CONNECARE

WP6 – DEPLOYMENT OF CLINICAL STUDIES

D6.4: RESULTS FROM CASE STUDY3

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

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Abstract	The current document reports on the evolution of the prehabilitation service at Hospital Clinic de Barcelona (HCB). It identifies three well-defined phases. The initial thirteen-month period (Phase I) was devoted to deployment of the prehabilitation service for high-risk candidates to major surgical procedures as a mainstream service at HCB. Phase II constitutes an 18-month period, ending on December 2018, wherein assessment of the prehabilitation service in a real life setting was undertaken, using an evaluation framework recently reported in (Baltaxe E et al. BMC Health Serv Res. 2019 Jun 11;19(1):370). Finally, Phase III, running during the entire 2019, addressed: (i) Achievement of maturity of the setting in Barcelona; (ii) Elaboration of risk predictive modelling aiming at personalization of the prehabilitation service; and, (iii) Consolidation of a roadmap for large scale deployment of the service both at regional (Catalan) and international (EU) levels. It is of note that the report summarizes the technological evaluations carried out in Barcelona for all three Case Studies addressed in the project. The current document corresponds to the updated version of the report submitted on 30th June 2019.

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1. Executive Summary

The current document, D6.4, contains information generated by IDIBAPS regarding the evolution of Prehabilitation as a mainstream service at Hospital Clinic of Barcelona (HCB) within the context of the EU project CONNECARE. The central objective of the activity of the project at IDIBAPS-HCB has been to contribute to the development and evaluation of digital tools supporting: (i) adaptive case management (ACM); and, (ii) collaborative work among stakeholders (patients/carers and professionals) involved in the service. Interoperability with existing technology at site level, as well as potential for scalability and transferability, are considered mandatory conditions in order to implement and adopt digital solutions supporting services in real-life scenarios. Additional, but equally important, aims of the project within the context of WP6 have been:

- **Aim 1.** To propose a portfolio of modular and personalized services under the concept of prehabilitation that could fit the needs of patients with a broad spectrum of surgical risk, well beyond the current population of high-risk candidates studied in Barcelona.
- **Aim 2.** To explore interventions addressed to post-surgical care aiming at enhancing recovery after patients' discharge.
- **Aim 3.** To learn from applying a recently reported evaluation framework for deployment of ICT-supported integrated care services that has been generated within CONNECARE.

The current document covers two items: (i) the technological work done in Barcelona for all three Case Studies; and, (ii) the evaluation framework (point 3) alluded to above. The current report is highly complementary with the material reported in a different deliverable, D6.3. We understand that the two documents provide solid grounds to generate preventive perioperative care services for adoption in other sites showing different degrees of care complexities.

The initial Section of the document aims to provide a rationale for the adaptations of the CONNECARE concept in Barcelona. It is valid for all three Case Studies. Consequently, the introductory sections relative to Barcelona's activities in D6.2 and 6.3 will be necessarily brief and will refer to the current document for details. The text of the current document purposely provides a concise description of facts aiming at a fluent reading of the content, but it has been completed with **ANNEXES** and references that address the reader to additional explanatory material, if needed.

It follows a very brief section devoted to the randomized controlled trial (RCT) on prehabilitation of high-risk candidates for major surgical procedures that generated evidence on efficacy, and potential for healthcare value generation, of the intervention. The bulk of the document is structured on three sequential phases that are representative of the evolution of the activity in Barcelona. Within each phase, we highlight major achievements and lessons learnt.

The following deliverables are highly recommended as background material, as well as the current set of WP6 deliverables (specifically D6.2 and D6.3):

Number	Title	Description
D2.1	Cook-book for project development	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 the first co-design period, from the project start to month 18th, 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 learnt during the first period and establishes the strategies for the second period for each of the five dimensions alluded to above. In the conclusions, the report proposes an outline for deliverable D6.1. aiming at assessing feasibility of the implementation studies in the CONNECARE sites, due at the end of January 2018.

2. Site adaptation of the CONNECARE concept in Barcelona

Since the initial design of the clinical implementation studies (first PDSA cycle), the main objective of the deployment in Barcelona has been to explore site adaptations of the CONNECARE concept with a twofold purpose: i) Achievement of large scale deployment of the Case Studies (1,2) in AISBE (Integrated Health District of Barcelona-Esquerra, 520 k citizens); and, ii) Contribute to their regional deployment in Catalonia, as described in the mid-term report.

Barcelona has undertaken the WP6 tasks taking into consideration the five dimensions described in D7.2, namely: 1) Analysis of deployment of integrated care services in real-life scenarios; 2) ICT-support of the integrated care services; 3) Health risk assessment and service selection; 4) Assessment Methodology; and, 5) Transferability and site adoption. The current report addresses the first three items for Case Study 3. Regarding the two last dimensions, it is of note that the characteristics of the assessment methodology are described in D7.2; whereas, the operational aspects of the proposed evaluation framework for four specific study protocols in Catalonia have been reported in (3). The fifth dimension, Transferability and site adoption, was developed during the last six months of the project, based on information generated by the entire CONNECARE consortium, in D7.4.

The Barcelona scenario – Main features of the Barcelona site, wherein CONNECARE is being implemented, can be found in two documents: Catalan open innovation hub on ICT-supported integrated care services for chronic patients[1] and description of the Integrated Care and Systems Medicine (InCaSyM - www.incasym.com) strategic actions (4). The ambition of the implementation in Barcelona is beyond the scope of the CONNECARE project. The developments in the Barcelona site during the period 2016-2019 are the end-result of the interplay between institutional contributions (healthcare providers' and regional authorities) and three different interweaved projects complementary to CONNECARE: ACT@Scale (6); SELFIE (7) and NEXTCARE(8), as described in (3). While CONNECARE focuses on innovative technological solutions supporting integrated care services; ACT@Scale, concluded in March 2019, addressed main drivers modulating large scale deployment; SELFIE, concluded in August 2019, explored an innovative health economics assessment methodology for integrated care services based on multi-criteria decision analysis (MCDA) (9)(10); and, NEXTCARE, to be ended on 15th January 2020, is an umbrella project governing practicalities of the regional implementation of integrated care services for chronic multimorbid patients focusing on cardiovascular disorders, chronic respiratory diseases and type 2 diabetes mellitus. The activities in the Barcelona site during the period 2016-2019 aim to foster the transition from previous pilot experiences (11–15) to large scale deployment of integrated care services fully aligned with the Chronic Care Program of the Catalan Health Plan 2016-2020. Promotion of synergies among the four projects alluded to above, and with institutional initiatives at regional level, while preventing redundancies among the different initiatives have been the two main priorities in the Barcelona site.

[1] https://ec.europa.eu/health/sites/health/files/non_communicable_diseases/docs/ev_20181212_co02_en.pdf

The current document only addresses outcomes of the CONNECARE project. However, interactions with the other three projects, as well as with ongoing institutional initiatives, are indicated across the text.

Risk factors for deployment of the clinical implementation studies – During the Project Board meeting held in Tel-Aviv on January 2018, we forecasted two main risk factors that may preclude a proper development of the clinical implementation studies in Barcelona. These potential problems were indicated in D6.1 (page 9, last paragraph): *"Two categories of risk factors limiting the outcomes of the implementation studies in Barcelona (IDIBAPS) have been identified. Firstly, the robustness and time of the technological developments carried out within the project, as indicated in Section 5 of the current document (D6.1).*

A second potential limiting factors is availability of large datasets needed to elaborate multilevel predictive modelling for case studies 1 and 2 & 3. The latter is a potential limiting factor external from the consortium that is actively worked out in order to prevent limitations in the planned tasks for 2018".

To prevent the potential negative impact of these two risk factors, specific contingency plans were activated in February 2018 such that we can ensure accomplishment of the site implementation plans agreed in the DoA. The current document addresses risks associated with the technological component; whereas most of the items related with data management will be analysed within WP7 *(Evaluation and Scale-up)*, wherein critical aspects and specific proposals will be reported.

Site evolution of the CONNECARE technological dimension – Four main technological developments can be identified within the project: (i) SMS (self-management system) to enhance interactions between patients and health professionals fostering patients' empowerment for self-management; (ii) ACM (Adaptive Case Management) aiming at supporting flexible workflow within a context of collaborative work among health professionals, and with patients; (iii) Clinical decision support systems supporting subject-specific predictive modelling to feed clinical decision support tools (CDSS) integrated with the ACM platform (SACM – Smart Adaptive Case Management); and, (iv) Digital tools supporting collaborative work with proper integration strategies with health information systems both at providers' level and at regional level. The first three integrated elements, ACM, SMS and the CDSSs (SACM), constitute the CONNECARE technological platform.

During the two initial PDSA cycles, all four clinical sites contributed the co-design process supporting the technological developments of the project, led by WP2. But, the technological risks triggered three main proposals that were activated at site level in order to comply with the specifics needs of CONNECARE in Barcelona, namely:

Need 1. To ask the technological partners the possibility of testing the CONNECARE platform as a whole, but also to address the different elements separately. Specifically, SACM and SMS.

Need 2. To explore alternative digital tools, complying with the CONNECARE concept, easily adaptable to the site requirements for large scale deployment of the services, and

Need 3. To take into account the interoperability requirements at site level in order to address both technical and functional integration with site-specific health information systems during the lifetime of the project.

Consequently, since March 2018, Barcelona have been keeping track of the evolution of the CONNECARE platform as a whole in order to assess its potential for fulfilling the requirements of the integrated care services associated to the three case studies of the project. However, during the entire period there has been a continuous and rich debate between two different strategies regarding the technological approach of the project; that is:

Strategy I. Development of a technological platform with the CONNECARE functionalities, as identified above, and make it interoperable with site-specific health information systems, or,

Strategy II. Adoption or adaptation, of different interoperable digital tools ensuring CONNECARE functionalities needed to provide functional and technological integration with different healthcare providers.

The team in Barcelona has undertaken a formal testing of the entire CONNECARE platform in a group of patients (n=20, see D6.2), but clearly adopted the second strategy that has been dynamically adapted to emerging needs identified during the process. This evolutionary process and the lessons learnt are described in the current document (D6.4) for each of the three clinical implementation studies. To this end, adaptations of three different digital health tools have been done in Barcelona, as described in detail in **ANNEX I**, namely: (i) MyPathway®, from the CONNECARE partner ADI; (ii) the CONNECARE SMS suitably adapted for perioperative case; and, (iii) Health-Circuit®, from Atos-Unify). Moreover, we explored, for Case Study 3, to build-up the SACM into the health information system at IDIBAPS-Hospital Clinic (**ANNEX II**). With the proposed approach, the SACM concept and clinical decision support systems (CDSS), can be embedded into each digital tool, as well as into the clinical workstations of healthcare providers.

Site logistics for assessment of the technological dimension – The assessment tools and methodology agreed between WP2 and WP7 have been fully implemented in Barcelona since very early phases of the project. Main specificities at local level have been: (i) Development of strong synergies with the technological partners of the NEXTCARE project, also led by EURECAT, ensuring proper coordination of the technological aspects of the two projects; and, (ii) To establish a well-defined methodology for co-design and decision making at local level through two meetings, technological and scientific, carried out at IDIBAPS-Hospital Clinic on a weekly basis.

The technological meeting is held every Thursday, from 2:00-3:00 pm, including people with technological (I Cano, F Burgos, and E Aumatell) and clinical (C Herranz, E Baltaxe, A Barberan, G Martinez, M Jose, C Hernandez and J Roca) backgrounds. Controversial and strategic aspects are further discussed and decided in a scientific meeting carried out weekly by a core group of professionals (I Cano, F Burgos, C Hernandez, C Herranz, E Baltaxe, J Roca and A Barberan) every Friday between 08:00 to 09:00 am. Moreover, since the initiation of the project there are continuous

iterations with the technological partners involved in CONNECARE and NEXTCARE in order to identify and foster synergies across the both initiatives.

The team in IDIBAPS-Hospital Clinic understands that the different digital tools, as well as the CONNECARE platform as a whole, should be embedded into well-defined integrated care service workflows (i.e. Case Studies). The technology can play either a disruptive or a supporting role. But in all circumstances, adoption of specific digital tools must follow proven generation of healthcare efficiencies. The added value of use of digital tools in CONNECARE will be analysed in WP7 using the mini-MAST tool (16) for assessment of mature technologies. In WP6, throughout the project lifespan, we are testing the process of refinement of the digital tools embedded into the clinical services. To this end, the technological assessment, as described below, will consider the following four dimensions: (i) robustness; (ii) safety; (iii) acceptability/usability by patients or health professionals; and, (iv) potential for scalability beyond the project lifetime.

The statements under the current subheading apply for all three case studies implemented in Barcelona: Case Study 1 (D6.2); Case Study 2 (D6.3); and, Case Study 3 (D6.4). Consequently, under the site adaptation subheading in D6.2 and in D6.3, we will refer to the current section describing the work accomplished for each of the study protocols undertaken. Access to complementary material and/or expanded text can be easily accessed through the on-line accessible Annexes. The current new edition of the document is strongly aligned with D7.3 and D7.4.

3. Prehabilitation service at HCB-IDIBAPS: Background

It is well known that major surgical interventions are associated with high reductions in functional capacity (17). This deconditioning places the patients at a higher risk of postoperative morbi-mortality, complicating the recovery phase after the surgical intervention (18). It has been reported that patients' functional capacity might not return to baseline for a prolonged period of time (19,20). Moreover, the perioperative process is often more complex for elderly and high-risk patients with comorbidities (21,22) in whom perioperative stress results in further deterioration of the baseline health status (23). It has been demonstrated that postoperative complications generate a considerable preventable use of healthcare resources and they are the strongest indicator of in-hospital costs in major surgical procedures (24). Therefore, the design and implementation of novel interventions, such as prehabilitation, to prevent postoperative complications was identified at HCB-IDIBAPS, in 2013, as a relevant objective to be achieved. Prehabilitation is a preparatory intervention, carried out on average during a 4 to 6-week period before the surgical intervention, aiming at reducing post-operative complications. Enhancement of patients' functional status through: (i) Exercise training & increase of daily-life physical activity; (ii) Nutritional optimization; and, (iii) Psychological support play central roles (23).

From 2013 to 2016, we conducted a randomized controlled trial at HCB-IDIBAPS in order to assess the efficacy of a prehabilitation intervention aiming at reducing postoperative complications in high-risk patients undergoing to major elective digestive surgery (25). The study results showed prehabilitation as a protective factor for postoperative complications reducing the number of patients suffering from complications by 51% (RR 0.5, 95% CI [0.3-0.8]; p-value=0.001). Moreover, the investigation also reinforced the role of prehabilitation preventing more than one complication and reducing the days of intensive care unit stay (26). The cost of the intervention was of €389 per patient. Importantly, the cost-consequences analysis showed the program as a "value-generation" intervention since no increase of the overall perioperative costs was evidenced. In fact, the assessment postulated the high potential of prehabilitation for cost-savings [€812 (CI 95% -878 – 2,642; p-value=0.365)][2].

The positive results of this RCT fostered the creation of the Prehabilitation Unit at HCB in April 2016, as detailed in the following section.

[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) (find full manuscript in **ANNEX IV**).

4. CONNECARE: Assessment and achievement of maturity of the prehabilitation Unit

The Prehabilitation Unit started to operate as a mainstream service at HCB in April 2016. From then on, we identify three distinctive phases of the development of the Unit, as described below:

Phase I, *April 2016 - May 2017 (M1-M13)* **–** The main goal was to define clinical service workflows and to build-up and refine the gym infrastructure at HCB. It is important to highlight that during the period the types of surgeries attended in the unit gradually augmented from one (i.e. digestive surgery) to five (i.e. digestive, cardiac, thoracic, urologic and gynaecologic surgeries).

The candidates to be included in the prehabilitation program were selected based in the following criteria: i) High-risk patients undergoing major surgery, defined as American Society of Anesthesiologist (ASA) score 3-4 and/or age > 70 years; ii) Patients undergoing solid organ transplantation; and/or, iii) Patients undergoing highly aggressive surgical procedures (i.e. pelvic exenterations, esofagectomies, total gastrectomies, etc.). These 3 inclusion criteria generate an overall average demand of 1,200 candidates to prehabilitation per year that cannot be covered due to limitations of the logistics and manpower devoted to the program. As mentioned, the intervention was also refined, as compared to the RCT period (2013-2016), such that the service workflow included the following five items: (i) motivational interview; (ii) promotion of physical activity; (iii) supervised exercise training; (iv) nutritional management; and, (v) psychological support.

From the technological standpoint, the team implemented integration of the Prehabilitation Unit to the Health Information System at HCB, as described in detail in **D5.5 - Final release of the Catalan CONNECARE system**. Testing of different wearable devices (i.e. Fitbit® and LifeVit®) for remote monitoring of daily physical activity was done. Moreover, follow-up of SACM-SMS developments as well as initial conceptual designs of dedicated apps were initiated.

Phase II, *June 2017-December 2018 (M14 – M32) –* During this 18-month period, the Prehabilitation Unit achieved full functionality performing at its maximal capacity relative to available resources. The results of the CONNECARE prehabilitation protocol reported in the current document pertain to this second phase.

Additional to the co-design activities planned in CONNECARE, three co-design workshops were planned during Fall 2017 aiming at defining Lean Thinking strategies to achieve scalability of the Prehabilitation service beyond the current setting.

From the technological standpoint, a contingency plan was initiated in March 2018 aiming at adapting a digital tool (MyPathway®, https://mypathway.healthcare/) (**ANNEX I**) owned by one of the CONNECARE's partner, ADI, to the requirements of the Prehabilitation service (applicable to Case Studies 2 and 3), as reported in the current document, and to those defined for home-based non-invasive ventilation (Case Study 1), as reported in D6.2. Moreover, in December 2018, we worked

together with EURECAT to adapt CONNECARE SMS to the needs identified for the Prehabilitation service.

Phase III, from *January 2019 till project end (M33 – M45)* – The activity is being devoted to achievement of full maturity of the Prehabilitation Unit at HCB in terms of both technological support and service workflow definition. In this regard, the three main objectives are: (i) Refinement of the digital tools to fully achieve a collaborative ACM approach which should lead to modularity and personalization of prehabilitation services; (ii) Technological and functional integration at HCB level, including developments of the ACM concept into the web-layer of the clinical workstation at HCB; and, (iii) Define the implementation steps needed for regional scalability of the prehabilitation program at Catalan level. Moreover, the current document describes the core traits of the protocol designed to generate risk predictive modelling for candidates to major abdominal surgery following a similar approach already reported for Case Study 1 in D6.2. The study protocol is currently being done. Finally, beyond CONNECARE lifespan, we are preparing transferability of the prehabilitation program at international level in Grenoble (F), Köln (D) and Gdanz (P), as part of an EIT-Health program (PAPRIKA, 2019-20121) (27). Detailed information about the activities currently undergoing is reported in the current document.

4.1 Clinical assessment of the Prehabilitation Unit - *Phase II (M14-M32)*

The results of the RCT carried out at HCB (26) demonstrated efficacy and potential for healthcare value generation of the prehabilitation intervention based essentially on exercise training and promotion of physical activity, as shown in **Figure 1** and **ANNEX IV** .

During Phase I of CONNECARE, three main goals were achieved: (i) Maturity of technological and organizational aspects of the Prehabilitation Unit; (ii) Well-defined service workflow addressed to high-risk candidates for major surgical procedures using a multimodal approach (i.e. exercise training, promotion of physical activity, nutritional optimization, and psychological support); and, (iii) Expansion of prehabilitation as mainstream service at HCB for up to five types of major surgical procedures, as alluded to above.

