care case-managers, 12 primary care physicians, and 9 primary care nurses.

3A. Staff satisfaction with the technology – NPS

Table 10: Rating of satisfaction in staff using the SACM – CS2

Professionals using SACM (N=20)				
Likert scale score (0=poor to 10=good)	**Overall satisfaction**	**Easiness of use**	**Ability to be used without help**	**Would you recommend it?**
Median (p25-p75)	6.5 (5-8)	6 (4.5-7.5)	6 (5.5-9)	6.5 (5-7.5)

Table 11: NPS score in staff using the SACM

NPS SCORE		
Score for 'would you recommend it'	N staff	% staff
0-6 (detractors)	10	50%
7-8 (passives)	7	35%

9-10 (promotors)	3	15%

The SACM NPS score was -35% among professionals involved in CS2. This rate is poor and reflect the difficulties experienced in using a tool under development and not fully integrated with existing systems.

3B. Staff satisfaction with the technology – SUS

Table 12: SUS score in staff using the SACM

SUS total score for the SACM App	
N	**21**
Mean (SD)	61.7 (19.0)
Score ≥68, n (%)	9 (43%)

4. Intervention effectiveness - Health & wellbeing questionnaires (SF-12)

Table 13: Changes in the SF-12 from baseline to the discharge – CS2

CS2				
CONNECARE patients				
	Baseline (N = 34)	**Discharge (N = 29)**	**Change (N = 29)**	
	Mean (SD)	**Mean (SD)**	**Mean (SD)**	**p-value***
SF-12 - Physical	30.3 (9.9)	45.3 (9.8)	+15.4 (11.7)	<0.001
SF-12 - Mental	52.2 (14.3)	52.8 (12.9)	+0.8 (15.2)	0.785
SF-12 - Total	82.6 (18.2)	98.1 (15.6)	+16.2 (14.3)	<0.001
Control patients				
	Baseline (N = 31)	**Discharge (N = 30)**	**Change (N = 30)**	

	Mean (SD)	Mean (SD)	Mean (SD)	p-value*
SF-12 - Physical	27.6 (6.7)	42.0 (7.7)	+14.1 (9.0)	<0.001
SF-12 - Mental	48.9 (14.5)	50.2 (13.5)	+2.0 (11.9)	0.354
SF-12 - Total	76.4 (15.4)	92.2 (18.1)	+16.1 (14.8)	<0.001

* Paired T test comparing baseline to discharge.

In CS2, significant changes in the physical dimension of SF-12 and the total SF-12 score were found when comparing baseline to discharge both in the intervention group and in the control group. Crude or adjusted (sex, age, and Charlson) linear regression models did not find statistically significant differences in the changes experimented by patients in the CONNECARE program or control patients.

5. Intervention's effectiveness - Service utilization during the follow-up

Table 14: Total use of health services during the study – CS2

Total use of health services during the study – CS2				
	Control (N = 31)	**CONNECARE (N = 29)**	**Model 1**	**Model 2**
	Mean (SD)	**Mean (SD)**	**p-value**	**p-value**
N unplanned visits	1.48 (1.52)	0.69 (0.97)	0.016	0.003
N unplanned visits related to the surgical procedure	0.90 (1.22)	0.41 (0.68)	0.062	0.012
N hospital admissions	0.03 (0.18)	0 (0)	-	-
N hospital admissions related to the surgical procedure	0.03 (0.18)	0 (0)	-	-

Model 1: Negative binomial regression model, crude. Model 2: Negative binomial regression model, adjusted by age, sex, and Charlson.

Being in the CONNECARE program significantly reduced the total number of unplanned visits and unplanned visits related to the surgical procedure (CS2). Analyses based on hospital admissions were not possible as only one hospital admission was recorded during the follow-up period (1 control patient). No deceases were registered during the follow-up for CS2 patients.