Next natural goals during the 18-month period of Phase II were: (i) To assess effectiveness of prehabilitation in a real life setting; (ii) To identify the cost-components and explore determinants of financial sustainability of the services; and, (iii) To perform a critical analysis of the implementation strategy followed at HCB in order to identify facilitators and barriers modulating transferability of the service to other geographical areas with similar or different healthcare systems.

To this end, we undertook the current study protocol summarized in the current document. Its main traits have been described in detail in the evaluation framework reported in (3) following an implementation science approach that focuses on four different domains, namely: (i) Assessment of prehabilitation health outcomes with a Quadruple Aim approach (28,29); (ii) Evaluation of the service implementation strategy; (iii) Assessment of the ecosystem maturity; and, (iv) Identification of key

performance indicators (KPIs) for service long-term follow-up in different scenarios beyond the implementation phase, after large scale adoption of the service.

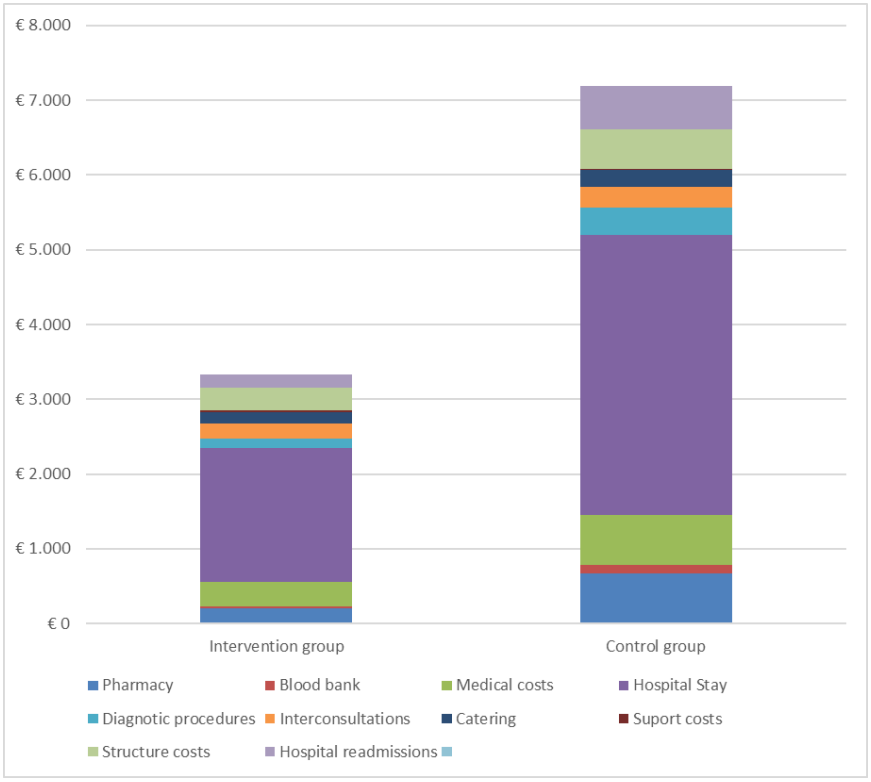


***Figure 1** - Comparison of costs from the hospital perspective between prehabilitation and the control groups (**ANNEX IV**).*

From June 2017 to December 2018, a total of 372 patients were enrolled in the Prehabilitation Unit at HCB. The inclusion/exclusion criteria have been mentioned above and are reported in detail in (3). All studies were done by face-to-face interactions with the prehabilitation team and promotion of physical activity was additionally supported using different commercialized stand-alone analogical tools monitoring physical activity. None of the patients was excluded from the prehabilitation program because of technological factors limiting usage of digital tools. Main variables characterizing of the subjects of the intervention group are reported in **Table 1**.

In this study group, the prehabilitation intervention had a mean duration of 55 (60.0) days. The mean hospital length of stay was 9.8 (10.2) days and the ICU stay was of 2.5 (4.7) days. The mean number of complications per patient was of 1.1 (1.4).

We are currently in the process of building a contemporaneous control group (1:1 ratio) with surgical patients' candidates to prehabilitation admitted in the HCB, but not included in the intervention group because of the limited capacity of the current prehabilitation program.

Comparability among intervention (prehabilitation) and control groups will be addressed using a two-step propensity score matching (PSM) approach. Firstly, we will do a one-to-one PSM using the following five variables: Type of surgery, age, sex, American Society of Anaesthesiology (ASA) risk

index(30), and multimorbidity using adjusted morbidity groups (GMA) grading (31). In a second step, we aim to enhance comparability between groups by using an inverse probability of treatment weighting (ITPW) approach.

The data analytics planned for the study requires integration of three datasets from different sources: (i) SAP system at HCB; (ii) ECAP (Primary Care) health information system; and, (iii) Registry data from the Catalan Health Surveillance System. However, as initially forecasted, we have faced limitations in terms of data management, due to different interpretations of the GDPR that have been delaying the elaboration of the control group. The activation of a contingency plan addressed to overcome those limitations should facilitate completion of data analytics by the end of January 2020.

Table 1. Main traits of the prehabilitation group enrolled from June 2017 to December 2018

	Prehabilitation group		
TYPE OF SURGERY	**AGE** mean (SD)	**ASA 1-2** n (%)	**ASA 3-4** n (%)
All surgeries (n, 372)	**70 (11)**	**253 (69)**	**117 (31)**
Esophagectomy (n, 30)	63 (9)	25 (85)	5 (17)
Pelvic exenteration (n, 2)	62 (1)	2 (100)	0 (0)
Peritonectomy (n, 1)	79	1 (100)	0 (0)
Gastric surgery (n, 37)	73 (9)	30 (81)	7 (19)
Pancreatic surgery (n, 10)	70 (12)	7 (70)	3 (30)
Colorectal surgery (n, 84)	73 (12)	64 (77)	19 (23)
Liver surgery (n, 37)	77 (7)	15 (40)	22 (60)
Cystectomy (n, 50)	68 (10)	48 (96)	1 (4)
Prostatectomy (n, 1)	70	1 (100)	0 (0)
Oncologic gynaecologic surgery (n, 4)	63 (5)	4 (100)	0 (0)
Hepatic transplantation (n, 2)	58 (8)	2 (100)	0 (0)
Cardiac revascularization surgery (n, 11)	64 (9)	2 (18)	9 (82)
Cardiac valve replacement surgery (n, 50)	64 (9)	13 (26)	37 (74)
Cardiac revascularization & valve replacement surgery (n, 9)	68 (7)	0 (0)	9 (100)
Other cardiac surgeries (n, 4)	74 (6)	2 (50)	2 (50)
Lung resection surgery (n, 37)	68 (11)	33 (92)	4 (8)
Mesothelioma surgery (n, 3)	62 (11)	3 (100)	0 (0)

The expected outcomes of the current clinical assessment will fully cover the goals indicated above and should provide solid grounds for further developments of the prehabilitation service.

4.2 Lean Thinking workshops exploring scalability - *Phase II (M14-M32)*

In October 2017, the Prehabilitation Unit at HCB was providing support to the intervention as a mainstream service for several surgical procedures. However, there is a clear need for refinement of the standard prehabilitation approaches in order to increase future transferability to other sites, facilitating regional deployment and sustained adoption of the service. To this end, we conducted three multidisciplinary workshops during a two-month period to explore the role of Design Thinking methodologies to enhance the prehabilitation service workflow. A detailed description of the setting and full explanation of the methodological aspects are reported in detail in **ANNEX III**.

Design Thinking refers to creative solution-based strategies used in a product design process, but also applied in other contexts such as business and social services (32). Design Thinking

strategies fall into the umbrella of human-centred design, a discipline originated in the field of computer science, artificial intelligence and ergonomics (33) that has evolved over time being increasingly applied to service design strategies. The key principles of the human-centred design approach were established in 2010 by the International Organization for Standardization (34).

Briefly, we generated a roadmap for three Design Thinking sessions, each of a five-hour duration, aiming to address three core aims, namely: i) Identify actionable factors modulating regional scalability of prehabilitation; ii) Enhance efficiencies of the service with the use of digital tools, and, iii) Design a business model contributing to sustainable adoption of the service. The ultimate aim was to foster regional scalability of prehabilitation in Catalonia (ES) (7.5 m citizens) (35). It is important to highlight that the content of the three Design Thinking workshops was based on preliminary work consisting of two actions. Firstly, we performed a survey aiming at gaining insight into the organizational aspects and service workflow of the Prehabilitation Unit at HCB. The survey was carried out with professionals involved in the design and management of the service. It also included other healthcare professionals having direct contact with the patients enrolled in the service, including: anaesthesiologists, physiotherapists, nurses, and psychologists. Secondly, we carried out in-depth face to face interviews with five patients and their respective caregivers who had participated in prehabilitation, aiming at capturing the patient experience perspective of the service.
The Design Thinking workshops included all the stakeholders' profiles, namely: healthcare professionals and managers, designers, health-technology agents, business school representatives and policy makers, as reported in https://stimulo.com/portfolio/prehab/ (**ANNEX III**) An average of 40 persons attended each of the sessions.

The first co-design session (*Immersion*) aimed to gain further insight on actionable factors limiting the scalability of prehabilitation and to identify opportunities for service improvement. The main objective of the second session (*Ideation*) was to generate, evaluate and develop both ideas and plans to solve the factors identified in the first session. Finally, the third session (*Validation*) was devoted to consolidate the concepts resulting from the second workshop, focusing on service optimization and financial sustainability in order to achieve full regional coverage of the service (**Table 2**).

Main bullet results from the co-design sessions were as follows:

- Importance of the personalization and modularity of the service to ensure adoption.
- Definition of specific work plans combining face-to-face and remotely supervised sessions with access to partnering health/wellness centres.
- Provide technologically-supported empowerment for self-management with off-line monitoring and access to a case manager.
- Use of adaptive case management technological support to the workflow in order to fulfil the requirements of flexibility and modularity of the service.
- Elimination of complex frontends and driving of the patient interaction and data collection through an artificial intelligence assisted chat (i.e. Chatbot).

- Definition of a business model envisaging operational costs financed by savings generated by the service.
- Eventually increase the cost-savings by the participation of external sport centres, physiotherapy companies and use of information and communication technologies as enabling tools.

It is of note that during the sessions, commonalities between the prehabilitation interventions and rehabilitation of chronic patients were found. In summary, Lean Thinking was identified as an appropriate methodological approach to explore future solutions to substantially enhance accessibility and sustainability, both financial and results, of rehabilitation programs.

Table 2. Main results of the Design Thinking sessions

	Aims	Tools	Results
PRELIMINARY FIELDWORK	• To capture the patient experience perspective of the service. • To identify factors of the prehabilitation service at HCB that may limit scalability.	• In-depth interviews to patients and caregivers. • Surveys to professionals involved in the prehabilitation unit.	• Identification of actionable areas to be addressed in Session I – Immersion (see text).
IMMERSION *(Session I)*	• To gain further insight on organizational and actionable factors of to enhance scalability of the existing prehabilitation to: a) Optimize service workflow. b) Identify ICT-support to scalability. c) Explore financial needs for adoption.	• Elaboration of the following material contributing to refinement of the Prehabilitation service: ○ Experience map (ANNEX III, Fig 1). ○ Empathy map (ANNEX III, S1 Fig). ○ Context map (ANNEX III, S2 Fig). ○ Priority map (ANNEX III, Fig 2).	• Agreement on the main challenges to face and solve in Sessions II and III. Main outcome of the Immersion was "to *provide an accessible, round-the-clock personalized and modular service that the patients should be able to use autonomously during the prehabilitation period. The service should combine remotely controlled actions and face to face interactions with health professionals".*
IDEATION *(Session II)*	• To generate, develop and assess ideas and plans to solve the challenges identified in Session I.	• Two inspirational presentations. • Small group creative sessions. • Positioning map (ANNEX III, Fig 3).	• Generation of a customer journey that should contribute to define a viable strategy for regional deployment of prehabilitation. To this end, an overview of the prehabilitation service workflow was produced, as a visual map depicting the end users touch points and needs for both ICT-support and business model.
VALIDATION *(Session III)*	• To consolidate the proposals and refine the actions resulting from Session II aiming to define a viable strategy for regional deployment of a refined service workflow.	• Three working groups to separately tackle specific areas and final overall group meeting to generate consensus on specific proposals for each area: ✓ Implementation strategies. ✓ Technology-related aspects. ✓ Business model & reimbursement incentives.	• Fulfill end-user touch points (see text for more details) • Creation of a capillary network of healthcare/wellness centers to enhance accessibility. • Mobile app fostering tailored patient empowerment for self-management and remote monitoring. • Interoperability of ICT-enabling tools with existing HIS. • ACM system to support prehabilitation knowledge intensive processes for enhanced service management. • To drive patient interactions and data collection through an AI assisted chat (i.e. Chatbot). • Cost-savings generated by prehabilitation should cover the operational costs of the service. Investments needed to launch the service, as well as reimbursement incentives, could be covered by innovative PPP models.

4.3 Overall technological approach

The results of the Lean Thinking approach described above reinforced awareness of the huge potential of digital tools to support the case studies in Barcelona and they contributed to consolidate our basic ideas about functionalities required to support large-scale implementation of the services. At the same time, the developments associated to the CONNECARE platform: SACM + SMS, while being conceptually attractive, were showing 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 precluding its use in the implementation studies 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 a contingency plan, early 2018, to cover the technological requirements of the implementation studies testing a number of prototypes, and existing commercial digital tools, aligned with the following technological approach:

Case studies in Barcelona focus on the implementation of integrated care services that facilitate care coordination across healthcare tiers, within and across organizations, as well as patient empowerment for self-management (**Figure 2**). To this end, digital health tools should be made available to:

- Healthcare professionals, in order to communicate with patients/carers and other professionals to coordinate care based on shared care plans with a predictive, preventive and adaptive case management approach.
- Patients, in order to participate in effective self-management strategies that include assessment, goal-setting, action planning, problem solving and follow-up.

Therefore, the technological approach in Barcelona considered the following strategy:

- First, to implement and assess personal health systems for patients (i.e., MyPathway® (**Annex I – Section 8.1**), the adaptation of the CONNECARE SMS (**Annex I – Section 8.2**) and Health-Circuit app (**Annex I – Section 8.3**).
- Second, to implement and assess collaborative tools for healthcare professionals (i.e., REDCap™ (https://redcap.clinic.cat/) and Health-Circuit (**Annex I – Section 8.3**)).
- Finally, based on the results of the technological evaluations, to integrate the most usable personal health system with the most accepted collaborative tools, as well as site-specific hospital information systems, by means of an HL7-FHIR interoperability middleware (see **D5.5 - Final release of the Catalan CONNECARE system**).

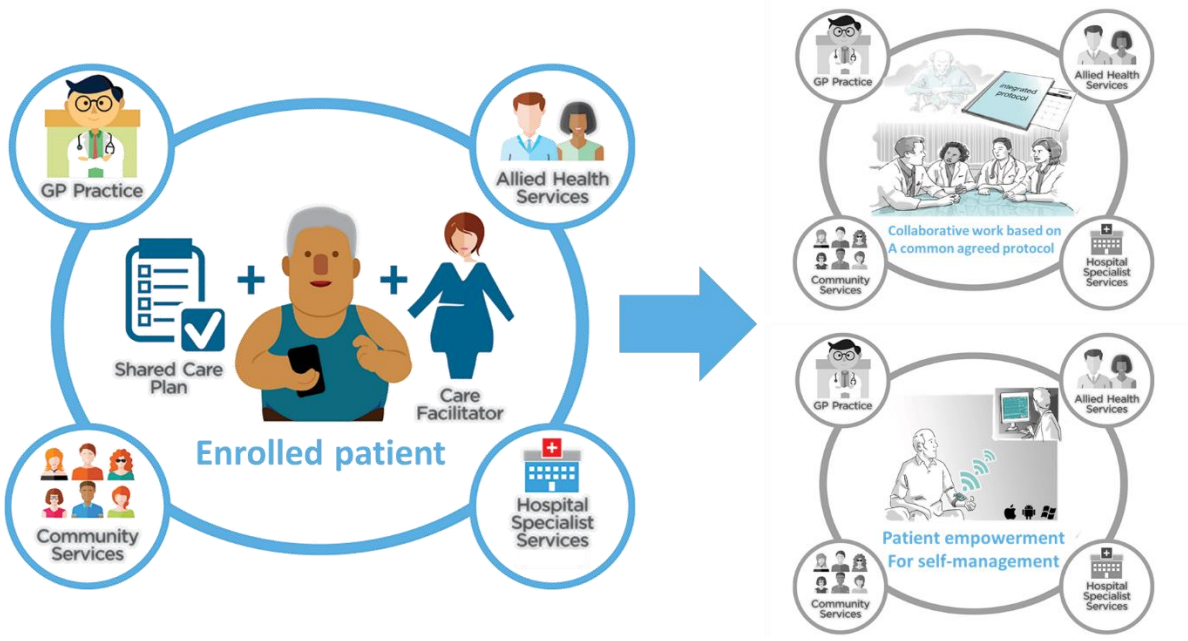


Figure 2 - Implementation of integrated care services that facilitate care coordination across healthcare tiers, within and across organizations, as well as patient empowerment for self-management, requires digital health tools that support collaborative work among all stakeholders, based on a common agreed care plan, and patient empowerment for self-management.

In parallel, the technological evaluation of the final release of the Catalan CONNECARE system (SACM+SMS, see **D5.5**) was also performed in Barcelona.

Personal Health Systems for Patients – since the CONNECARE Self-Management System (SMS) was not technically decoupled from the CONNECARE platform (SACM+SMS), the partner ADI offered MyPathway® (https://mypathway.healthcare/) to conduct two simultaneous studies assessing performance of local adaptations of MyPathway® to support patient empowerment for self-management in specific healthcare services in Barcelona: Prehabilitation and Home-based non-invasive ventilation (**Annex I – Section 8.1**). Briefly, adaptation of MyPathway® was achieved from March 2018 to March 2019, but, although usability and acceptability of the app by the patients was rather good, the final release was not considered sufficiently mature for real life deployment. Moreover, it did not implement functionalities to support collaborative work, in a flexible manner, involving multiple players: patient/carer and several professionals.

For these reasons, the team in Barcelona decided to discontinue the work on MyPathway® and, since November-December 2018, explored two alternative complementary digital solutions: the adaptation of the CONNECARE SMS for CS3 in Barcelona and its decoupling from the SACM (**Annex I – Section 8.2**), and Health-Circuit (**Annex I – Section 8.3**).

Briefly, the adaptation of the CONNECARE SMS for CS3 in Barcelona consisted of a reworking of the functionalities of overall CONNECARE SMS to the requirements of the multimodal prehabilitation service currently deployed at HCB, including changes modularity of the technical solution and adaptation to the interface level. The system has been developed by partner

EURECAT with close and continuous iterations with the prehabilitation team at HCB-IDIBAPS. A version is available at HCB for testing since 11th June 2019. Immediately after the initial testing, it was moved to production status, on October 2019 (see D6.3), undertaking its integration with the health information system at HCB (**ANNEX II)**, as detailed in **D5.5 - Final release of the Catalan CONNECARE system**. Since the adapted version of the CONNECARE SMS has been decoupled from the CONNECARE SACM, a new web backend was also developed 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. However, the backend of the CONNECARE SMS for CS3 in Barcelona does not provide build-up capacities for adaptive case management.

The team in Barcelona also explored the adaptation of a new digital tool, Health-Circuit, conceived as a tool complementary to the adapted version of the CONNECARE SMS for CS3 in Barcelona. Health-Circuit embraces the newest generation of cloud-based, GDPR-compliant, enterprise-proven team collaboration technology to allow patients and healthcare professionals to breakdown silos and collaborate seamlessly from any device (mobile phone, tablet, or desktop) towards the health continuum care pathway. The potential of Health-Circuit in terms of acceptability, usability by patients and health professionals was tested at HCB for prevention of hospitalizations in a vertical integration service in AISBE (Barcelona), described in detail in Study Case 1 (D6.2). In order to conduct the usability and acceptability study, a new app frontend was developed to adapt to the needs of an elder, frail population.

Collaborative tools to support adaptive case management – Taking into account the maturity of the various personal Health Systems considered during the study period, further developments of the new web backend for the CONNECARE SMS have been planned in the forthcoming months to include adaptive case management capabilities as well as a multimedia communication to support collaborative work. Whereas adaptive case management will be provided first by integration with a widely accepted electronic case report form, REDCap™ (https://www.project-redcap.org), and then by extension of the backend functionalities, messaging functionalities will be developed first as an extension of the web backend functionalities, and then integrated as one component of Health-Circuit. More interestingly, Health-Circuit allows developing and incorporating intelligent bots to assist case management through complex care paths as well as to improve current health risk assessment and patient stratification strategies.

Lessons learnt from the technological approach in Barcelona – From the evaluation of the above technological support to implementation of integrated care services in Barcelona, main recommendations would be to consider the adaptation and integration of mature technological tools to cover the four main functional requirements illustrated in Figure 3, and listed below:

- Support collaborative work among stakeholders with a GDPR-compliant **"corporate" communication** platform that allow patients and health professionals stay connected and share

required information throughout the care process. Please, notice that the term **"corporate"** refers to communication across healthcare tiers and across providers.

- Allow patients and health professionals to keep engaged and guided throughout the care process by means of a **workflow engine** with adaptive case management functionalities.
- Easy to use and technologically mature mHealth applications to support patient empowerment for self-management.
- Integration of the tools with site-specific hospital information systems, and existing health information platforms (health information exchange platform at regional level in Catalonia, HC^3), by means of an HL7-FHIR interoperability middleware.

Figure 3 – Main functional requirements for supporting digital health tools to effectively support implementation of integrated care services in Barcelona.

4.4 Risk assessment protocol - *Phase III (M33-M45)*

There is an ongoing protocol to elaborate multilevel predictive modelling tools, using machine learning, to enhance risk assessment of patient's candidates to major surgery. Both goals and methodological approach will mimic the description done in D6.2 for home hospitalization. The study will be constrained to patient's candidates for abdominal surgery. As indicated above, the work has experienced delays to constraints in data management. It is expected to be completed within the first trimester of 2020.

The current study represents a first step toward personalization of perioperative care. It has a threefold objective: (i) retrospectively assess risk levels for major abdominal surgery in our setting at HCB; (ii) compare how predictive modelling generated in the ongoing study compares with the different rule-based predictions recommended at international level; and, (iii) assess risk levels of the patients that underwent prehabilitation (Table 1) using the predictive modelling generated in the study. A second step to be initiated during 2020 is to produce risk assessment tools for perioperative care to facilitate personalization of the service.

5. Future steps of the prehabilitation program

The Barcelona team estimates that the prehabilitation setting is reaching full maturity in terms of: (i) Adoption a portfolio of well-defined modular services; (ii) Implementation of selected digital tools; and, (iii) Roadmap for further developments at HCB level by the end of July 2019. During the last period of the project ending in December 2019, we identify three simultaneous activities. That is, (i) Technological refinement of the HCB setting: (ii) Evolution of the current prehabilitation focus on moderate to high-risk patients to a broader approach aiming at population-health approach of prevention of surgical complications covering the entire spectrum of risk, as well as define the characteristics of a realistic post-surgical care program, as pictured in D6.3; and, last but not least, (iii) Consolidation of the roadmap for scalability of prehabilitation in Catalonia and at international level.

Regionalization of prehabilitation in Catalonia - Prehabilitation is one of the relevant programs within the ***Catalan open innovation hub on ICT-supported integrated care services for chronic patients***, selected as EU Best Practice (36)[3]. Since the early phases of the project, prehabilitation setting at HCB and IDIBAPS was conceived as an early deployment phase before adoption of the service at regional level. We are currently in a position to share, and debate, the portfolio of modular services with key healthcare providers, namely: (i) Catalan Health Institute (ICS) responsible for approximately 55% of hospital healthcare provision in Catalonia, and, (ii) two hospitals (Vic and Granollers) that have the HCB as reference centre. Moreover, we will be in a position to address integration of selected digital tools into the patients' personal health folder (La Meva Salut), extensively deployed by the Catalan Government and fully integrated into the health information exchange platform at regional level (HC3).

International implementation of the prehabilitation service – Since January 2019, the prehabilitation service at HCB is jointly driving, with ATOS (NEXTCARE project) and EURECAT, transferability of prehabilitation to other three areas at EU level: Köln (D), Grenoble (F) and Gdansk (PL), within the frame of the EIT-Health project PAPRIKA (2019-2021) (27). The project has three well defined phases briefly described as follow: (i) Full maturity of the Barcelona setting and co-design for customization of the prehabilitation program in the other three sites, during 2019; (ii) Evaluation of prehabilitation deployment in all sites and elaboration of business plans, during 2020; and, (iii) Commercialization of the prehabilitation service at international level, during 2021. A meeting held on 17-18 June 2019 in Barcelona contributed to consolidate the site customization phase in France, Germany, and Poland. It is expected that the process will generate input for the transferability proposals at CONNECARE level.

[3] https://ec.europa.eu/health/sites/health/files/non_communicable_diseases/docs/ev_20181212_co02_en.pdf

6. Conclusions

The activity carried out in Barcelona during the period has generated robust information on efficacy, as well as potential for health value generation, of the current prehabilitation service at HCB, addressed to high risk candidates for major surgical procedures. The ongoing data analytics on the activity of the Prehabilitation Unit over an 18-month period, June 2017 to December 2018, will likely produce data supporting effectiveness. Moreover, the evaluation framework applied in Barcelona (3) should provide valuable data on barriers/facilitators useful to make proposals for large scale deployment of the service at regional and international levels.

The pragmatic technological approach of the CONNECARE project in Barcelona has significantly increased our knowledge on the characteristics required to the digital tools to efficiently support the service. at the end of the project, we should provide technological solutions for case management using an adaptive approach (ACM), as well as efficient smart support to collaborative work.

Major challenges to be faced before the end of the project are: (i) Elaboration of enhanced risk assessment strategies contributing to personalization of the prehabilitation service; (ii) Consolidation of a modular service portfolio covering a broader spectrum of patients' risk; (iii) Elaborate and refine specific financial proposals to ensure sustainability of the prehabilitation services; and, (iv) Generate a well-defined roadmap for scalability of the prehabilitation service.

7. References

1. Hernandez C, Casas A, Escarrabill J, Alonso J, Puig-Junoy J, Farrero E, et al. Home hospitalisation of exacerbated chronic obstructive pulmonary disease patients. Eur Respir J. 2003/02/07. 2003;21(1):58–67.

2. Puig-Junoy J, Casas A, Font-Planells J, Escarrabill J, Hernández C, Alonso J, et al. The impact of home hospitalization on healthcare costs of exacerbations in COPD patients. Eur J Heal Econ. 2007;

3. Baltaxe E, Cano I, Herranz C, Barberan-Garcia A, Hernandez C, Alonso A, et al. Evaluation of integrated care services in Catalonia: population-based and service-based real-life deployment protocols. BMC Health Serv Res [Internet]. 2019 Jun;19(1):370. Available from: https://doi.org/10.1186/s12913-019-4174-2

4. INCASYM. Implementation of Intregrated Care Services with a Digital Health & Systems Medicine Approach.

5. CONNECARE (H2020-PHC-25-2015-689802) – Personalized Connected Care for Complex Chronic Patients (www.connecare.eu). 2016-2019.

6. ACT@Scale (HP-PJ-2015-709770) – Advancing Care Coordination and Telehealth at Scale (www.act-at-scale.eu). 2016-2019.

7. SELFIE (H2020-PHC-23-2014-634288) – sustainable integrated care models for multimorbidity delivery, financing and performance (www.selfie2020.eu). 2016-2019.

8. NEXTCARE (COMRDI15-1-0016) - Innovation in Integrated Care Services for Chronic Patients (www.nextcarecat.cat). 2016-2019.

9. Tsiachristas A, Cramm JM, Nieboer A, Rutten-van Mölken M. Broader economic evaluation of disease management programs using multi-criteria decision analysis. Int J Technol Assess Health Care. 2013 Jul;29(3):301–8.

10. Rutten-Van Mölken M, Leijten F, Hoedemakers M, Tsiachristas A, Verbeek N, Karimi M, et al. Strengthening the evidence-base of integrated care for people with multi-morbidity in Europe using Multi-Criteria Decision Analysis (MCDA). BMC Health Serv Res. 2018;

11. Hernandez C, Alonso A, Garcia-Aymerich J, Grimsmo A, Vontetsianos T, Cuyàs FG, et al. Integrated care services: lessons learned from the deployment of the NEXES project. Int J Integr Care [Internet]. 2015 Mar [cited 2017 Feb 26];15(1):e006. Available from: http://www.ncbi.nlm.nih.gov/pubmed/26034465

12. Hernández C, Alonso A, Garcia-Aymerich J, Serra I, Marti D, Rodriguez-Roisin R, et al. Effectiveness of community-based integrated care in frail COPD patients: A randomised controlled trial. NPJ Prim Care Respir Med. 2015;25(October 2014):15022.

13. Barberan-Garcia A, Vogiatzis I, Solberg HSS, Vilaró J, Rodríguez DAA, Garåsen HMM, et al. Effects and barriers to deployment of telehealth wellness programs for chronic patients across 3 European countries. Respir Med [Internet]. 2013 Apr [cited 2017 Apr 21];108(4):628–37. Available from: http://www.ncbi.nlm.nih.gov/pubmed/24451438

14. Hernandez C, Aibar J, de Batlle J, Gomez-Cabrero D, Soler N, Duran-Tauleria E, et al. Assessment of health status and program performance in patients on long-term oxygen therapy. Respir Med [Internet]. 2015 Apr [cited 2017 May 8];109(4):500–9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/25771036

15. Cano I, Alonso A, Hernandez C, Burgos F, Barberan-Garcia A, Roldan J, et al. An adaptive case management system to support integrated care services: Lessons learned from the NEXES project. J Biomed Inform. 2015;55.

16. Kidholm K, Ekeland AG, Jensen LK, Rasmussen J, Pedersen CD, Bowes A, et al. A model for assessment of telemedicine applications: mast. Int J Technol Assess Health Care [Internet]. 2012;28(01):44–51. Available from:

http://dx.doi.org/10.1017/S0266462311000638

17. Christensen T, Kehlet H. Postoperative fatigue. World J Surg. 17(2):220–5.
18. Killewich LA. Strategies to Minimize Postoperative Deconditioning in Elderly Surgical Patients. J Am Coll Surg. 2006 Nov;203(5):735–45.
19. Lawrence VA, Hazuda HP, Cornell JE, Pederson T, Bradshaw PT, Mulrow CD, et al. Functional independence after major abdominal surgery in the elderly. J Am Coll Surg. 2004;
20. Robinson TN, Wu DS, Pointer L, Dunn CL, Cleveland JC, Moss M. Simple frailty score predicts postoperative complications across surgical specialties. Am J Surg. 2013 Oct;206(4):544–50.
21. Ferguson TB, Hammill BG, Peterson ED, DeLong ER, Grover FL. A decade of change - Risk profiles and outcomes for isolated coronary artery bypass grafting procedures, 1990-1999: A report from the STS National Database Committee and the Duke Clinical Research Institute. Ann Thorac Surg. 2002;
22. Cheema FN, Abraham NS, Berger DH, Albo D, Taffet GE, Naik AD. Novel approaches to perioperative assessment and intervention may improve long-term outcomes after colorectal cancer resection in older adults. Annals of Surgery. 2011.
23. Carli F, Scheede-Bergdahl C. Prehabilitation to enhance perioperative care. Anesthesiol Clin. 2015 Mar;33(1):17–33.
24. Vonlanthen R, Slankamenac K, Breitenstein S, Puhan MA, Muller MK, Hahnloser D, et al. The impact of complications on costs of major surgical procedures: A cost analysis of 1200 patients. Ann Surg. 2011;
25. Barberan-Garcia A, Ubre M, Roca J, Lacy AM, Burgos F, Risco R, et al. Personalised Prehabilitation in High-risk Patients Undergoing Elective Major Abdominal Surgery. Ann Surg [Internet]. 2017 May 9 [cited 2017 Jul 4];267(1):50–6. Available from: http://www.ncbi.nlm.nih.gov/pubmed/28489682
26. Barberan-Garcia A, Ubré M, Roca J, Lacy AM, Burgos F, Risco R, et al. Personalised Prehabilitation in High-risk Patients Undergoing Elective Major Abdominal Surgery : A Randomized Blinded Controlled Trial. Ann Surg. 2018;267(1).
27. PAPRIKA (EIT HEALTH 2020-19365). Patients empowerment for major surgery @home (www.eithealth.eu/paprika). 2019-2021.
28. Bodenheimer T, Sinsky C. From triple to Quadruple Aim: Care of the patient requires care of the provider. Ann Fam Med. 2014;12(6):573–6.
29. West CP. Physician Well-Being: Expanding the Triple Aim. J Gen Intern Med. 2016;31(5):458–9.
30. American Society of Anesthesiologists. Relative Value Guide 2016 Book: A Guide for Anesthesia Values. American Society of Anesthesiologists 2015, editor. 2015.
31. Vela E, Tényi Á, Cano I, Monterde D, Cleries M, Garcia-Altes A, et al. Population-based analysis of patients with COPD in Catalonia: a cohort study with implications for clinical management. BMJ Open [Internet]. 2018 Mar 6 [cited 2018 Mar 11];8(3):e017283. Available from: http://www.ncbi.nlm.nih.gov/pubmed/29511004
32. Liu Y. The Cognitive Artifacts of Designing. Lawrence Erlbaum Associates by Willemien Visser. Int J Hum Comput Interact. 2009 Jan;25(1):99–102.
33. Norman DA, Draper SW. User centered system design : new perspectives on human-computer interaction. L. Erlbaum Associates; 1986. 526 p.
34. ISO 9241-210:2010(en), Ergonomics of human-system interaction — Part 210: Human-centred design for interactive systems.
35. Department of Health C. Catalonia Health Plan for 2016-2020 (in Catalan) [Internet]. 2016.

Available from: http://salutweb.gencat.cat/web/.content/_departament/pla-de-salut/Pla-de-salut-2016-2020/documents/Pla_salut_Catalunya_2016_2020.pdf

36. Commission E. Market place on best practices on digitally-enabled, integrated, person-centered care [Internet]. 2018. Available from: https://ec.europa.eu/health/non_communicable_diseases/events/ev_20181212_es

37. Lloyd H, Fosh B, Whalley B, Byng R, Close J. Validation of the person-centred coordinated care experience questionnaire (P3CEQ). Int J Qual Heal Care. 2018 Dec;

38. Jordan PW. Usability Evaluation In Industry. CRC Press; 2014.

39. Liang J, Xian D, Liu X, Fu J, Zhang X, Tang B, et al. Usability Study of Mainstream Wearable Fitness Devices: Feature Analysis and System Usability Scale Evaluation. JMIR mHealth uHealth. 2018 Nov;6(11):e11066.

40. Frederick F R. The One Number You Need to Grow. Harv Bus Rev. 2004;81(12):46–54.

41. Uijen AA, Schellevis FG, van den Bosch WJHM, Mokkink HGA, van Weel C, Schers HJ. Nijmegen Continuity Questionnaire: Development and testing of a questionnaire that measures continuity of care. J Clin Epidemiol [Internet]. 2011 Dec [cited 2017 Feb 26];64(12):1391–9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/21689904

42. Hernández C, Aibar J, Seijas N, Puig I, Alonso A, Garcia-Aymerich J, et al. Implementation of Home Hospitalization and Early Discharge as an Integrated Care Service: A Ten Years Pragmatic Assessment. Int J Integr Care [Internet]. 2018 May 16 [cited 2018 May 23];18(0):12. Available from: https://www.ijic.org/article/10.5334/ijic.3431/

43. Johnston AB, Burnett DC. WebRTC : APIs and RTCWEB protocols of the HTML5 real-time web. Digital Codex LLC; 2013.

8. ANNEX I – Technological evaluations in Barcelona

8.1 Technological evaluation: MyPathway® - *Phase II (M14-M32)*

In March 2018, MyPathway®, offered by the CONNECARE partner ADI (https://mypathway.healthcare/) was taken into consideration for its potential usefulness to support the prehabilitation service in Barcelona. MyPahtway® 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 challenge then was to adapt MyPathway® to support the prehabilitation service in Barcelona in a way that it could capture signals from an activity tracker that registered daily-steps. This would encourage patients to perform physical activity and it would allow off-line remote monitoring by healthcare providers. As mentioned, the app was simple, supported communication between provider and patient and it had already been proven in another hospital. These were core reasons to support the decision to move forward undertaking adaptation of MyPathway® to the prehabilitation frame at HCB. An ultimate aim of the team was to adopt MyPathway®, or an alternative digital tool meeting the requirements, for regional deployment of prehabilitation. To this end, we assessed MyPathway® telemedicine application in terms of its usability, maturity and its potential to foster community-based activities of the service.

Two simultaneous studies assessing performance of local adaptations of MyPathway® to support specific healthcare services: Prehabilitation and Home-based non-invasive ventilation (Home-based NIV) (D6.2), were conducted at HCB during the first quarter of 2019. Since several methodological aspects of the assessment were common for the two services, and some aspects of the results can be shared, the commonalities of both studies are reported jointly.

The adapted digital tool for prehabilitation provides functionalities to 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). Moreover, a professional web portal facilitates remote monitoring by health professionals, physiotherapists, and interactions with patients.

Technological requirements are as follows. Patients need to own or have access to an Android or iOS mobile phone or tablet 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 messages or ORMs. The ORM message is securely bypassed between SAP (health information system at HCB) and MyPathway® with a Fast Healthcare Interoperable Resource platform (HAPI FHIR) deployed in the intranet of hospital information systems (as detailed in **D5.5 - Final release of the Catalan CONNECARE system**). Such bypass consists on creating a new user (patient) in the backend of MyPathway® and sending a corresponding invitation letter to the e-mail 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.

8.1.1 Protocol 1 - MyPathway® support to Prehabilitation

Protocol 1 description – MyPathway® was tested in 8 patients undergoing the Prehabilitation program 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; iii) A tentative surgical schedule allowing for at least 4 weeks for the prehabilitation intervention; 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 activity tracker (LifeVit®), use as a pedometer to monitor the steps. Different questionnaires to assess usability, satisfaction and perception of continuity of care were completed by patients (with or without assistance) using the app for at least 2 weeks, namely: i) Person-centred coordinated care experience questionnaire (P3CEQ) (37); ii) System Usability Scale (SUS) (38)(39); iii) Overall Satisfaction and Net Promotor Score (40); and iv) Niejmegen Continuity Questionnaire (NCQ) (41).

Protocol 1 technological developments - As depicted in **Figure 4**, the PREHAB service considered as key supporting technologies an adaptive case management platform to enhance collaborative work among health professionals and patients themselves using a personal health system for patient self-management at community level with off-line remote capture of patient reported outcomes (PROMs) and monitoring of daily physical activity (PA). Most importantly, these key supporting technologies were required to be integrated with Hospital Clínic information systems (i.e. SAP) and the regional health information systems for a large scale development in the region (i.e., Catalonia).