6. Intervention's costs & Cost-effectiveness

6A. Cost of the CONNECARE program

Estimating the overall cost per patient of implementing the CONNECARE program is not trivial. For the purpose of the current study, a hospital-based nurse case-manger was recruited for the duration of the study (Jul 2018 – Oct 2019), with a total cost per month of 3500€. During the whole study period, she recruited and managed 91 patients in the CONNECARE program (52 CS1 + 39 CS2), taking responsibilities in the management of the patients as well as providing technical support and assistance, collecting research-related data and participating in the overall development of the CONNECARE H2020 project. Therefore, in a real-life non-research scenario, it is estimated that a single hospital-based nurse case-manger could manage up to 500 simultaneous patients, resulting in a cost of 7€ per patient and month. During the study, the rest of involved medical staff either in the hospital or in the primary care assumed any potential increase in workload related to the use of the CONNECARE platform at no additional cost. In this sense, it must be noticed that, in one hand, a fully implemented CONNECARE program would imply a higher number of CONNECARE patients and thus an increase in workload; on the other hand, a fully mature and integrated platform would be much less requiring for involved professionals. In any case, the re-structuration of staff's time to include the new tasks would be fully assumed by the health system and no additional personnel would be required, thus no additional cost would be generated. The cost of licensing and running the CONNECARE platform as well as the costs to maintain, evolve and support it cannot be easily stablished. In this sense, the costs of other health services like Home-based oxygen therapy, where a supplier covers the role of providing devices, licenses and technical support, have been used to generate a per year per patient estimation of 200€. Therefore, a total cost of 23.67€ /patient and month has been estimated as direct costs of the CONNECARE program for the purpose of the current analyses. Given that the duration of the intervention was 3 months, the final costs of the CONNECARE program was 71.01€. Additionally, 2 sensitivity scenarios were also analyzed were CONNECARE program costs were incremented by +50% and +100%. No indirect costs were considered.

6B. Cost of unplanned visits and hospital admissions

According to the official data of 2013 (CVE-DOGC-A-13051031-2013), the overall cost of unplanned medical visits in the health region of Lleida is 62€. Similarly, the cost of hospital admissions is 555€ per day. No indirect costs were considered.

6C. Cost and cost-effectiveness analyses

Table 15. CS2 within trial costs (average cost per patient) and cost-effectiveness, considering all unplanned visits and hospital admissions.

CS2 costs and cost-effectiveness, considering all unplanned visits and hospital admissions (all costs in €).				
	Standard Care (n=30)	**CONNECARE (n=29)**	**Difference**	**ICER**
Unplanned visits*	93.00	42.76	-50.24	
Hospital admissions*	148.00	0.00	-148.00	
TOTAL medical costs per patient	241.00	42.76	-198.24	
1st scenario				
CONNECARE program	0	71.01	+71.01	
TOTAL costs per patient	241.00	113.77	-127.23	-1590.38
2nd scenario (+50% CONNECARE program cost)				
CONNECARE program	0	106.52	+106.52	

TOTAL costs per patient	241.00	149.28	-91.72	-1146.5
3rd scenario (+100% CONNECARE program cost)				
CONNECARE program	0	142.02	+142.02	
TOTAL costs per patient	241.00	184.78	-56.22	-702.75

ICER, incremental cost-effectiveness ratio: Incremental cost associated with 1 additional point gain in SF12

*** Costs based on the Catalan Institute of Health (CVE-DOGC-A-13051031-2013).**

Table 16. CS2 within trial costs (average cost per patient) and cost-effectiveness, considering all unplanned visits and hospital admissions related to the surgery procedure.

CS2 costs and cost-effectiveness, considering all unplanned visits and hospital admissions related to the surgery procedure (all costs in €).				
	Standard Care (n=30)	**CONNECARE (n=29)**	**Difference**	**ICER**
Unplanned visits related to the surgery procedure *	57.87	25.66	-32.21	
Hospital admissions related to the surgery procedure *	148.00	0.00	-148.00	
TOTAL medical costs per patient	205.87	25.66	-180.21	

1st scenario				
CONNECARE program	0	71.01	+71.01	
TOTAL costs per patient	205.87	96.67	-109.20	-1365
2nd scenario (+50% CONNECARE program cost)				
CONNECARE program	0	106.52	+106.52	
TOTAL costs per patient	205.87	132.18	-73.69	-921.13
3rd scenario (+100% CONNECARE program cost)				
CONNECARE program	0	142.02	+142.02	
TOTAL costs per patient	205.87	167.68	-38.18	-477.38

ICER, incremental cost-effectiveness ratio: Incremental cost associated with 1 additional point gain in SF12

* Costs based on the Catalan Institute of Health (CVE-DOGC-A-13051031-2013).

APPENDIX III

Israel - Data analyses - Implementation Study 2

General description of the statistical analyses:

Statistical analyses were conducted using SPSS (Ver. 24.0). Statistical level of significance was set to α = .05 (family-wise). For significant effects, multiple comparisons were conducted applying Bonferroni's adjustment for significance level (family-wise α = .05).

1. Patients' usage of the ICT tools and devices

1A. Using the Pedometer (Fitbit)

Table 1: Days Fitbit transmitted by period – CS2*

Days Fitbit transmitted	Pre-hab		Month 1		Month 2		Month 3	
N	33		26		22		20	
Mean (SD)	33.61 (21.53)		24.27 (7.98)		24.18 (9.15)		23.20 (9.39)	
Skewness (Se)	0.87 (0.41)		-1.23 (0.46)		-1.33 (0.49)		-1.20 (0.51)	
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**
less than 10 days	4	12.1	1	**3.8**	2	**9.1**	3	**15.0**
10-20 days	7	21.2	4	**15.4**	4	**18.2**	3	**15.0**
21 days and above	22	66.7	21	**80.8**	16	**72.7**	14	**70.0**

*** The number of patients declined because patients dropped out of the project over time, only 20 patients remained three months following the discharge from a hospital**

Table 2: Average daily number of steps by period – CS2

Average daily number of steps (out of the valid transitions > 0)	Pre-hab		Month 1		Month 2		Month 3	
N	33		26		22		20	
Mean (SD)	7,322 (2,726)		4,051 (2,649)		4,900 (2,465)		5,921 (2,044)	
Skewness (Se)	0.96		1.09		1.35		0.27	
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**
less than 2000 steps	0	**0**	6	**23.1**	1	**4.5**	0	**0**
2,000-5,000 steps	5	**15.2**	12	**46.2**	11	**50.0**	6	**30.0**
5,001-10,000 steps	23	**69.7**	7	**26.9**	8	**36.4**	14	**70.0**
more than 10,000 steps	5	**15.2**	1	**3.8**	2	**9.1**	0	**0**

Important comment: 14 patients in CS2 reported steps beyond the time of leaving the study, with 6,087 average daily number of steps.

Statistical analyses on all period data

Research Question 1: Do the percentage of days reporting usage of Fitbit (=total number of days reporting out of the total number of days in intervention) and the average number daily steps reported differ for men and women?

Statistical Analyses: Multivariate one-way analyses of covariance (MANCOVA) was conducted, with percentage of days reporting usage of Fitbit and average number of daily steps reported as the dependent variables, and sex as the independent variable. Participants age and Charlson scores were entered as covariates. **The analyses revealed a null effect of sex**. Multivariate *F* (2, 21) = 0.08, Wilk's Lambda = .99, *p-value* = .92. Univariate analyses revealed that men and women did not differ significantly with respect to percentage of days reporting usage of Fitbit (M_{men} = .54 , M_{women} = .51, *p-value* = .70), as also was the case for the univariate tests for the average number of daily steps reported (M_{men} = 4,465 , M_{women} = 4,746, *p-value* = .73).

Research Question 2: Does age affect the percentage of days reporting usage of Fitbit and the average number of daily steps reported?

Statistical Analyses: Two multiple linear hierarchical regressions predicting percentage of days reporting usage of Fitbit and the average daily steps reported were conducted. Predictors entered in step 1 were: Sex and Charlson scores, In Step 2: Age. **Results indicated that age did not significantly predict the percentage of days reporting usage of Fitbit**, beyond sex and the Charlson score,(R^2*change* = .08, Beta = .39, *p-value* = .15). **Also with respect to the average daily steps reported, the age effect was not significant for the CS2 sample**, (R^2*change* = .02, Beta = -.18, *p-value*=.55)**.**

Research Question 3: **Do the percentage of days reporting usage of Fitbit (=total number of days reporting/total number of days in intervention) and the average number of daily steps reported change along intervention period?**

Statistical Analyses: Two two-way mixed-design analyses of co-variance (ANCOVAs) were conducted for percentage of days reporting usage of Fitbit and average number of daily steps reported as dependent variables. The repeated measure factor was period (pre-hab, months 1,2,3), and age-group (<>median of 69) was the between-subjects factor in all the analyses. **There was no significant change in the percentage of days reporting usage of Fitbit** (*F* (3, 15) = 1.26, Wilk's Lambda = .82, *p-value* = .37). **However, Change in daily number of steps was found significant** *F* (3, 15) = 5.40, Wilk's Lambda = .48, *p-value* = .01, η2=.52. In this sample, there was an expected **decrease** in the number of daily steps from the PreHab period (M = 7, 011) to the first month after intervention (M = 3, 953), adjusted *p-value*= .004, but an **increase from the first month to the third one** (M = 5,692, adjusted *p-value*= .006. **The age-group factor was not significant in both samples** (*p* = .10) as were the **Time X Agegroup**

interactions (*p* = .83), suggesting that the **increase in number of steps emerged for both younger and older patients.**