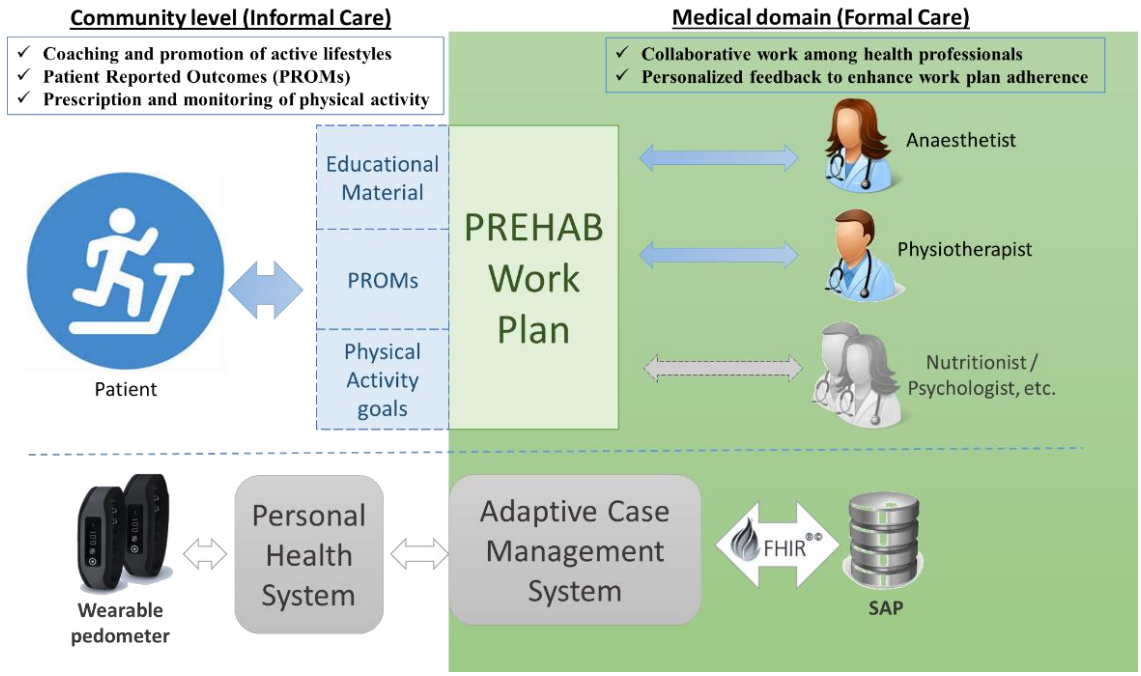


Figure 4 - The figure shows two interoperable domains with technological elements providing support to the PREHAB services promoting active lifestyles as part of the action plan of the patient. On the left hand side, the Informal Care area considers the patient access to the PREHAB Personal Health System wherein she/he can answer questionnaires (PROMs), perform physical activity monitoring through wearable pedometers and have access to tailored educational information, as defined in the PREHAB work plan (centre of the figure). On the right hand side, the Formal Care domain includes the PREHAB team (Anaesthetist, physiotherapist, Nutritionist, Psychologist, etc.), with access to an adaptive case management system for work plan prescription, follow-up and coaching. The adaptive case management system supports execution of the patient work plan and provides a bridge of interoperability and collaborative tools among the patient (through the PREHAB personal health system), the PREHAB team and the electronic medical record (i.e. SAP in case of Hospital Clínic).

The requirements of the PREHAB service, summarised in **Table 3**, included the support of specific PROMs (i.e., HAD, YALE and a specific service satisfaction questionnaire) and the capacity to prescribe and remotely monitor patients' daily PA. In a first phase, FitBit® activity trackers were integrated so that tracked number of steps were collected through the integration of the FitBit® API. However, this required the persistent background execution of the FitBit® app for continuous synchronization between the activity tracker and the FitBit® cloud, as well as the need for a FitBit® account, which introduced too much complexity to end-users. For this reason, a second phase is directly (i.e., API-based) integrating LifeVit® activity trackers with the PREHAB personal health system using Bluetooth connectivity, removing the need for synchronization with third party cloud services.

Table 3 – Adaptation requirements for MyPathway to support the prehabilitation service on Barcelona (Case Study 3)

Feature	Description
Spanish and Catalan languages	Hospital Clínic facilitates translation to Spanish and Catalan both for the clinician's portal and the patient's web/app
Monitoring of patient's physical activity	Patient-specific target daily physical activity (i.e., number of daily steps) will be prescribed by healthcare professionals (number of target daily steps should be customisable dynamically and the prescription could be cancelled anytime.). Patients will receive physical activity prescriptions in MyPathway® timeline (in the form of a daily goal), which can be manually answered or chosen to be directly linked via Bluetooth (requires integration of SDK) with a LifeVit pedometer (AT-250/AT-260) for automatic collection of daily steps. Patients will receive daily and weekly feedback (rewards, encroaching messages) with respect to the adherence to the physical activity goals.
PROMs	Spanish validated versions of the following questionnaires should be available for allocation at patient discharge: • YALE • HAD • Patient Satisfaction questionnaire of the prehabilitation unit
Integration with hospital information systems	Patient referral to the prehabilitation program will trigger the creation of a new user in the clinician's portal and will send the invitation to the patient for registering to MyPathway. Acceptance of the invitation will trigger the allocation of the on-boarding material (Introductory video of the prehabilitation unit and a pdf document with basic information of the prehabilitation program) to the patient timeline.

Figure 5 below illustrates with screenshots the main functionality of the PREHAB personal health system.

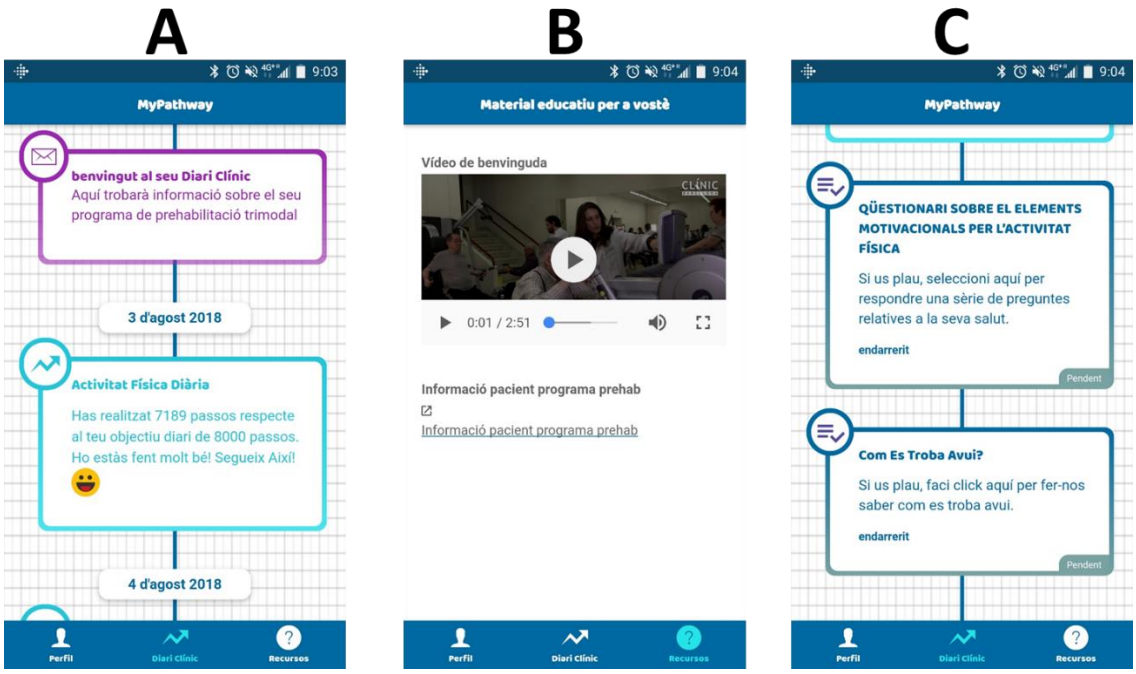


Figure 5 – Look-and-feel of main functionalities of PREHAB personal health system: Welcome message (Panel A – purple timeline message) with link to on-boarding material – video and pdf document (Panel B), daily physical activity goal (Panel A – light blue timeline message) with tracking of goal progress and

motivational feedback and self-administered PROMs (Panel C – dark blue timeline messages) at patient discharge.

Protocol 1 results - Eight patients tested MyPathway® app integrated with the LifeVit® activity tracker in the prehabilitation program. Seven of them completed the four questionnaires indicated above and reported incidences and experiences during the exercise training period with the digital tools. The summary results were as follows:

Nijmegen Continuity Questionnaire (NCQ) (41) – It measures patients' experienced continuity of care associated to the intervention using a scale ranging from 1 (minimum) to 5 (maximum). The results showed a median score of 3.60 (mean 3.53 and standard deviation 1.14).

Person Centered Coordinated Care Experience (P3CEQ) (37) – It reflects the conjunction of two constructs: person-centred care and care coordination. Maximum score (0 to 18) would represent *"care and support that is guided by and organized effectively around the needs and preferences of individuals"*. In the pilot, the P3CEQ median score was 15,5 (mean 15,83 and standard deviation 1,94), which can be considered as a good scoring.

In general, patients feel treated as persons rather than illnesses. They also indicated that enough relevant information about their health situation had been provided and they felt supported by the health care team. Also they feel involved in the decision making. However, the specific role of the app on these perceptions is very difficult to be established. The analysis of annotations written by the patients seem to indicate that some patients understand the questions administered as if they are about their general health care experience, whereas others were thinking about the prehabilitation intervention specifically.

Overall Satisfaction and Net Promoter Score (NPS) (40) - 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 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". In our pilot study, 15% of the patients were "promoters", 70% were "neutrals" and the remaining 15% were "detractors". The general questions about satisfaction included the following: i) General impression; ii) Easy to use; and iii) Ability to use without help. The answers 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	SD
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

System Usability Scale (SUS) (38,39) - The SUS was developed by John Brooke in 1986 and consists of a 10-item questionnaire scored on a 5-point Likert scale from 0 (strongly disagree) to 5 (strongly agree). The overall score is calculated from a sum of all item scores multiplied by 2.5 and can range from 0 to 100. A system or product that received score of 68 and above is considered to have good usability. The results of our pilot experience were: Median 71.3, Mean 72.1 and Standard Deviation 23.2. According to these results, MyPathway® is considered to have good usability.

Report on incidences – Two patients described problems with the Bluetooth connection between the activity tracker (LifeVit®) and MyPathway® during the testing period. In one of the cases, discrepancies between readings of the LifeVit and MyPathway® were detected during the entire follow-up period. Two other patients had sporadic connection problems between the app and LifeVit®, but they both were able to complete the program. Two other patients did not make use of the app despite it was functionally active. They monitored physical activity using the pedometer. One patient used temporarily the app but it spontaneously showed the following message: "The service is temporary unavailable". One patient had a non-compatible Android version, so the app could not be installed.

Some patients complained about the securing system of the activity tracker, which sometimes got open. Patients were worried about losing it and some of them did not wear it for this reason.

8.1.2 Protocol 1 - MyPathway® support to Home-based NIV

Protocol 2 description - A randomized controlled trial (RCT) has been conducted between mid-January to mid-June 2019, to assess the supporting role of MyPathway® in patients under Home-based NIV: 34 in the intervention arm and 33 in the control arm, as part of Case Study 1. The protocol and results are reported in detail in D6.2. In the intervention arm, MyPathway® was used for the following purposes: i) bi-directional interaction between patients and clinical staff; ii) to deliver of motivational messages and educational material regarding changes in physical activity and/or nutritional habits; iii) for goal setting in terms of NIV adherence and life-style changes; and iv) monitoring of NIV adherence. The primary objective of the study is to increase patients' self-efficacy. Secondary outcomes include enhanced treatment adherence and effectiveness. Assessment of MyPathway® usability and patient satisfaction with the digital tool were ancillary aims of the study.

Protocol 2 technological developments - As depicted in **Figure 6**, the NIV service considered similar key supporting technologies as protocol 1. In contrast to protocol 1, the NIV service had different requirements (**Table 4**), including the use of specific questionnaires to report predefined clinical problems: i) dry mouth, ii) red eyes, iii) mask noise, iv) mask leak sensation, v) diurnal somnolence and vi) weight gain. In addition, since a key requirement of the NIV service is the capacity to prescribe and remotely self-report daily use of NIV, MyPathway was extended to allow for manual prescription of daily NIV use goals.

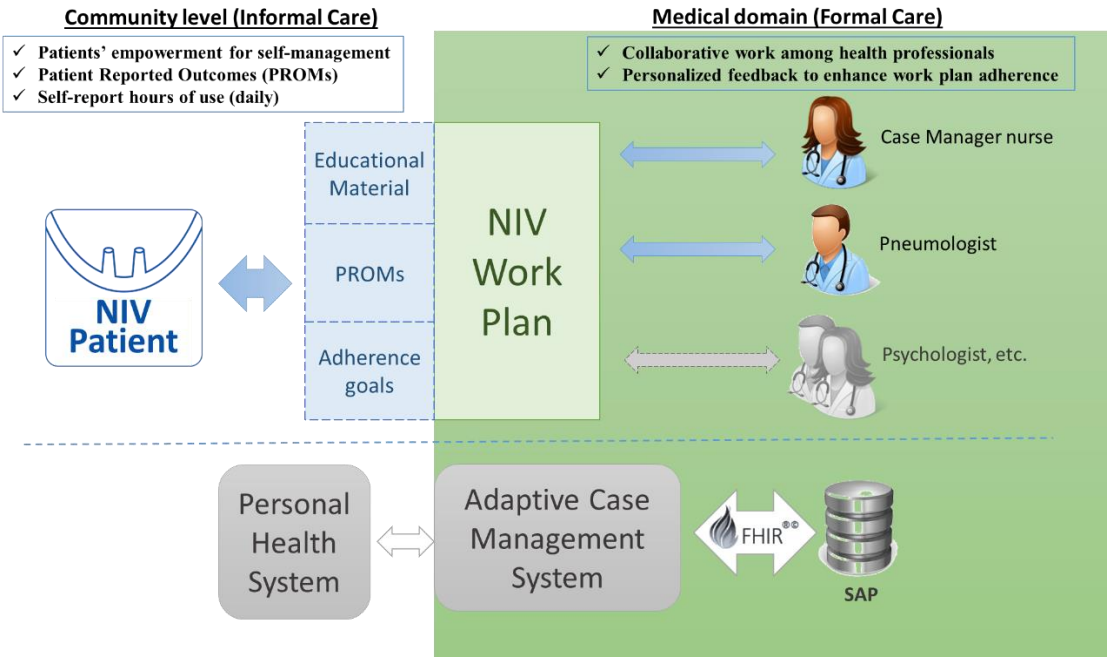


Figure 6 - The figure shows two interoperable domains with technological elements providing support to NIV. On the left hand side, the Informal Care area considers the patient access to the NIV Personal Health System wherein she/he can answer study questionnaires (PROMs), report hours of daily use and have access to tailored educational information, as defined in the NIV work plan (centre of the figure). On the right hand side, the Formal Care domain includes the NIV team (Case manager nurse, pneumologist, Psychologist, etc.), with access to an adaptive case management system for work plan prescription, follow-up and coaching. The adaptive case management system supports execution of the patient work plan and provides a bridge of interoperability and collaborative tools among the patient (through the NIV personal health system), the NIV team and the electronic medical record (i.e. SAP in case of Hospital Clínic).

Table 4 – Adaptation requirements of MyPathway to support the NIV service on Barcelona (Case Study 1)

Feature	Description
Spanish and Catalan languages	Hospital Clínic facilitates translation to Spanish and Catalan both for the clinician's portal and the patient's web/app
Monitoring of patient's daily use of NIV	Patient-specific target daily use of NIV (i.e., number of daily hours) will be prescribed by healthcare professionals (number of target daily hours should be customisable dynamically and the prescription could be cancelled anytime). Patients will receive the prescription in MyPathway® timeline (in the form of a daily goal), to be manually answered by the patient. Based on self-reported hours of use of NIV, motivational feedback will prompt the patient to continue in the same line or try change his/her behaviour by identifying any of the specific problems mentioned below.
PROMs	Periodically (weekly or when the patient self-report less than 4 hours of daily use), MyPathway will use specific questionnaires to report predefined clinical problems: i) dry mouth, ii) red eyes, iii) mask noise, iv) mask leak sensation, v) diurnal somnolence and vi) weight gain.
Integration with hospital information systems	Patient referral to the NIV program will trigger the creation of a new user in the clinician's portal and will send the invitation to the patient for registering to MyPathway. Acceptance of the invitation will trigger the allocation of the on-boarding material to the patient timeline.

Figure 7 below illustrates with screenshots the main functionality of the NIV personal health system.

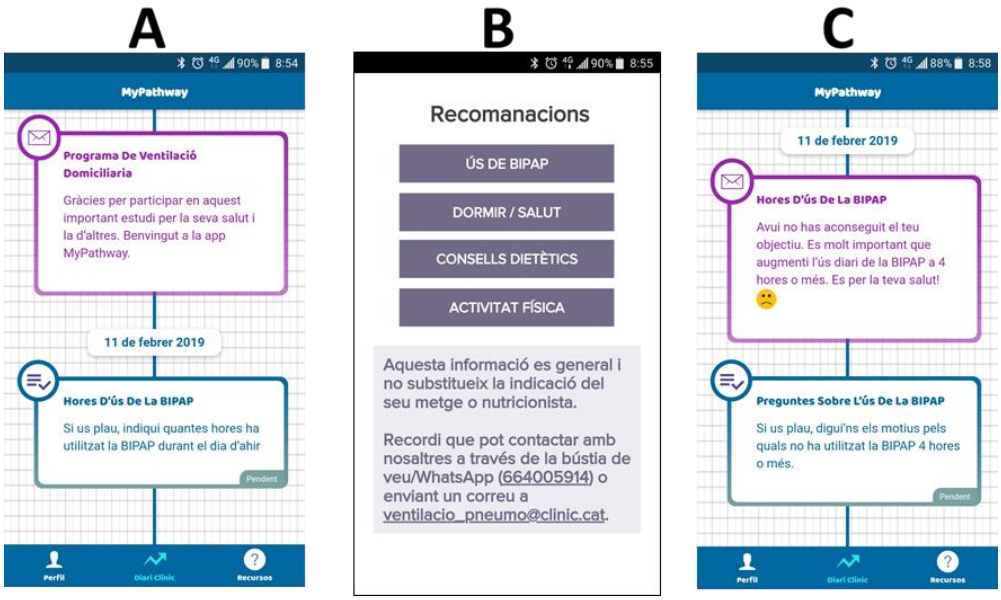


Figure 7 – Look-and-feel of main functionalities of NIV personal health system: Welcome message (Panel A – purple timeline message) with link to on-boarding material and daily NIV use goal (Panel A – blue timeline message), educational material (Panel B), and tracking of goal progress with motivational feedback and self-administered PROMs (Panel C –blue timeline messages).

Protocol 2 results - MyPathway® support to Home-based NIV – The system was simpler than in prehabilitation because no interoperability with sensors was required. It was only prepared to exchange messages. In the study, both Android and iOS modalities of operating systems were tested. Detailed results of the RCT carried out with MyPathway® in Case Study 1 are reported in D6.2. But similar findings were obtained. That is, usability/acceptability of the App by the patients was rather acceptable. But the system did not show expected robustness for deployment in real life scenarios.

Conclusions on use of MyPathway® in Prehabilitation – Adaptation of the app to the prehabilitation requirements was achieved after one full year of continuous iterations between the team in Barcelona and ADI, from March 2018 to March 2019. The MyPathway® system was operational for Android, but it could not be tested for iOS until this June 2019. Usability and acceptability of the app by the patients was rather good, but the current available version of the digital solution lacks robustness and it is not prepared for real life deployment yet.

We can conclude that the simplicity of the solution, if it were robust, would be attractive to cover current unmet needs regarding interactions between patients and professionals. However, MyPathway® shows 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.