1B. Using the messaging function in the app

Table 3: Number of messages sent using the app – all period

N of messages	**33**	
Mean (SD)	4.72 (6.25)	
Skewness (Se)	2.40 (.41)	
	N patients	**N patients**
0 messages	9	9
1-2 messages	6	6
3-5 messages	9	9
6-10 messages	4	4
> 10 messages	5	5

Statistical Analyses

Research Question 1: Does the number of messages sent differ for men and women?

Statistical Analyses: One-way analyses of covariance (ANCOVA's) was conducted, with total number of messages sent as the dependent variables and sex as the independent variable. Participants age and Charlson scores were entered as covariates. **The analyses revealed a null effect of sex.** *F* (1,29) = 0.08, *p-value* = .78.

Research Question 2: Does age affect the number of messages sent by each participant?

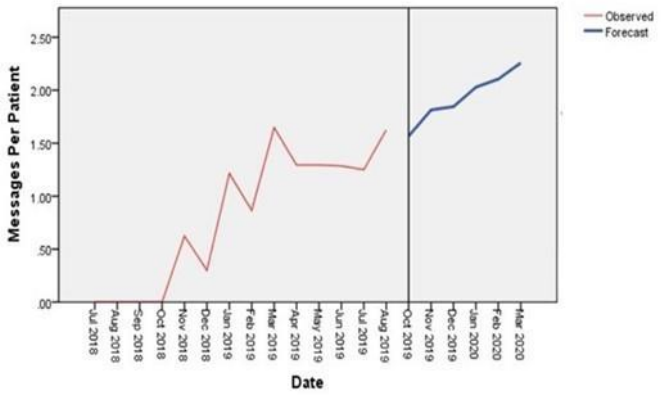
Statistical Analyses: Multiple linear hierarchical regressions predicting the number of messages sent by each participant was conducted. Predictors entered in step 1 were: Sex and Charlson scores, In Step 2: Age. **Results indicated that age did not significantly predict the number of messages sent,** beyond sex and the Charlson score (R^2*change* = .001, Beta = -.03, *p-value* = .88).

Research Question 3: Does the use of messaging changes as study proceeds?

For that purpose, we first calculated for each study month: 1) the total number of patients participating in the study, and 2) the total number of messages sent (over all the participants). Then, for each month, we computed the ratio messages per patient.

Statistical Analysis: Time-series analyses was computed with the ratio messages:patient as the dependent variable and month as the independent one. The analyses also included predicted values for 5 months post study.

Observed and predicted number of messages per patient by study month



The time series analysis for the ratio messages:patient by study month for the CS2 sample revealed an increase in the number of messages per patient sent over the study period. However, for the CS2 sample, the messages per patient ratio increased along the study period.

1C. Responding to EQ5D questionnaires in the app

Due to a very low compliance, no analyses were performed for this measure.
In CS2 8 patients reported 1-5 times, and 3 patients reported more than 5 times.

1D. Monitoring blood pressure or any other measurement

Table 4: Percentage of blood pressure measured reported out of times prescribed:

Prescription Type	Mean (SD)	N
Every day	15% (24%)	2
Twice a week	48% (68%)	2
Once a week	5% (0.3%)	2
Not prescribed	--	26

1E. Reporting performance of simple tasks

Table 5: Means (SD) of the percentage of simple tasks performance out of total prescribed

Pre Surgery		Post surgery	
Mean	**SD**	**Mean**	**SD**

24.5%	25.3%	14.6%	26.9%

2. Patient's Experience

2A. Person-centred coordinated care experience questionnaire (P3CEQ)

Table 6: SCALE: 0 - Not at all 3 - Always

N = 28	
% of patients answered "always"	
F1. Did you discuss what was most important for YOU in managing your own health and wellbeing?	32%
F2. Were you involved as much as you wanted to be in decisions about your care?	68%
F3. Were you considered as a 'whole person' rather than just a disease/condition in relation to your care?	79%
F4. Did your care-team / providers involve your family/friends/carers as much as you wanted them to be in decisions about your care?	39%
F5. Have you had enough support from your care team / providers to help YOU to manage your own health and wellbeing?	68%
F6. To what extent do you receive useful information at the time you need it to help you manage your health and wellbeing?	75%

2B. Nijmegen Continuity Questionnaire (NCQ)

Table 7: SCALE: 1 - Strongly agree 5- Strongly disagree

N = 25	
% of patients answered "Agree" or "Strongly agree"	
G1. My care providers transfer information very well to one-another	92%
G2. My care providers work together very well	88%
G3. My care providers are very well connected	84%
G4. My care providers always know what one-another is doing	80%

G5. I have to wait too long to obtain a service/appointment	20%

2C. Patients satisfaction with the technology – NPS

*** Since the ratings are strongly negatively skewed, central locations will be described using median instead of mean.

Table 8: Rating of satisfaction with Fitbit app NPS

FITBIT NPS (N = 26)				
Likert scale score (0 = poor TO 10 = good)	**5. Overall satisfaction**	**6. Easiness of use**	**7. Ability to be used without help**	**8. Would you recommend it?**
Skewness (Se)	-1.63 (0.46)	-1.96 (0.46)	-3.69 (0.46)	-2.33 (0.47)
Median	9.00	10.00	10.00	10.00
25th Pct	8.00	9.00	9.00	8.00
75th Pct	10.00	10.00	10.00	10.00

Table 9: Rating of satisfaction with SMS app NPS

SMS App NPS (N = 25)				
Likert scale score (0 = poor TO 10 = good)	**Overall satisfaction**	**2. Easiness of use**	**3. Ability to use without help**	**4. Would you recommend it?**
Skewness (Se)	-.79 (0.46)	-.99 (0.46)	-.95 (0.47)	-.70 (0.47)
Median	8.00	8.00	8.00	8.00
25th Pct	3.50	4.50	1.50	.75
75th Pct	9.50	10.00	10.00	10.00

The answer to the question "How likely is it that you recommend the CONNECARE system to a family member or friend?" was used to calculate the NPS. Subtracting the percentage of Detractors from the percentage of Promoters. The NPS ranges between −100 and +100, a positive score is considered good.

Table 10: NPS SCORE	Fitbit		SMS	
'would you recommend it'	N patients	% patients	N patients	% patients
0-6 (detractors)	3	12%	10	40%
7-8 (passives)	5	20%	7	28%
9-10 (promotors)	17	68%	8	32%

The NPS score was 56% for the Fitbit which rates it as great, and -8% for the SMS which is a low rating

2D. Patients satisfaction with the technology – SUS

Based on research, a SUS score above a 68 would be considered above average and anything below 68 is below average.

Table 11: SUS total score for the SMS App		
N	**25**	
Mean (SD)	62.2 (24.11)	
Skewness (Se)	-0.87 (0.46)	
	N	**N**
Score above 68	13	13

2E –Patients satisfaction with the Technology based on recruitment date

NPS - Likert scale Average score (0 = poor to 10 = good)		Oct-Dec 2018 (N=2)	Jan-Mer 2019 (N=6)	Apr-Jun 2019 (N=5)	Jul - Sep 2019 (N=12)
SMS App	**1. Overall satisfaction**	3.5	7.5	5.6	6.1
	2. Easiness of use	3.5	7.0	6.4	6.6
	3. Ability to use without help	5.0	7.5	5.4	6.5
	4. Would you recommend it?	3.5	6.3	6.2	9.5

	NPS score for 'would you recommend it'	-50%	17%	-20%	-8%
	SUS Score	53.75	62.92	59.58	63.33
FITBIT	**1. Overall satisfaction**	10	8.7	8.2	8.9
	2. Easiness of use	10	9.3	8.6	9.6
	3. Ability to use without help	10	9.2	7.6	9.3
	4. Would you recommend it?	10	8.0	8.3	8.6
	NPS score for 'would you recommend it'	100%	50%	20%	58%

	NPS SCORE based on 'would you recommend it'				
		Oct-Dec 2018 (N=7)	Jan-Mar 2019 (N=10)	Apr-Jun 2019 (N=7)	Jul - Sep 2019 (N=8)
App	0-6 (detractors)	50%	33%	20%	50%
	7-8 (passives)	50%	17%	80%	8%
	9-10 (promotors)	0%	50%	0%	42%
FITBIT	0-6 (detractors)	0%	17%	0%	17%
	7-8 (passives)	0%	17%	80%	8%
	9-10 (promotors)	100%	67%	20%	75%

3. Staff's Experience

Six staff members (3 CM nurses and 3 physiotherapists), were asked to answer the questionnaire anonymously three times during the study period - November 2018, March-May 2019 and at the end of the study.