Based on the above analysis, we decided to discontinue the work on MyPathway® and, since November-December 2018, we have been exploring two alternative complementary digital

solutions briefly described below: the CONNECARE SMS suitably adapted for the prehabilitation case study and Health-Circuit.

8.2 Technological evaluation: the CONNECARE SMS - *Phase III (M33-M45)*

Briefly, the CONNECARE SMS suitably adapted to the prehabilitation case study consists of an adaptation of the functionalities of overall CONNECARE SMS to the requirements of the multimodal prehabilitation service currently deployed at HCB, including changes modularity of the technical solution and adaptation to the interface level. Main functionalities of the system are physical activity prescription and monitoring, daily nutritional advice and mindfulness listening exercises. The PREHB system have been developed both for Android[4] and iOS[5] devices with close and continuous iterations between Eurecat and the prehabilitation team at HCB-IDIBAPS.
Since the adapted version of the CONNECARE SMS has been decoupled from the CONNECARE SACM, a new web backend was developed by the CONNECARE partner 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.
The technological evaluation of the adaptation of the CONNECARE SMS is reported in detail in D6.3.

8.3 Technological evaluation: Health-Circuit - *Phase III (M33-M45)*

Digital support to (i) patient management with an ACM approach, and (ii) collaborative work of stakeholders across levels of care are two central elements in CONNECARE. In the process of bringing the CONNECARE concept into the clinical scenario, the team in Barcelona is exploring the adaptation of a new digital tool, HEALTH-CIRCUIT covering collaborative work among multiple stakeholders with an ACM approach. Moreover, the tool shows further potential to assist case management through complex care paths and generate decision support using intelligent Chatbots. In this regard, HEALTH-CIRCUIT is conceived as a tool complementary to the adapted version of the CONNECARE SMS for CS3 in Barcelona that may significantly contribute to face key challenge for chronic care management. We believe that its potential to foster large-scale deployment of prehabilitation must be taken into account.

HEALTH-CIRCUIT embraces the newest generation of cloud-based, GDPR-compliant, enterprise-proven team collaboration technology to allow patients and healthcare professionals to breakdown silos and collaborate seamlessly from any device (mobile phone, tablet, or desktop) towards the health continuum care pathway. The potential of HEALTH-CIRCUIT in terms of acceptability, usability by patients and health professionals is currently being tested at HCB in the following use cases: (i) fostering team work in the Home Hospitalization service and support for remote

[4] https://play.google.com/store/apps/details?id=org.eurecat.prehab&hl=en_US
[5] https://apps.apple.com/us/app/prehab/id1466618747

consultations though teleconference (Case Study 1); (ii) exploring its potential to support cohort studies in real-life settings; and, (iii) prevention of hospitalizations in a vertical integration service in AISBE, Barcelona, Catalonia (ES). The latter, described in detail in Study Case 1 (D6.2) has triggered the generation of a new app frontend to adapt to the needs of an elder, frail population (Figure 8).

Technology maturity (TRL – Technology Readiness Level 1-9) - The main supporting technology (Circuit-Unify by ATOS, https://unify.com/en/solutions/team-collaboration/circuit) is already an enterprise-proven team collaboration platform (TRL 9). As stated before, HEALTH-CIRCUIT is currently being tested at HCB in several use cases (TRL 5). As detailed below, there is an ongoing preparation of agreements between Atos (Atos Global IPR Dpt. & Atos local Legal Dpt.) and HCB&IDIBAPS to consolidate a strategic alliance to use and enrich the Circuit-Unify by Health-Circuit.

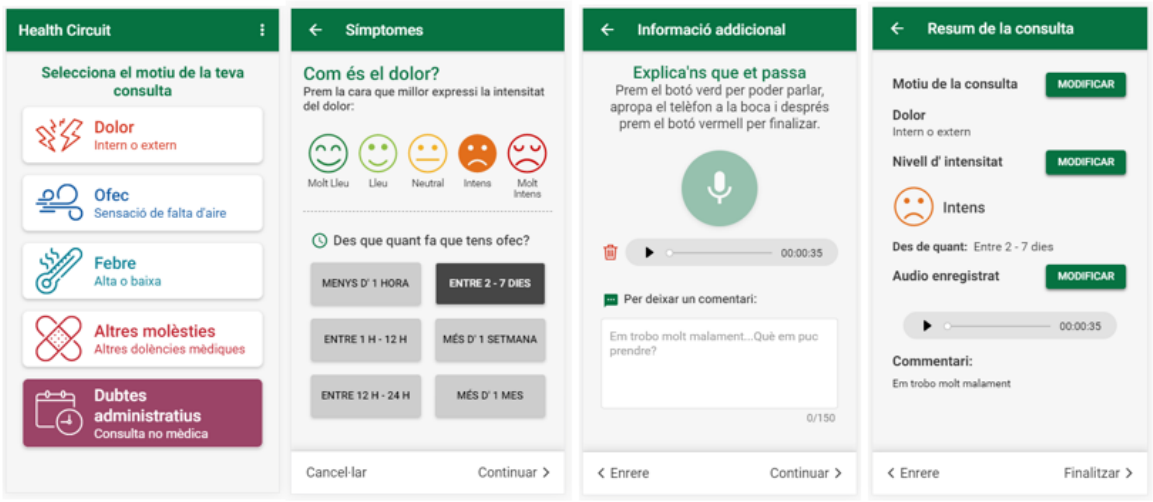


Figure 8 - Main screen of the user-friendly frontend app integrated into Health-Circuit (see D6.2 for further details)

What HEALTH-CIRCUIT is attempting is not completely new (**Figure 9**). What is new is the research that went into it, to focus on proven cost-efficient integrated healthcare processes (26,42) and how intelligent Chatbots can support the decision making process. Moreover, while most competitors reach feature parity regarding messaging and web calling, HEALTH-CIRCUIT uniquely integrates with Atos Unify and third party telephony systems, preventing communication silos within companies.

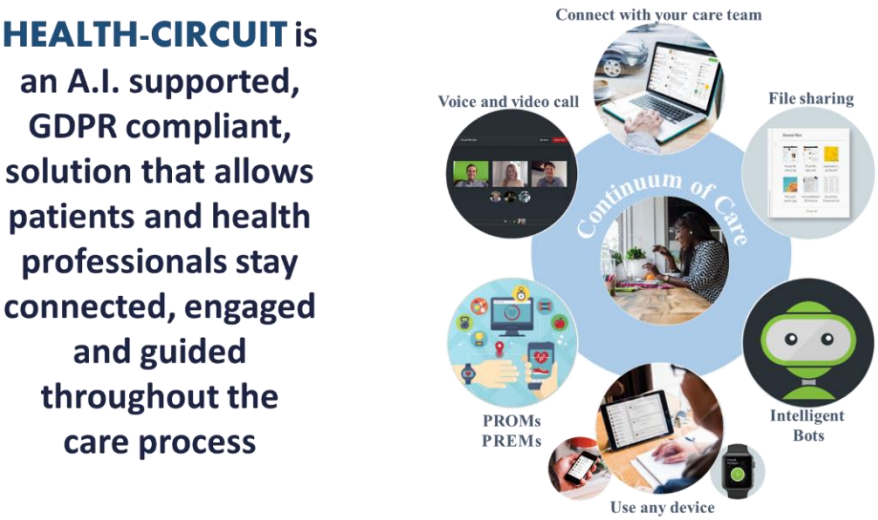


Figure 9 - Health circuit functionalities.

HEALTH-CIRCUIT provides enterprise-grade, proven scalability and quality for real-time communication, supporting up to 300 concurrent participants for voice, video and screen-share sessions and more than 1,000 conversation participants. HEALTH-CIRCUIT is built around WebRTC technology (43) that: (i) consolidates messaging, file sharing, screen sharing, high definition video and high fidelity voice conferencing with an industry standard AES encryption; and, (ii) integrates intelligent bots to guide professionals though continuum care pathways (**Figure 10**) and to improve health risk assessment and service selection. HEALTH-CIRCUIT (the generic version is Circuit-Unify, by ATOS, TRL 9) is designed to operate on top of existing hospital information systems.

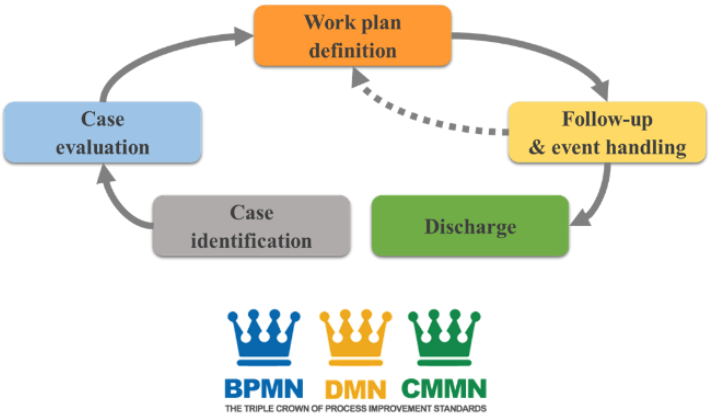


Figure 10 - Health circuit use intelligent bots to adopt process management standards for guiding professionals through continuum care pathways.

The current testing and developments agenda for HEALTH-CIRCUIT at HCB includes the setup of a spin-off of Hospital Clínic of Barcelona during spring 2020 as part of the innovation program The Collider, a program of the Barcelona Mobile World Capital, providing key inputs for pragmatic applications of the CONNECARE concept into real life clinical customers.

9. ANNEX II – Health information systems at IDIBAPS-Hospital Clínic of Barcelona

Current situation at IDIBAPS-HOSPITAL CLÍNIC OF BARCELONA

Current health information systems (HIS) at IDIBAPS-Hospital Clínic (**Figure 11**) allow the integration of different professionals and areas, as well as customization by user role and context by means of a web layer (IPA – *innovation of care processes*) on top of SAP ensuring usability and user friendless. SAP behind ensures robustness. Access to authorised professionals to the HIS from anywhere (e.g. from patient home as in the home hospitalisation program) and from any device (e.g. laptop, smartphone, etc.) is ensured by means of the use of a virtual private network and/or a virtual desktop infrastructure.

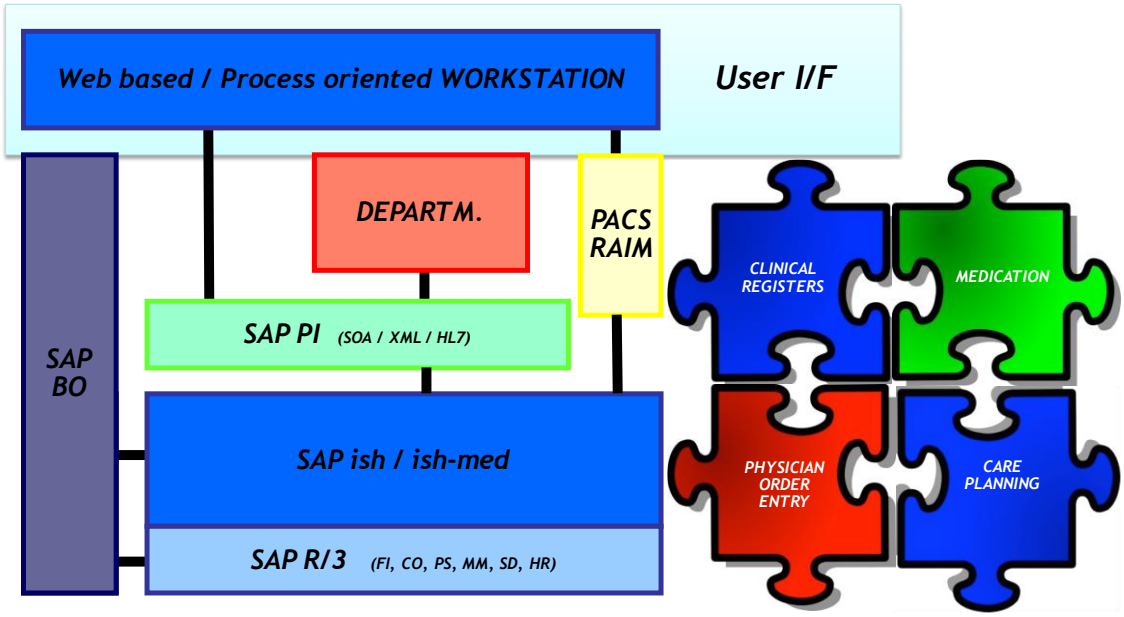
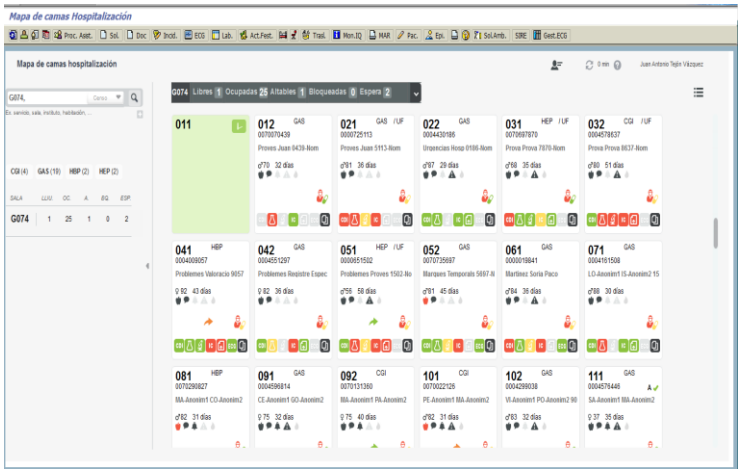


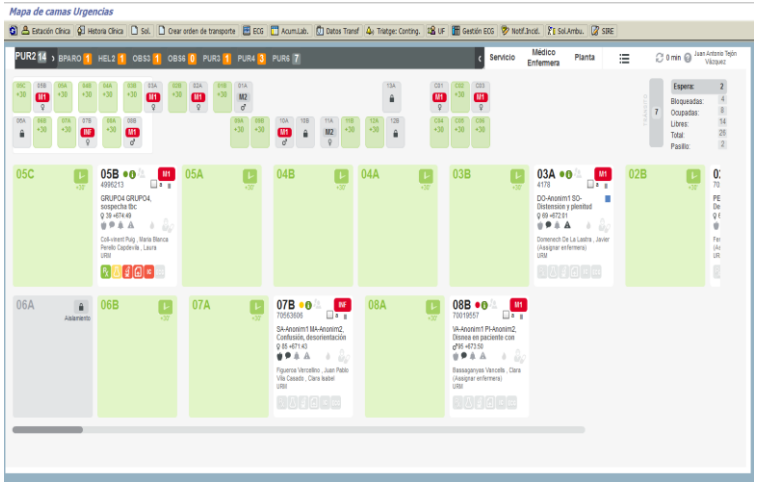
Figure 11 – Architecture of health information systems (HIS) at IDIBAPS-Hospital Clínic.

IPA, the web layer on top of SAP, is currently developed for:

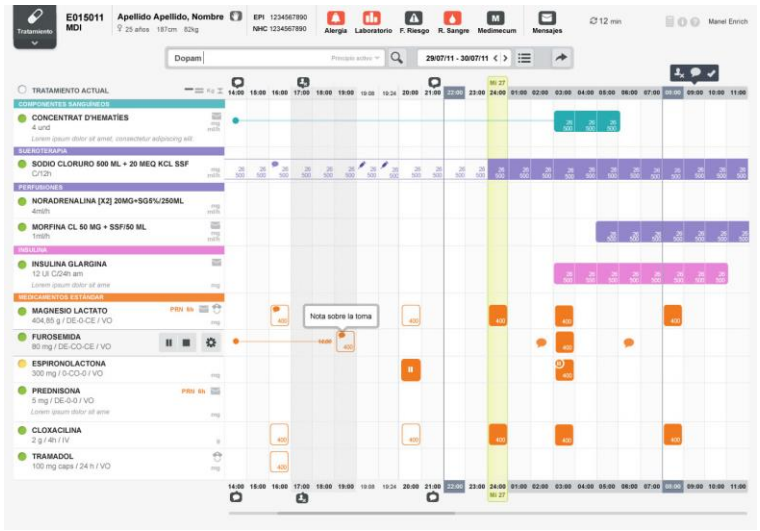
The map of beds of hospitalized patients:



The map of emergency room boxes:



The hospital electronic prescription system:



And the clinical registries:

Facing the future at IDIBAPS-HOSPITAL CLÍNIC OF BARCELONA

The future vision of HIS at IDIBAPS-Hospital Clínic of Barcelona **(Figure 12**) is aligned with the organizational vision of integrated care as a must: "*Organization and effective coordination between providers of the different healthcare levels covering a population area*". With professionals (CLINICAL MANAGEMENT), to transfer power and responsibility where the knowledge is and most of health system decisions are made, that is to doctors and nurses, and with patients (PATIENT'S ORIENTATION), so that healthcare departments and resources should be organized to best solve patient needs, counting on different levels and healthcare providers.

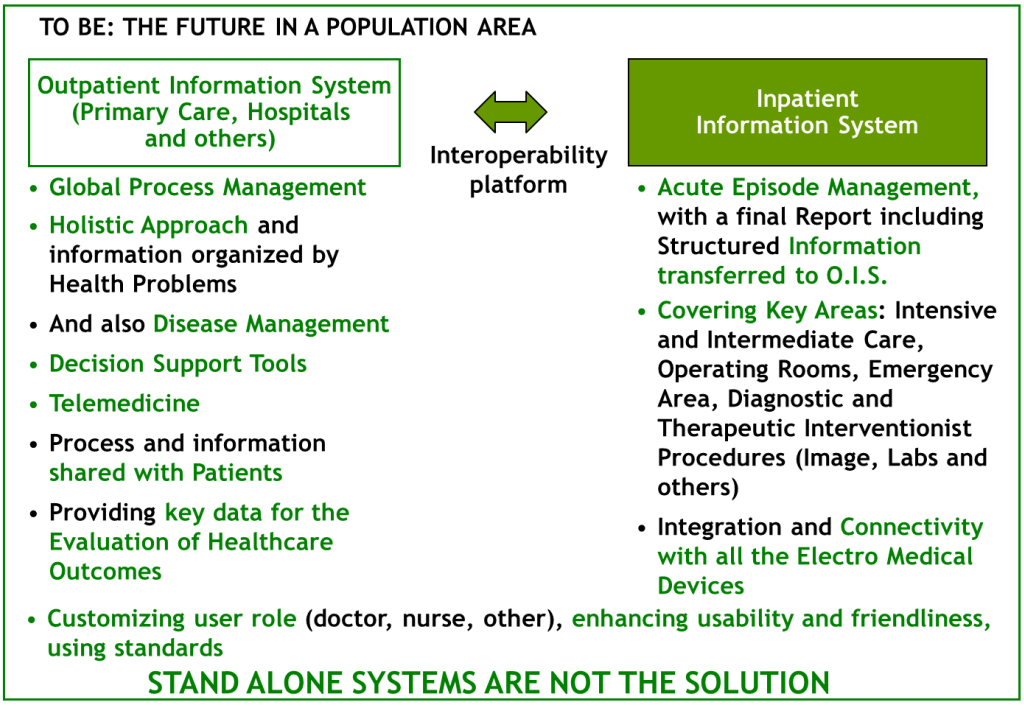


Figure 12 – future vision of HIS at IDIBAPS-Hospital Clínic of Barcelona.