3A. Staff satisfaction with the technology – NPS

The answer to the question "How likely is it that you recommend the CONNECARE system to a family member or friend?" was used to calculate the NPS. The NPS ranges between −100 and +100, a positive score is considered good.

Table 12:		NCM			Physio	
	Likert scale Average score (0 = poor to 10 = good)	March 19 (n=3)	Sep 19 (n=3)		May 19 (n=3)	July 19 (n=3)
SMS App	1. Overall satisfaction	3.0	4.7		5.0	5.0
	2. Easiness of use	2.3	5.0		5.0	4.7
	3. Ability to use without help	2.7	4.7		4.3	4.0
	4. Would you recommend it?	2.7	4.3		5.0	4.3
	NPS score for 'would you recommend it'	-100%	-67%		-67%	-100%
FITBIT	1. Overall satisfaction	7.7	8.3		7.7	6.7
	2. Easiness of use	7.3	8.3		7.0	6.7
	3. Ability to use without help	7.7	8.3		6.3	6.7
	4. Would you recommend it?	7.7	8.3		7.0	6.3
	NPS score for 'would you recommend it'	0%	33%		-33%	33%
SACM	1. Overall satisfaction	4.0	5.7		5.7	4.0
	2. Easiness of use	3.0	5.0		5.0	4.3
	3. Ability to use without help	3.0	5.3		5.3	3.3
	4. Would you recommend it?	3.0	4.0		4.7	3.7
	NPS score for 'would you recommend it'	-100%	-33%		-67%	-100%

3B. Staff satisfaction with the technology – SUS total score

Based on research, a SUS score above a 68 would be considered above average and anything below 68 is below average. No respondent rated a final grade above 68

Table 13: SUS total score - mean (SD)	NCM			Physio	
	March 2019 (n=3)	Sep 2019 (n=3)		May 2019 (n=3)	July 2019 (n=3)
SMS App	16.00 (6.08)	20.00 (6.08)		26.67 (12.74)	22.33 (5.86)
SACM	16.67 (5.03)	19.67 (5.86)		21.00 (13.23)	28.00 (3.46)

3C. ACT@Scale - Staff engagement

Table 14: ACT@SCALE	NCM			Physio		
% answered "Agree" / "Very agree"	Nov '18 (n=1)	Mar '19 (n=3)	Sep '19 (n=3)	Nov '18 (n=3)	May '19 (n=3)	July '19 (n=3)
1. I have a clear understanding of what this project is trying to achieve	100%	100%	100%	100%	100%	67%
2. I feel I am able to influence the way in which the project is managed and delivered	100%	100%	100%	33%	33%	0%
3. I was consulted about the implementation of the project	100%	67%	33%	33%	33%	33%
4. I believe patients are benefiting from participating in this project	100%	67%	100%	100%	100%	100%
5. The implementation of the project was well planned	0%	67%	0%	0%	33%	33%

6. I was given appropriate training and education to support my role in the project	100%	100%	67%	67%	67%	33%
7. My views about the project are gathered and acted upon	100%	67%	33%	33%	67%	67%
8. I was actively involved in the development and implementation of the project	0%	67%	67%	0%	33%	0%
9. I believe that the approach to integrated care used in the project is now part of 'normal' practice	100%	100%	67%	33%	33%	67%
10. I have been supported to develop the skills and knowledge necessary to deliver the service	100%	67%	67%	33%	33%	0%
11. My involvement in the implementation of this project has positively changed my views on integrated care	100%	100%	100%	100%	100%	67%
% answered "Agree" / "Very agree"						
1. The contents and teaching methods are tailored to my needs	100%	67%	100%	67%	67%	33%
2. All different categories of staff have the same access to training	100%	67%	33%	100%	67%	33%
3. There was sufficient staff time available to support my training	100%	33%	33%	33%	33%	33%

4. Frontline staff are quite involved in training or supporting (e.g. through mentorship) their colleagues in relation to the project	100%	67%	33%	67%	67%	67%

4. Intervention effectiveness - Health & wellbeing questionnaires

(only intervention Before VS After)

Table 15:	Before (N = 33)		After (N = 33)		P-value
	Mean	SD	Mean	SD	(before-after)
Barthel	95.91	6.31	97.88	4.93	.42
Lawton	21.21	2.58	21.46	3.43	.94
SF-12 - Physical	7.21	3.89	8.27	3.83	.16
SF-12 - Mental	13.79	4.34	14.45	4.45	.12
SF-12 - Total	21.00	7.39	22.08	7.30	.48
HADS-Anxiety	4.30	3.28	3.42	3.13	< .001
HADS-Depression	5.21	4.60	2.62	2.74	.32
EQ-5D-5L – Q1-Q5	1.83	0.66	1.62	0.59	.14
EQ-5D-5L – Health Today	63.88	17.87	70.93	16.53	.03
Sweet 16	15.03	1.18	15.22	.88	.12

Statistical analyses

Research Question 1: Did the questionnaires' total scores change following intervention?

Statistical analysis: One-way ANOVA for repeated measures with total score as the dependent variables and time (before/after) as the independent variable was conducted for each of the total scores of the questionnaires. As can be seen, from before to after intervention, **there was an improvement in improvement in anxiety (i.e., decrease) and feeling of general health.**

To test change in the individual items' ratings of the Barthel, Lawton, and EQ-5D-5L questionnaires, additional one-way ANOVAs for repeated measures were conducted for each individual item of these questionnaires. **Regarding the Barthel items**, no changes emerged for this questionnaire's item. **Regarding the Lawton items, there was an improve only in shopping**. Finally, regarding the **EQ-5D-5L** there was a significant **decrease in pain and discomfort and an increase in feeling of health.**

5. Intervention's effectiveness - Service utilization and costs

(Intervention VS Control, Before VS After)

Table 16: Length of hospital admission

	Intervention			Control			P-value (t-test)
	N	**Mean**	**SD**	**N**	**Mean**	**SD**	
All patients	25	2.48	1.806	65	2.74	2.612	0.454
Urology Surgeons	5	2.20	0.837	12	2.08	0.900	0.808
Orthopedic Surgery	9	2.56	2.651	24	3.67	2.959	0.332
General Surgery	3	2.33	0.577	8	3.75	4.400	0.604
Gynecology Surgery	8	2.63	1.598	21	1.67	1.278	0.103

Table 17: Emergency department visits – no hospitalization

	Intervention		**Control**		**P-value (t-test)**
N	**40**		**96**		
	Mean	**SD**	**Mean**	**SD**	
One month before recruit/intervention	0.09	0.30	0.13	0.38	.63
During intervention	0.25	0.57	0.09	0.29	.06
One month after recruit/intervention	0.00	0.00	0.01	0.11	.52

Table 18: Number of hospitalizations per capita

	Intervention		**Control**		**P-value (t-test)**
N	**40**		**96**		
	Mean	**SD**	**Mean**	**SD**	

One month before recruit/intervention	0.16	0.51	0.10	0.38	.56
During intervention	0.13	0.42	0.16	0.51	.76
One month after recruit/intervention	0.00	0.00	0.01	0.11	.52

Table 19: Mortality (N)

	Intervention	Control	P-value (χ2)
N	**40**	**96**	
One month before recruit/intervention	0	0	--
During intervention	0	0	--
One month after recruit/intervention	0	1	--

Table 20: Number of general practitioner visits per capita

	Intervention		Control		P-value (t-test)
N	**40**		**96**		
	Mean	**SD**	**Mean**	**SD**	
One month before recruit/intervention	5.22	2.98	4.32	2.83	.14
During intervention	5.56	4.63	4.40	3.76	.17
One month after recruit/intervention	1.38	1.21	0.97	1.22	.12

Table 21: Number of specialists visits per capita

	Intervention		Control		P-value (t-test)
N	**40**		**96**		
	Mean	**SD**	**Mean**	**SD**	
One month before recruit/intervention	2.59	2.63	2.96	2.85	.53
During intervention	2.19	2.32	2.04	2.13	.75
One month after recruit/intervention	0.53	0.95	0.53	0.93	.99

Table 22: Overall cost per capita (Euro)

	Intervention		Control		P-value (t-test)
N	40		96		
	Mean	SD	Mean	SD	
Before recruit/intervention	640.26	1,267.79	452.73	1,215.84	0.23
During intervention	2,373.25	3,595.06	2,194.81	3,425.97	0.69
After recruit/intervention	330.65	455.06	549.61	2,005.71	0.6

Table 23: Total hospital-related care cost (Euro)