Major challenges of this vision are:

- Nursing care plans automation - introducing mobility (deployment)
- Operating Room management optimisation (new module)
- Clinical Workstation (Portal)
- Artificial Intelligence
    - Clinical Decision Support Systems:
        - Prescription aid tools based on protocols and drugs interactions (OntoFarma)
        - Lab test duplication avoidance tool
        - Radiology test decision support tool (ESR iGuide)
        - Chest pain clinical guide at the Emergency room
    - Big Data / Analytics / Artificial Intelligence (legal issues, data quality issues):
        - Predictive tools (generalisation)
        - Integrating EHR and genomics (…)
- Disease management (shared follow-up, TeleHealthcare, devices/gadgets, …)

Present regional (Catalonia) digital health tools

The multi-provider nature of the Catalan healthcare model had always given providers autonomy in the management of centres and freedom in selecting, building, and managing their health IT (HIT) systems. Historically there had been no guidelines regarding the HIT systems that health providers should have in place. Therefore, **the Catalan health system traditionally had a completely decentralized governance model for IT**. This led to a situation with more than 60 different HIT systems for primary care and hospital care without any kind of integration, and heterogeneity among providers in terms of the level of adoption of HIT.

For instance, in the case of hospital care there are multiple HIT systems supporting different clinical protocols, messages, catalogues, etc., meaning that each provider has to build multiple interfaces for the same purpose (to interact with other providers). **Major providers have HIT systems based on SAP**. For instance, ARGOS is a SAP-based HIT developed by IBM that runs in the 8 hospitals of the ICS and some other hospitals.

At the level of primary care, there are several HIT systems (e.g., eCAP, OMI-AP, GO-WIN, SIAP-Win); **eCAP is the dominant one**. eCAP was developed in 2000 by clinicians of the Catalan Health Institute (ICS). The motives for the development of eCAP were: the existence of three different HIT systems for primary care within ICS; provider lock-ins; and interoperability issues among those HIT systems. More than 80% of primary care centres run eCAP.

The multiplicity and heterogeneity of HIT systems, data models and standards, and working processes turned into a problem as the DoH defined efficiency, continuity of care and integrated care as priorities in the successive health plans since early 2000s. The implementation of these priorities required standardizing and sharing information within and across health providers. This motivated the DoH to build and rollout the *Historia Clínica Compartida* (HC3), a **Shared Electronic Medical Record**, in 2008. The purpose was that any healthcare professional could access data about his/ her patients regardless which providers had generated the data. The HC3

interconnected all the electronic health record systems (EHR) of the healthcare providers operating in the Catalan public health system (**Figure 13**). The HC3 was neither conceived as the sum of the EHRs of the health providers nor as a way to replace the existing EHR of providers, but as an **infrastructure that would organize the access to health data stored in the EHRs of health providers and in some databases of the DoH**. The HC3 consisted of a central node working either as an index or a repository of documents that would give access to all doctors (through a web browser) to the information coming from the EHRs of the diverse providers:

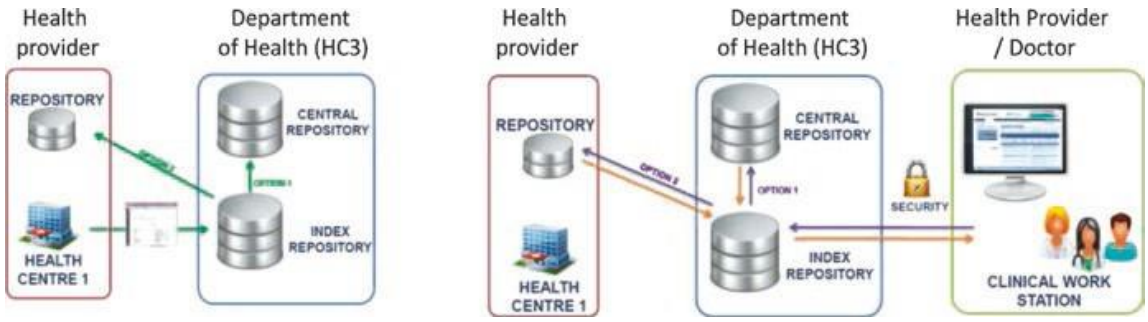


Figure 13 – Interconnection via HC3 of all the electronic health record systems of the healthcare providers operating in the Catalan public health system.

The information displayed in the doctors' browser came from (1) health providers: primary care (**diagnoses, healthcare reports, immunizations, and chronic patient labels**), specialized care, long-term care and mental care (**discharge report, emergency reports, specialized outpatient clinic reports**), and diagnosis procedures (**pathology and laboratory reports, radiology image, imaging diagnosis reports, interventions**); and (2) the DoH: medical activity database (**diagnoses, procedures**), prescribed/dispensed drugs (**electronic prescription**), and advanced directives. The HC3 provided a set of tools for direct messaging between health professionals to facilitate their cooperation.

The HC3 grew with new users, functional requirements (e.g. types of health data, identification codes, interconnection of the HC3 with the Spanish Shared Electronic Medical Record and with the European Patients-Smart Open Services), and technological requirements (e.g. compression of data, new security layers, HL7 messages). Moreover, the Health Plan for the period 2011–2015 defined a project, within the line of action number 9 called "Sharing information, transparency, and assessment", to transform the HC3 from a repository of health data into a network of information and services that facilitated the integration of providers. All this involved extending the HC3 with new sources and for- mats of data, access modes and services, and standardizing the patient trajectory and the management of clinical protocols across providers.

The Catalan Department of Health (DoH) launched the project of the **Carpeta Personal de Salut (CPS)** in 2008 as part of the execution of the Catalan health IT strategic plan for the period 2008–2011. The leader and sponsor of the CPS was the coordination of Health IT of the DoH. With the CPS they wanted to promote responsibility and participation of citizens in matters of their own

health (preventive actions and self-care); to have a secure environment for citizens to interact with health system, providers and professionals; and to improve the health care quality and coordination between different care areas, levels and professionals. Following existing regulations about the information rights and autonomy of the patient, the health data displayed in the CPS would come from the HC3. The HC3 was the main source of data of the CPS. The CPS would be a module of the HC3, acting as a web-browser based viewer for citizens to the data generated in the public health system:

Another line of action of the health IT strategic plan, related with the development of the CPS, was the diffusion of digital certificates among citizens in order to interact with the health system. Following the regulations about the protection of personal data, CPS management decided that citizens would use their personal identification code and a digital certificate to access the CPS. Data transfer would be (https) encrypted with 128-bit key.

In 2014, CPS was renamed to **Cat@Salut La Meva Salut** (**Figure 14**) to transform the CPS into a dynamic and proactive environment rather than a passive one. This required integrating non-face to face care into the existing clinical working stations, and giving recognition to the non-face to face activity of health professionals as part of their duties. One of the services defined by the non-face to face care model was eConsultation (a non-face-to-face, secure consultation service between citizens and health professionals). With eConsultation, citizens can send (through the CPS) at any time a request to the health professional (doctor or nurse), receive email notifications when the professional responds the request, check the response at the CPS, and see a record of all the queries. This service is integrated with the clinical workstation of professionals.

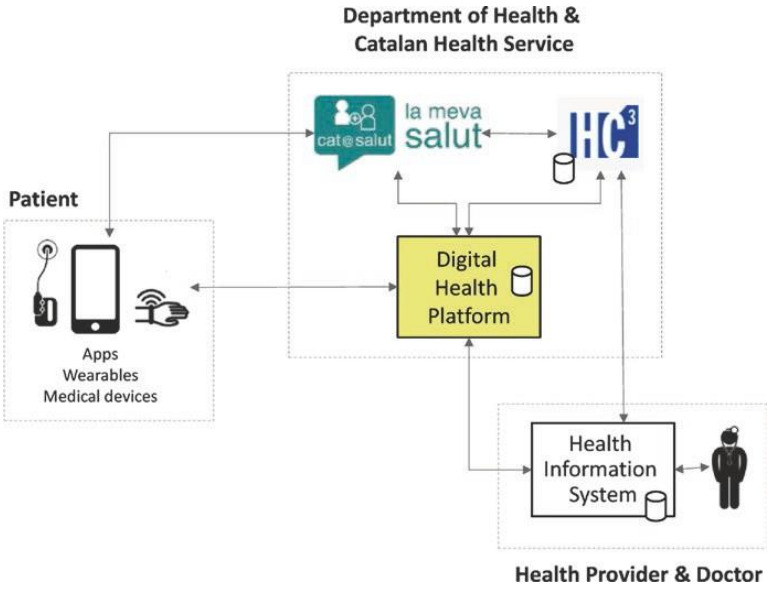


Figure 14 – Architecture of the Catalan personal health folder (Cat@Salut – La Meva Salut).

In parallel, the DoH and the Department of Social Welfare and Family, collaborated with the mHealth Competence Center of the Mobile World Capital Barcelona in the development of the Mobility Master Plan for Health. As part of the implementation of the **mHealthPlan, a health apps marketplace for the accreditation of trustworthy apps through a quality certificate** was created. The accreditation process assesses four main aspects of apps: (1) design and usability (assessment of the user experience); (2) content and functionality (assessment of the quality and utility of content); (3) confidentiality and security of data (assessment of the management and processing of data); and (4) technological requirements (assessment of the reliability and adaptability requirements).

From mid-2015 the DoH started working on the design of another core architectural component of the health apps marketplace: **the Digital Health Platform**. Those health apps (and later wearables and medical devices) that are accredited will are allowed to store and/or retrieve information from the Digital Health Platform. So the Digital Health Platform will act as a repository of patient-generated health data and in turn, it is interoperable with the CPS, HC3 and/or health information systems of health providers. Patients will access the content of the Digital Health Platform through the CPS. In other words, the Digital Health Platform will give the public health system access to health data generated by patients outside the public health system.

Regional (Catalonia) future strategy

An enhanced Electronic Health Record is the longitudinal basic piece of the current master plan and represents the functional and technical repository of all the relevant information of the citizen that it is necessary to record and share throughout the health system. It is a conceptual and technological evolution of the clinical records that are stored in the systems of different service providers, with and without logical connection between them. This common solution of health history will take into account and align components of processes, data and technology (how multidisciplinary health data is recorded, stored and shared).

The 2018 Master Plan of Health Information Systems of Catalonia considers the implementation of the enhanced Electronic Health Record and its integration with existing health information systems. Having a common Electronic Health Record will require a process of accreditation and standardization of common data, service agreement levels and technical mechanisms to update-access of health data near real time. This repository will replace progressively the current systems based on interoperability (the HC3) and the sending of records across multiple circuits, and will allow the various actors to consult the data they need in every moment.

The fact of sharing more and better quality data will make it possible to examine and analyse large volumes of information, and compare risk factors and different practices and treatments, to return the results to patients, professionals and health managers, improve the decision making and advance on the path of a predictive and personalized medicine. The plan includes the construction of an advanced analytical repository (**Figure 15**) for the treatment of structured and unstructured

data (text, image, information coming from sensors and electro-medicine and entered by the users themselves) almost in real time:

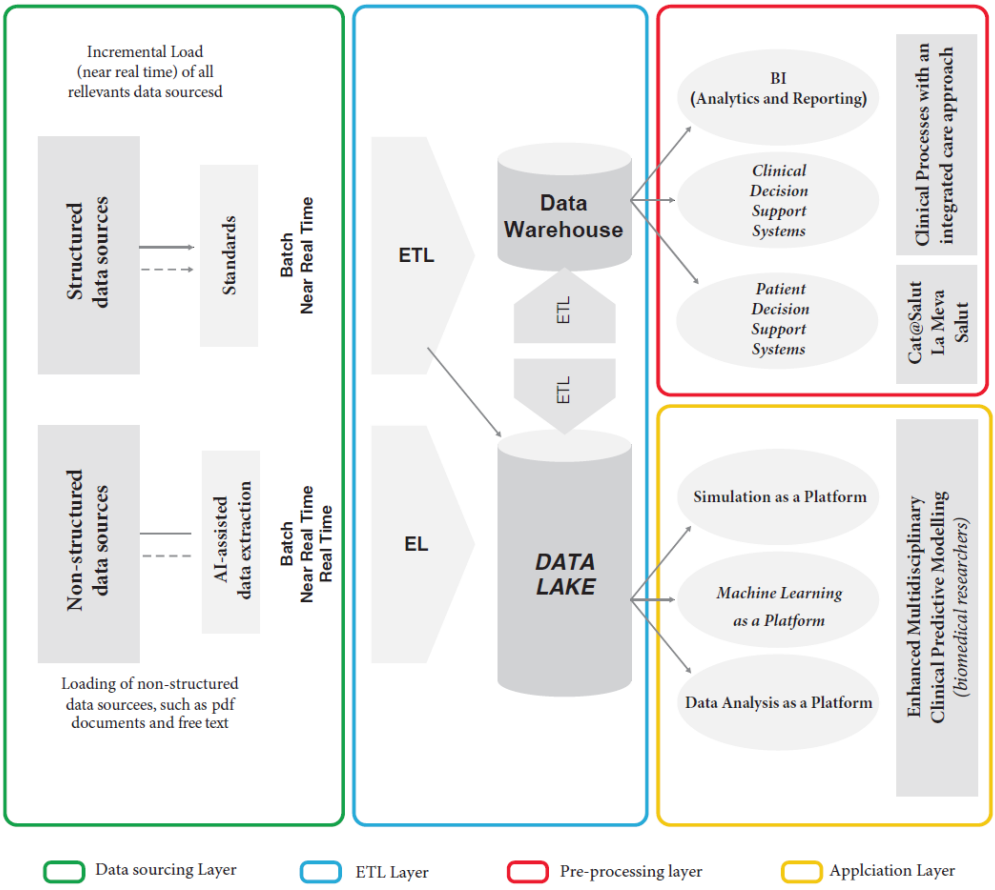


Figure 15 – Scheme of the advanced analytical repository for the treatment of structured and unstructured data for the future common Electronic Health Record of the Catalan Healthcare System.

The enhanced Electronic Health Record has also the aim to become a comprehensive information system, with different services, that can be offered to organizations suppliers who need or wish to evolve or transform their current systems.

10. ANNEX III - Role of design thinking for adoption of integrated care: Scalability of a prehabilitation service

Anael Barberan-Garcia, Ramon Martínez, Isaac Cano, Genevieve Shaw, Fernando Ozores, Ferran Pruneda, Josep Roca and Graciela Martínez-Pallí. ***Role of design thinking for adoption of integrated care: Scalability of a prehabilitation service.*** *IFIC 2019 (submitted)*

Role of design thinking for adoption of integrated care:

Scalability of a prehabilitation service

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Abstract

Background: The efficacy of prehabilitation (PreHab) to reduce surgical complications, and facilitate post-surgical recovery, has been demonstrated. Deployment of PreHab, as a mainstream service at Hospital Clínic de Barcelona, is showing effectiveness and potential for cost savings. However, there is a need for PreHab refinement to address regional scalability.

Aim: To explore the role of Design Thinking to enhance the service workflow aiming at fostering large scale deployment.

Methods: Three co-design sessions covered: i) Analysis of challenges and identification of creative focus areas *(Immersion)*; ii) Generation and evaluation of ideas to solve the focus areas *(Ideation)*; and, iii) Consolidation of concepts and generation of a work plan to foster PreHab scalability *(Validation).* The sessions had 40 attendees on average, including healthcare professionals, designers, managers, health-technology agents, business school representatives and policy makers.

Results: Personalization and modularity of the service were identified as core traits to ensure adoption. Individualized work plans should combine face to face supervised sessions and community-based remotely supervised activities, including access to partnering health/wellness centers. Technologically supported patient empowerment for self-management with off-line remote monitoring and access to a case manager was a key requirement. Other technological aspects prioritized were: i) an adaptive case management approach for coordination of a service request; and, ii) availability of an intelligent patient's assistant (Chatbot). The business model envisages operational costs financed by savings generated by the PreHab service.

Conclusions: Design Thinking is suitable for the co-design of integrated healthcare services and to address challenges associated with large scale adoption.

Introduction

Design Thinking (DT) refers to creative solution-based strategies used in a product design process, but also applied in other contexts such as business and social services [1, 2]. DT strategies fall into the umbrella of human-centered design, a discipline originated in the field of computer science, artificial intelligence and ergonomics [3], that has evolved over time being increasingly applied to service design strategies. The key principles of the human-centered design approach were established in 2010 by the International Organization for Standardization [4] (ISO).

Recently, attempts to use DT methodologies in the healthcare scenario aiming at refining clinical processes have been reported [5, 6]. In this context, the different stakeholders are called upon to jointly think outside the box to employ creative thinking, with the final aim of optimizing complex processes while fulfilling the needs and preferences of the service end-users: patients, caregivers and healthcare professionals. The current report explores the potential of these methodologies to enhance scalability and to implement the adoption of integrated care services for chronic patients, taking as a use case refinement of the prehabilitation (PreHab) service currently implemented at Hospital Clinic of Barcelona (HCB), where it has demonstrated efficacy to reduce surgical complications and potential for cost savings [7].

PreHab can be defined as a patient-tailored preoperative short-term intervention, four weeks on average, encompassing, but not limited to: endurance physical training, promotion of physical activity, smoking cessation counseling, dietary supplementation and psychological management. The final aim of PreHab is to enhance the functional capacity of patients undergoing elective major surgery as an attempt to minimize postoperative morbidity and accelerate recovery [8].

Since 2016, the PreHab Unit at HCB has supported the intervention as a mainstream service for several surgical procedures. However, there is a clear need for refinement of the standard PreHab approaches in order to increase transferability to other sites, facilitating regional deployment and sustained adoption of the service. Specifically, the current report assesses application of DT methodologies to enhance the current PreHab service workflow.

Material and methods

We generated a roadmap for three DT sessions, each of a five-hour duration, aiming to address the core aims of the study, namely: i) identify actionable factors modulating regional scalability of Prehab; ii) enhance efficiencies of the service with the use of information and communication technologies (ICT), and, iii) design a business model contributing to sustainable adoption of the service. The ultimate aim was to foster regional scalability of Prehab in Catalonia (ES) (7.5 m citizens)[9-10]. The first two columns of Table 1 summarize the aims and methodological aspects of each study phase.

The content of the three DT sessions was based on preliminary work consisting of two actions. Firstly, we performed a survey aiming at gaining insight into the organizational aspects of the PreHab structure (PreHab unit) and service workflow at HCB. The survey was carried out with professionals involved in the design and management of the service. It also included other healthcare professionals having direct contact with the patients enrolled in the service, including: anesthesiologists, physiotherapists, nurses and psychologists. Secondly, we carried out in-depth face to face interviews with five patients and their respective caregivers who had participated in PreHab, aiming at capturing the patient experience perspective of the service (Fig 1). Patients surveyed in this phase had been candidates for cardiac transplantation, resection of lung parenchyma or major abdominal surgery due to cancer.

The three DT workshops included all the stakeholders' profiles, namely: healthcare professionals and managers, designers, health-technology agents, business school representatives and policy makers, as described in detail below for each session (S1 Table).

The Ethics Committee for Clinical Research at HCB approved the study (HCB/2016/0883). The interviews were recorded and informed consent was understood, accepted and signed by all patients and caregivers. The study was registered at ClinicalTrials.gov (NCT02976064).

Session I: Immersion

The central aim of the first workshop was to gain further insight on actionable factors limiting the scalability of PreHab and to identify opportunities for service improvement; that is, creative focus. The process for structuring the creative focus encompassed four main areas covering specific actions: i) analysis and elaboration of a patients' experience map during PreHab (Figure 1), based on the information gathered during the preliminary work alluded to above; ii) generation of an empathy map (S1 Fig) aiming at maximizing the engagement of patients and professionals; iii) formulation of a context map (S2 Fig) identifying external factors and main driving forces that modulate the scalability of PreHab; and, iv) definition of a priority map (Figure 2) elaborated as a contribution to conform a future strategy for the regional deployment of the service.

Session II: Ideation

The objective of the second workshop was to generate, evaluate and develop both ideas and plans to solve the creative focus identified in the first session. The expected output of Session II was to generate a customer journey that should contribute to define a viable strategy for regional deployment of PreHab. At the beginning of the session, attendees received a portfolio containing the following supporting material: i) eight ideas of successful companies solving similar challenges to the ones raised in the Prehab service; and, ii) the @pentagrowth model tool [11] to summarize the five dimensions to be taken into account for service refinement, namely: i) Connect network; ii) Collect inventory; iii) Empower users; iv) Enable partners; v) Share knowledge.

The Ideation Session was divided into three parts, namely: i) two initial inspirational presentations aiming to stimulate creativity; ii) small group-based creative sessions for generating potential solutions; and, iii) pooling the ideas resulting from the two previous steps

into a positioning map (Figure 3) depicting the PreHab potential in terms of both adherence and scalability.

Session III: Validation

Finally, the third session aimed to consolidate the concepts resulting from the second workshop, focusing on service optimization and financial sustainability in order to achieve full regional coverage of the service. Accordingly, the final outcome of the session was to define a viable strategy for regional deployment of a refined service workflow.

To this end, workshop attendees were divided into three groups to separately tackle specific areas. The first group focused on the elaboration of proposals for implementation strategies based on the input of the different stakeholders (i.e. end-user touch-points). The main aim of the second group was to tackle technology-related aspects modulating the scalability of the service. The formulation of a business model to ensure sustainability and the ideation of reimbursement incentives to foster coverage of the service were explored by the third group. The session ended with a synthesis of the outcomes of the three groups aiming at defining the pillars of a viable strategy for the regional deployment of PreHab.

Results

The third column of Table 1 summarizes the results of each phase of the study. Briefly, in the preliminary fieldwork, the surveyed professionals recognized the active role of the patients and the personalization of the service workflow, as two key factors for successful completion of the work plan. They insisted on the need for strategies fostering patient empowerment for self-management. Healthcare professionals also highlighted the multidisciplinary nature of PreHab as the most valued characteristic of the program. They also stressed the need for complementing face to face supervised activities conducted by physiotherapists with additional community-based activities, as part of the service work plan. It is of note that community-based tasks can be remotely controlled or carried out with face to face supervision by professionals working in partnering centers (i.e. sport centers, wellness clubs, etc.). Moreover, the professionals identified a clear need for coordinating the tasks scheduled in the patients' action plan. Accordingly, the use of information and communication technologies (ICT) enabling information sharing, remote off-line control and collaborative work among professionals (hospital-based team, wellness centers, primary care team, etc.) across healthcare tiers was identified as a major issue.

Table 1. Main results of the design thinking sessions.

	Aims	Tools	Results
PRELIMINARY FIELDWORK	• To capture the patient experience perspective of the service. • To identify factors of the prehabilitation service at HCB that may limit scalability.	• In-depth interviews to patients and caregivers. • Surveys to professionals involved in the prehabilitation unit.	• Identification of actionable areas to be addressed in Session I – Immersion (see text).
IMMERSION *(Session I)*	• To gain further insight on organizational and actionable factors of to enhance scalability of the existing prehabilitation to: a) Optimize service workflow. b) Identify ICT-support to scalability. c) Explore financial needs for adoption.	• Elaboration of the following material contributing to refinement of the PreHab service: o Experience map (Fig 1). o Empathy map (S1 Fig). o Context map (S2 Fig). o Priority map (Fig 2).	• Agreement on the main challenges to face and solve in Sessions II and III. Main outcome of the Immersion was "to *provide an accessible, round-the-clock personalized and modular service that the patients should be able to use autonomously during the PreHab period. The service should combine remotely controlled actions and face to face interactions with health professionals".*
IDEATION *(Session II)*	• To generate, develop and assess ideas and plans to solve the challenges identified in Session I.	• Two inspirational presentations. • Small group creative sessions. • Positioning map (Fig 3).	• Generation of a customer journey that should contribute to define a viable strategy for regional deployment of prehabilitation. To this end, an overview of the prehabilitation service workflow was produced, as a visual map depicting the end users touch points and needs for both ICT-support and business model.
VALIDATION *(Session III)*	• To consolidate the proposals and refine the actions resulting from Session II aiming to define a viable strategy for regional deployment of a refined service workflow.	• Three working groups to separately tackle specific areas and final overall group meeting to generate consensus on specific proposals for each area: ✓ Implementation strategies. ✓ Technology-related aspects. ✓ Business model & reimbursement incentives.	• Fulfill end-user touch points (see text for more details) • Creation of a capillary network of healthcare/wellness centers to enhance accessibility. • Mobile app fostering tailored patient empowerment for self-management and remote monitoring. • Interoperability of ICT-enabling tools with existing HIS. • ACM system to support prehabilitation knowledge intensive processes for enhanced service management. • To drive patient interactions and data collection through an AI assisted chat (i.e. Chatbot). • Cost-savings generated by PreHab should cover the operational costs of the service. Investments needed to launch the service, as well as reimbursement incentives, could be covered by innovative PPP models.

HCB: Hospital Clínic de Barcelona; ICT: Information and communication technologies; HIS: Hospital Information Systems; ACM: Adaptive case management; AI: Artificial intelligence; Chatbot: A computer program designed to simulate conversation with human users, especially over the Internet; PPP: public-private procurement.

Both patients and caregivers valued their experience very positively. In all cases, the most valued intervention was the exercise training program because patients were able to perceive the improvement of their physical performance and health status. They positively identified group-based mindfulness sessions, as well as personalization of the intervention, as effective ways to encourage both adherence to the work plan and reduce anxiety. However, they identified as a weakness the limitations of the existing infrastructure (i.e. bigger both gym and locker rooms and showers), which would help to improve the experience. Interestingly, patients indicated the relevance of a future extension of the service during the postoperative period. As mentioned, the outcomes of the two preliminary surveys addressed to professionals and to patients/caregivers, respectively, were used to define both the aims and content of the first session (Table 1).

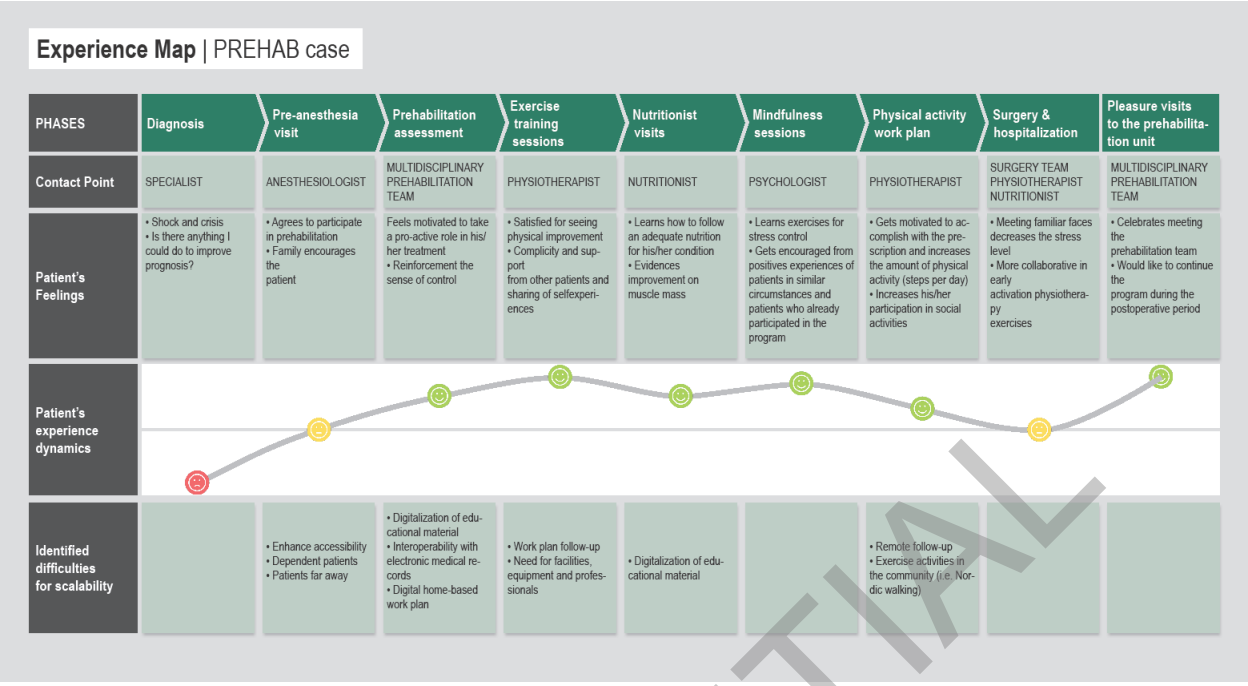
Immersion

A total of 36 attendees, representatives of the different stakeholder profiles, contributed to the first session (S1 Table). The experience map (Fig 1) shows high levels of satisfaction and acceptability of the patients through the overall service workflow. We can observe, however, a high diagnosis-related level of anxiety at service inclusion, progressively decreasing throughout the PreHab period. Three main ideas were extracted from the analysis of the experience map of the current service: i) Limitation of resources in terms of space and facilities available, as well as regarding the number of health professionals involved in the service delivery; ii) Effectiveness of the current service provision relies upon a close and personalized face-to-face follow-up of patients which may be detrimental for its future scalability; and last but not least,

iii) Additional ICT-support may contribute to generate efficiencies and to extract metrics for service monitoring.

Figure 1. Patient experience map. The prehabilitation (PreHab) experience map represents the complexity of the PreHab experience while capturing the common points of change and transition throughout the different stages of the perioperative process (columns), namely: i) Diagnosis; ii) Visit to the pre-anesthesia clinic; iii) First visit to the PreHab unit and baseline multidisciplinary assessment; iv) Exercise training sessions supervised by a specialized physiotherapist; v) Nutritional follow-up visits by a registered nutritionist; vi) Group-based mindfulness sessions driven by a specialized psychologist; vi) Community-based physical activity plan based on increasing the number of steps per day (pedometer); vii) Surgery and hospitalization period; viii) Pleasure visits to the PreHab unit.

On the rows we can observe four main domains: i) The contact points of each stage of the PreHab process and the representative professional for each contact point; ii) Patient's feelings, thoughts, and actions relative to each stage of the PreHab period; iii) A graphical representation of the patient's experience dynamics through the PreHab process; and, iv) The difficulties identified in each stage which may be limiting service scalability.

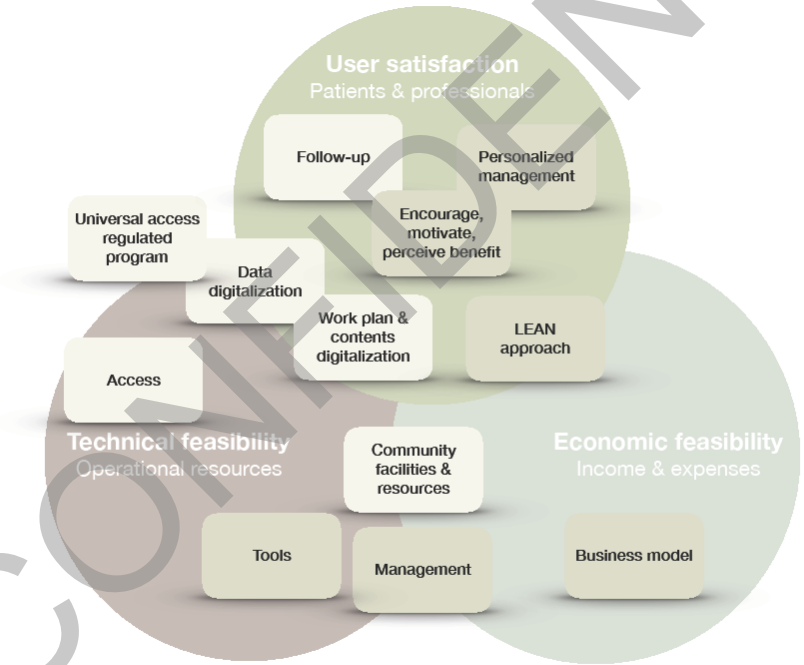


A subsequent brainstorming session contributed to identify several different factors with potential impact on the service scalability. All the ideas raised in the brainstorming session were pooled in a context map (S1 Fig) under the following labels: i) Social and healthcare sector trends; ii) Technology; iii) Patients' and healthcare professionals' needs; iv) Stakeholders' characteristics; and, v) Financial barriers for further developments. Finally, the most relevant ideas were agreed and clustered into the three dimensions of a priority map (Fig 2): i) Users' satisfaction; ii) Technological viability; iii) Economic viability that were identified as key areas of action to foster PreHab scalability and adoption. It was agreed that actions should converge toward the service definition depicted in Table 1 (second row, third column); that is: "to *provide an accessible, round-the-clock personalized and modular service that the patients should be able to use autonomously during the PreHab period. The service should combine remotely controlled actions and face to face interactions with health professionals".* The attendees agreed on the concept that there was a need for development of agile operational processes aiming at service refinement, using Lean philosophy and tools[12, 13]. Overall, five areas for action were formulated: i) Personalization of interventions; ii) Stimulation of a pro-

active role of patients, aiming at empowerment for self-management and promotion of physical activity; iii) Enhanced flexibility of interventions through a highly modular service design; iv) Improved accessibility and logistics; and, v) Achievement of financial sustainability of the services to ensure long-term adoption of cost-effective healthy lifestyles interventions.

Figure 2. Priority map. The figure organizes the relevant factors for a successful scalability of the prehabilitation program in three main domains, namely: i) User satisfaction; ii) Technical feasibility, and, iii) Economic feasibility.

Light beige squares contain concepts emerged from the Patient experience map (Fig 1). Dark beige squares contain concepts emerged from the Context map (S2 Fig).



Ideation

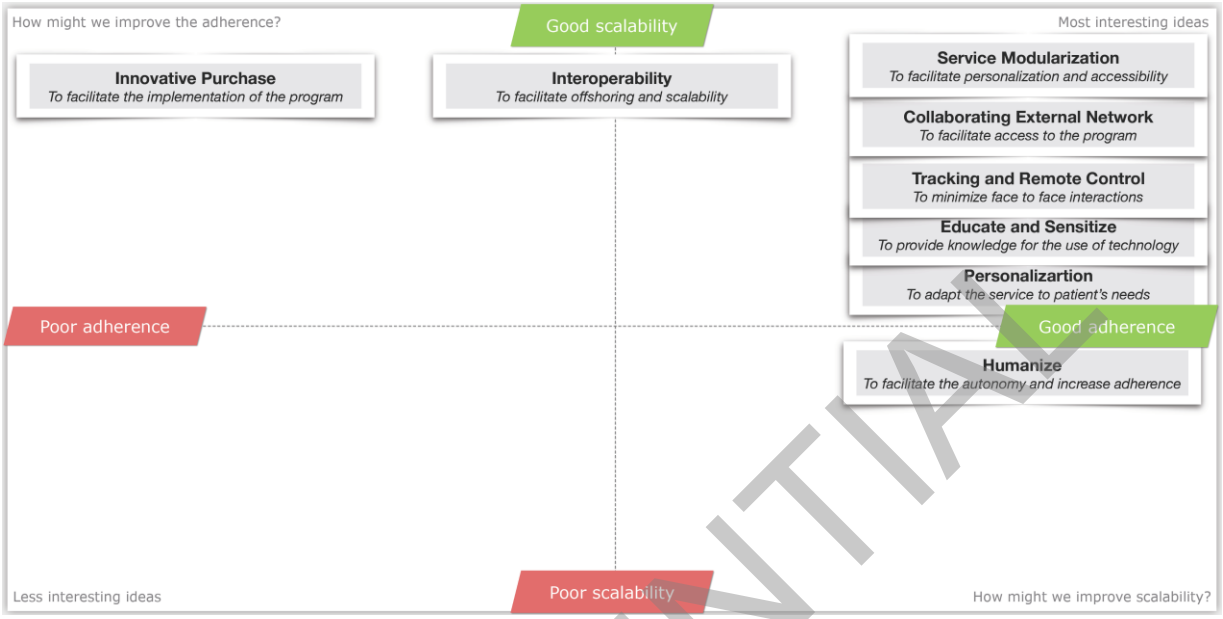
A total of 44 professionals covering the different profiles attended the second session (S1 Table). The first inspirational presentation, of approximate 10 min duration (Table 1), updated the audience on the current status of the PreHab service, its architecture, wireframes, and

roadmap for 2017. The second talk, 15 min, was geared towards exploring previous experiences in other fields that have solved the similar challenges. It was followed by ten simultaneous small group creative sessions, 4-5 persons each, that approached the main previously identified challenges under the following success criteria: i) Allow scalability while preserving the quality of the service; ii) Allow reproducibility of the service outcomes in different sites, that is, service transferability; iii) Enhance the adherence of patients to the work plan; iv) Provide key performance indicators to track service effectiveness; v) Foster accessibility to the program; vi) Ensure economic viability for sustainability; and, vii) Conceive the service within a LEAN approach [12, 13] to allow agile implementation and management using minimal resources.

The ideas resulting from the creative sessions were debated by the whole group and then prioritized and pooled into a positioning map (Fig 3). Finally, the ideas incorporated in the positioning map (S2 Fig) were used to generate a general overview for the refined PreHab service workflow to be assessed during the third session.

Figure 3. Positioning map. This figure shows the best ideas and concepts that emerged from the small creative groups. The ideas were selected in terms of their potential to enhance the patient's adherence to the work plan and their degree of scalability, namely: i) Facilitate **innovative purchase** to foster the implementation of the service; ii) Promote **interoperability among different information systems** to promote off-shoring and scalability of the service; iii) **Monitor** patients by means of wearables to track physical activity and physiological signs in order to enhance patients' adherence to the work plan and foster accessibility and scalability of the service; iv) Provide **educational material** using information and communication technologies in order to support self-management while fostering the accessibility to the service; v) Generate a capillary **network of collaborative wellness and sport centers** to enhance accessibility to the service; vi) **Personalize the program** taking into account patients'

characteristics; vii) Promote the **humanization of the service** by means of a call center to handle events and enhance patients' adherence to the work plan (S3 Fig).



Validation

The third session was attended by a total of 43 professionals (S1 Table). The categories displayed in Figs 2 and 3 were further debated and elaborated in three subgroups of attendees in order to achieve a well-defined action plan for scalability of the service, as summarized in Table 1 (fourth row, third column). Briefly, selected actions agreed by the whole group are described below.

Group A – End user touch points. One of the main expectations for the end users was the personalization of the program to be achieved through its modularity. It should take into account both biological factors and determinants of adherence to the intervention. Therefore, the subject-specific tailoring of the intervention should envisage the following aspects: i) Aerobic capacity; ii) Nutritional status; iii) Iron reserve profiling at program inclusion; iv) Self-efficacy; v) Facilitators and barriers to physical activity; vi) Psychological & behavioral aspects; and, vii) Logistic factors. Moreover, a key aspect identified by the clinicians was the need for

creating a capillary network of community-based health & wellness centers (i.e. primary care, sport centers and gyms) to enhance accessibility. Also, the use of a mobile app, interoperable with the PreHab service, allowing tailored remote promotion and monitoring of physical activity (i.e. steps per day and physical activity intensity), patient-reported outcomes (i.e. motivational factors for physical activity, Borg scale and quality of life) and, eventually, other physiological data depending upon patients' characteristics, was considered a highly valuable supporting tool to effectively manage the service in the community setting.

Group B – Technology. To facilitate proper interactions between specialized and community-based actions of the PreHab service, as well as to support collaborative work among actors (patients, caregivers, professionals across healthcare tiers), there is a clear need for interoperability of ICT-supporting tools and current hospital information systems. The provision of access to online patient-tailored educational material and to remote support to enable patient empowerment for self-management was highly valued by clinicians.