	Intervention		Control		P-value (t-test)
N	40		96		
	Mean	SD	Mean	SD	
Before recruit/intervention	427.27	1,210.65	257.92	909.35	0.19
During intervention	2,078.70	3,533.25	1,974.03	3,346.23	0.81
After intervention	47.53	110.91	367.79	1,977.66	0.43

Table 24: Total pharmacy cost (Euro)

	Intervention		Control		P-value (t-test)
N	40		96		
	Mean	SD	Mean	SD	
Before recruit/intervention	**94.55**	**281.82**	**47.01**	**101.04**	**0.03**
During intervention	94.55	165.19	65.97	150.39	0.15
After intervention	127.27	305.45	55.84	89.87	0.09

Table 25: Total laboratory testing cost (Euro)

	Intervention		Control		P-value (t-test)
N	**40**		**96**		
	Mean	**SD**	**Mean**	**SD**	
Before recruit/intervention	7.79	12.47	8.57	20.00	0.78
During intervention	**3.38**	**6.49**	**6.75**	**16.10**	**0.05**
After intervention	3.64	13.77	4.16	10.91	0.89

Table 26: Private institutes' visits cost (Euro)

	Intervention		Control		P-value (t-test)
N	**40**		**96**		
	Mean	**SD**	**Mean**	**SD**	
Before recruit/intervention	10.13	34.55	48.83	581.82	0.54
During intervention	63.38	360.52	20.52	145.45	0.139
After recruit/intervention	13.77	40.00	8.31	38.18	0.55

6. Costs effectiveness of net expenses (in Euro) –

For each patient in the intervention group, total cost during the intervention was calculated by adding the intervention cost itself (**248 Euro**) to the overall health costs from Maccabi database, which than was compared to the average cost of the matched patients from the control group:

Table 27:	Overall Expenses			Hospital Expenses		
N	**30**			**30**		
	Mean	**SD**	**One sample test P-value**	**Mean**	**SD**	**One sample test P-value**
During intervention	961.38	3567.19	0.15	750.75	3151.72	0.2
During + one month after intervention	800.73	3882.46	0.27	526.11	3183.82	0.38

One month after intervention	-160.65	1094.92	0.43	-224.64	962.48	0.21

APPENDIX IV

Groningen - Data analyses Implementation Study 2

Table 4.4.1. Overview of usage of ICT and patient compliance.

Prescription type, N (%)	Blood pressure monitor/ heart rate	Thermo meter	Weight	Pain-Questionaire	Post-surgery Questionnaire
Prescribed (for 14 days)	**29 (58)**	**30 (60)**	**25 (50)**	**24 (48)**	**24 (48)**
- Completed ≤ 1	**3 (10.3)**	**2 (6.7)**	**3 (12.0)**	**3 (12.5)**	**2 (8.3)**
- Completed 2-7	**6 (20.7)**	**9 (30.0)**	**7 (28.0)**	**3 (12.5)**	**4 (16.7)**
- Completed 8 – 12	**8 (27.6)**	**10 (33.3)**	**10 (40.0)**	**8 (33.3)**	**8 (33.3)**
- Completed ≥ 13	**12 (41.4)**	**9 (30.0)**	**5 (20.0)**	**10 (41.7)**	**10 (41.7)**

Table 4.4.2. Overview of results and usage Fitbit.

Days Fitbit transmitted	**Pre-operative**		**Month 1**		**Month 2**		**Month 3**	
N	45		44		38		37	
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**
less than 10 days	12	**26.7**	5	**11.4**	2	**5.3**	3	**8.1**
10-20 days	10	**22.2**	4	**9.1**	4	**10.5**	5	**13.5**
21 days and above	23	**51.1**	35	**79.5**	32	**84.2**	29	**78.4**

Table 4.4.3. Overview of health outcome before and after surgery.

	Before (N = 49)		**After (N = 37)**		**P-value (before-after)**
	Mean	**SD**	**Mean**	**SD**	
Frailty (GFI)	**2.14**	1.61	**1.70**	1.70	0.431

Katz (ADL)	**0.24**	0.69	**0.41**	0.87	0.012
Lawton (iADL)	**7.43**	1.23	**7.38**	1.28	0.143
HADS-Anxiety	**3.49**	3.23	**2.49**	2.2	0.399
HADS-Depression	**3.65**	2.86	**2.11**	2.03	0.002
EQ-5D-5L – Q1-Q5	**1.28**	0.41	**1.28**	0.36	0.276
EQ-5D-5L – Health Today	**75.04**	18.83	**74.35**	19.00	0.895