To fulfill requirements of standardization, flexibility and modularity of the prehabilitation service, an adaptive case management (ACM) system was proposed to support process workflow specification, case management and decision automation[14, 15]. The ACM system would provide the required process engine functionality to current hospital information systems. Finally, it was decided that the best solution to enhance end-user adoption was to eliminate complex frontends and drive patient interaction and data collection through an Artificial Intelligence assisted chat (i.e. Chatbot), which would result in a flexible interface closer to the human language[16].

Group C – Business. Preliminary studies on efficacy and costs of the current PreHab service at Hospital Clinic de Barcelona [7, 17], as well as different randomized controlled trials [18, 19], indicate high potential for health value generation both at provider and at health system levels. This suggests that the operational costs of PreHab can be fully covered by savings

generated through the adoption of the service. Moreover, such savings can be eventually increased by adopting the service refinements elaborated in the DT sessions (i.e. participation of external sport centers, physiotherapy services companies and use of ICT as enabling tools) (Table 1). The group acknowledged that both investments and reimbursement incentives required for service launching may need to be covered by innovative public-private procurement modalities to accelerate the process of scalability of the service.

Discussion

The on-going prehabilitation service at HCB has shown effectiveness and potential for health-value generation, which fostered its adoption in 2016 as mainstream service for high-risk patients undergoing different types of surgical procedures [7]. Major challenges of the service were the analysis of its potential for transferability to other sites, as well as the elaboration of strategies for its regional scalability. Both aspects have been addressed in the current study that proves the usefulness of DT tools to identify key elements that must be taken into account for regional deployment of the service, as summarized in Table 1.

Two other priority areas to be addressed are: i) Continuous service assessment in real world settings, aiming at ensuring long-term reproducibility of the initial study results; and, ii) Analysis of a potential evolution of PreHab toward a population-health approach, which implies tailoring the intervention according to a subject-specific health risk assessment, as well as extending the scope of the intervention in order to also enhance post-surgical care recovery.

The workshops facilitated stepwise progress towards identifying the three pivotal dimensions requiring intervention: i) Enhanced service design; ii) Technological support; and, iii) Financial sustainability. It is acknowledged that site customization of the service will be required for large scale implementation at regional or international levels. Personalization and modularity of the PreHab service have been stressed as two core traits needed for successful site implementation. Likewise, empowerment of patients for self-management of their condition constitutes an essential goal of the service. Moreover, the requirements for ICT in the scalability of PreHab have been formulated. It is of note that the technological support facilitating service modularity and personalization as well as interoperability between community-based facilities (including patient's home) and hospital-based information systems currently being achieved in the health district of Barcelona-Esquerra (512k inhabitants)[20].

Last, but not least, the core criteria to achieve financial sustainability of the PreHab service has also been formulated.

Beyond PreHab, we believe that the current study indicates a high potential of DT methodologies for contributing to the refinement and site adaptation of service workflows in a broad spectrum of complex interventions as often encountered in the integrated care scenario. In particular, specific achievements of the current study may be useful for the design and implementation of innovative rehabilitation services, as described in [17].

Conclusions

Design thinking methodologies were useful for defining the traits of a general strategy for the regional deployment of the prehabilitation service, which has demonstrated effectiveness and potential for cost-savings at Hospital Clinic of Barcelona. Moreover, the approach shows high potential for service refinement in other complex healthcare interventions.

Acknowledgments

We would like to acknowledge the staff members of the Prehabilitation group at Hospital Clínic de Barcelona and the Barcelona Design Cluster (BCD) for their collaboration to the achievement of this work. I Anael Barberan-Garcia, the corresponding author of this manuscript, certify that I have listed everyone who contributed significantly to the work.

References

1. Visser W. The cognitive artifacts of designing. Lawrence Erlbaum Associates, Inc., Publishers; 2006. doi: https://doi.org/10.1080/10447310802583933
2. Brown T. Design Thinking. Harvard Business Review. 2008. Available from: https://hbr.org/2008/06/design-thinking
3. Norman DA, Draper SW. User-Centered System Design: New Perspectives on Human-Computer Interaction. Lawrence Erlbaum Associates, Inc., Publishers; 1986.
4. International Organization for Standardization. ISO 9241-210:2010. Ergonomics of human-system interaction - Part 210: Human-centred design for interactive systems. 2010. Available from: https://www.iso.org/obp/ui/#iso:std:iso:9241:-210:ed-1:v1:en
5. Bazzano AN, Martin J, Hicks E, Faughnan M, Murphy L. Human-centred design in global health: A coping review of applications and contexts. PLoS One. 2017 Nov 1. doi: https://doi.org/10.1371/journal.pone.0186744
6. Catalani C, Green E, Owiti P, Keny A, Diero L, Yeung A, et al. A clinical decision support system for integrating tuberculosis and HIV care in Kenya: a human-centered design approach. PLoS One. 2014 Aug 29. doi: https://doi.org/10.1371/journal.pone.0103205
7. Barberan-Garcia A, Ubré M, Roca J, Lacy AM, Burgos F, Risco R, et al. Personalised prehabilitation in high-risk patients undergoing elective major abdominal surgery: A randomized controlled blinded trial. Ann Surg. Jan 2018. doi: 10.1097/SLA.0000000000002293.
8. Carli F, Scheede-Bergdahl C. Prehabilitation to enhance perioperative care. Anesthesiol Clin. 2015 Jan 9. doi: https://doi.org/10.1016/j.anclin.2014.11.002
9. Generallitat de Catalunya. Departament de Salut. Health Plan for Catalonia 2011-2015. Barcelona, 2012. Available from:

http://salutweb.gencat.cat/web/.content/home/el_departament/pla_de_salut/documents/arxius/health_plan_english.pdf

10. Generallitat de Catalunya. Departament de Salut. Catalonia Healthcare Plan 2016-2020. Barcelona, 2016. Available from: http://salutweb.gencat.cat/ca/el_departament/Pla_salut/pla-de-salut-2016-2020/
11. Pentagrowth model. [cited 9 August 2018]. Available from: https://www.ideasforchange.com/pentagrowth?lang=en
12. Coletta AR. The Lean 3P advantage. A practitioner's guide to the production preparation process. Productivity Press; 201
13. Hicks C, McGovern, Prior G, Smith I. Applying lean principle to the design of healthcare facilities. Int J Prod Econ. Dec 2015. doi: https://doi.org/10.1016/j.ijpe.2015.05.029
14. Swenson KD. Mastering the Unpredictable: How Adaptive Case Management Will Revolutionize the Way That Knowledge Workers Get Things Done. Meghan-Kiffer Press, Tampa; 2010.
15. Herrmann C, Kurz M. Adaptive case management: Supporting knowledge intensive processes with IT systems. In: Communications in Computer and Information Science. 2011. 80–97.
16. Dahiya M. A Tool of Conversation: Chatbot. Int J Comput Sci Eng. 2017; 5(5):158–61. http://www.ijcseonline.org/pub_paper/27-IJCSE-02149.pdf
17. Barberan-Garcia A, Gimeno-Santos E, Blanco I, Cano I, Martínez-Pallí G, Burgos F, et al. Protocol for regional implementation of collaborative self-management services to promote physical activity. BMC Health Serv Res. 2018;18(1):560.
18. Arthur HM, Daniels C, McKelvie R, Hirsh J, Rush B. Effect of a preoperative intervention on preoperative and postoperative outcomes in low-risk patients awaiting elective coronary artery bypass graft surgery. A randomized, controlled trial. Ann Intern Med. 2000; 133(4):253-62.

19. Barakat HM, Shahin Y, Khan JA, McCollum PT, Chetter IC. Preoperative supervised exercise improves outcomes after elective abdominal aortic aneurism repair: A randomized controlled trial. Ann Surg. Jul 2016. doi: 10.1097/SLA.0000000000001609.
20. Font D, Escarrabill J, Gómez M, Ruiz R, Enfedaque B, Altimiras X. Integrated Health Care Barcelona Esquerra (Ais-Be): A global view of organizational development, re-engineering of processes and improvement of the information systems. The role of the tertiary university hospital in the transformation. Int J Integr Care 2016;16:8. doi: 10.5334/ijic.2476.

Supporting information

1S Fig. Empathy map. The final aim of the empathy map was to have a good understanding about patients enrolled in the PreHab service. We empathized with the patients considering the following aspects: i) What they think and feel (upper triangle); ii) What do they see? What is their environment? (right triangle); iii) What do they hear? Who is influencing them? (left triangle); and, iv) What do environment say and how do they act? (down triangle).Moreover we considered their "pains and frustrations" and their "gains and motivations".

S2 Fig. Context map. We organized the brainstormed concepts within eight different domains framing the general situation, namely: i) Trends of the healthcare sector; ii) Policy-related trends of the healthcare; iii) General society trends; iv) Technological factors influencing the situation; v) Healthcare professionals needs; vi) Patients' needs; vii) Potential uncertainties and difficulties which can raise during the implementation of the service; and, viii) Different stakeholders of the service.

The final aim of the context map was developing a shared big-picture view of the environment of the PreHab service to establish a common backdrop for a strategic vision of a complex situation. The general concepts and ideas raised from its debate were finally pooled into a **Priority map** (**Figure 2**).

S3 Fig. Workflow of the prehabilitation service.

S1 Table. Profile and number of attendees to the design thinking sessions.

Experience Map | PREHAB case

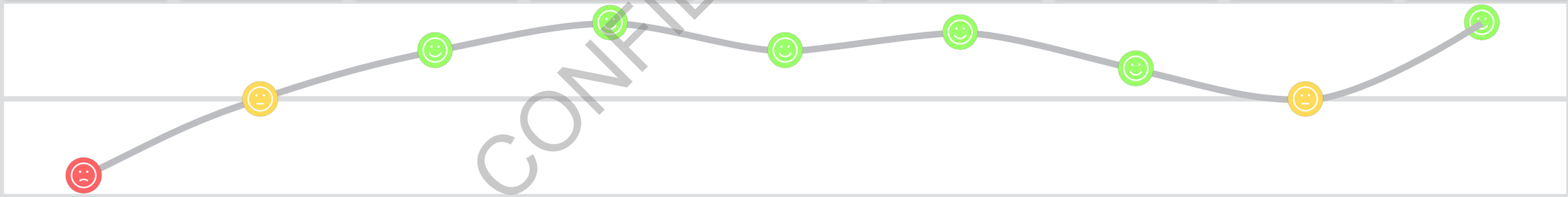
PHASES	Diagnosis	Pre-anesthesia visit	Prehabilitation assessment	Exercise training sessions	Nutritionist visits	Mindfulness sessions	Physical activity work plan	Surgery & hospitalization	Pleasure visits to the prehabilitation unit
Contact Point	SPECIALIST	ANESTHESIOLOGIST	MULTIDISCIPLINARY PREHABILITATION TEAM	PHYSIOTHERAPIST	NUTRITIONIST	PSYCHOLOGIST	PHYSIOTHERAPIST	SURGERY TEAM PHYSIOTHERAPIST NUTRITIONIST	MULTIDISCIPLINARY PREHABILITATION TEAM
Patient's Feelings	• Shock and crisis • Is there anything I could do to improve prognosis?	• Agrees to participate in prehabilitation • Family encourages the patient	Feels motivated to take a pro-active role in his/her treatment • Reinforcement the sense of control	• Satisfied for seeing physical improvement • Complicity and support from other patients and sharing of selfexperiences	• Learns how to follow an adequate nutrition for his/her condition • Evidences improvement on muscle mass	• Learns exercises for stress control • Gets encouraged from positives experiences of patients in similar circumstances and patients who already participated in the program	• Gets motivated to accomplish with the prescription and increases the amount of physical activity (steps per day) • Increases his/her participation in social activities	• Meeting familiar faces decreases the stress level • More collaborative in early activation physiotherapy exercises	• Celebrates meeting the prehabilitation team • Would like to continue the program during the postoperative period
Patient's experience dynamics									
Identified difficulties for scalability		• Enhance accessibility • Dependent patients • Patients far away	• Digitalization of educational material • Interoperability with electronic medical records • Digital home-based work plan	• Work plan follow-up • Need for facilities, equipment and professionals	• Digitalization of educational material		• Remote follow-up • Exercise activities in the community (i.e. Nordic walking)		

Figure 2

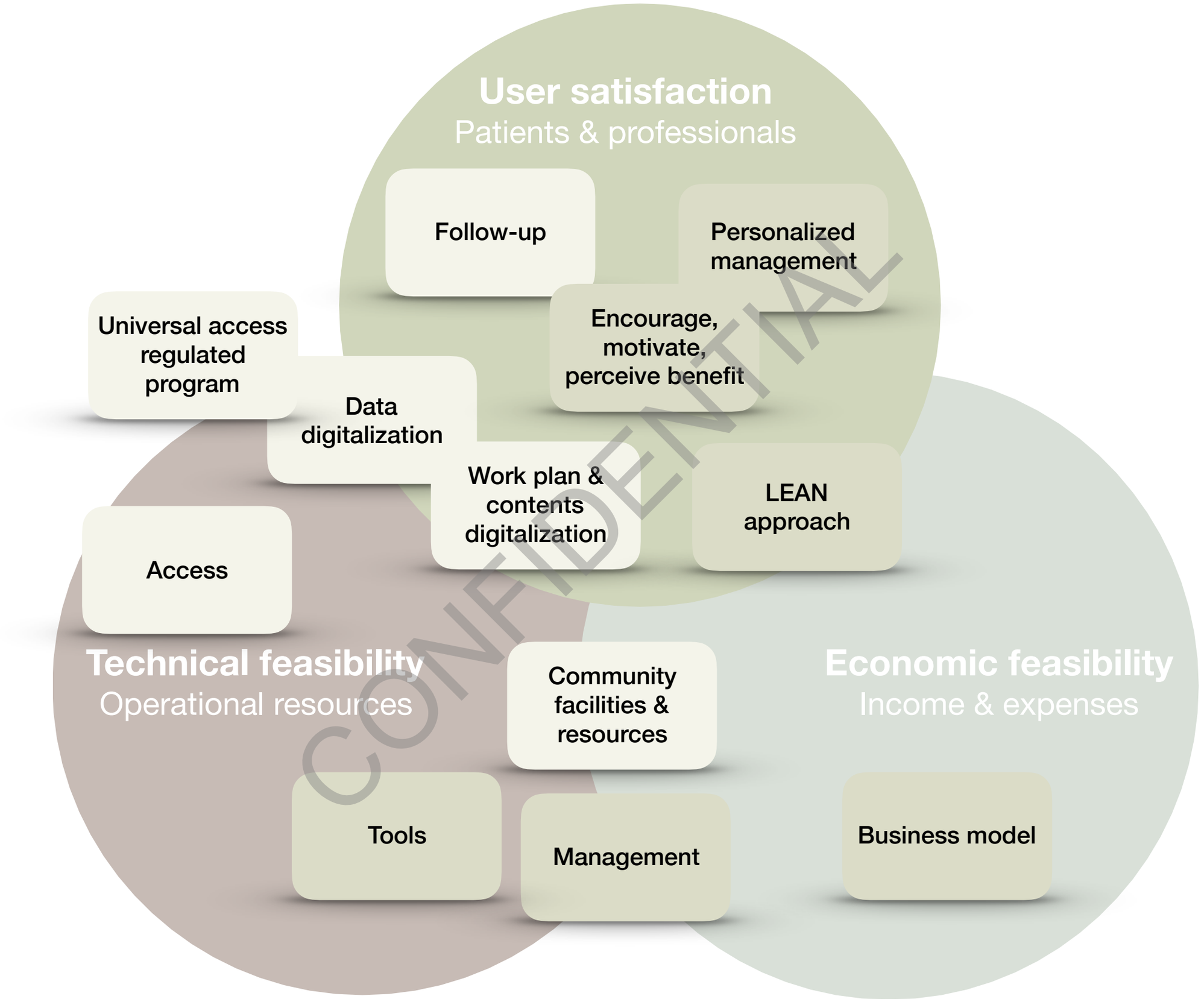
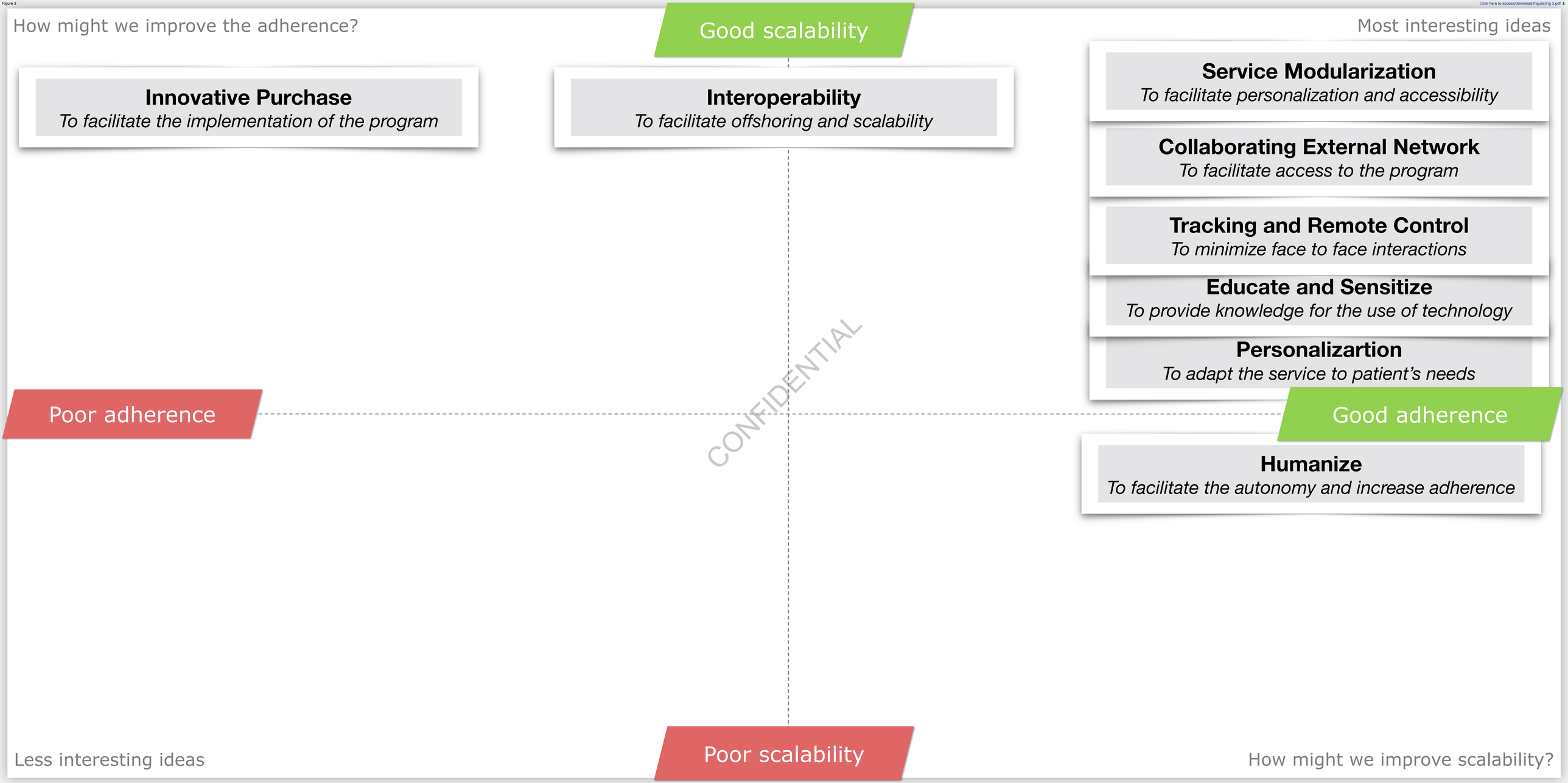


Figure 3



1S Figure

2S Figure

3S Figure

11. ANNEX IV - Post-discharge impact and cost-consequence analysis of prehabilitation in high-risk patients undergoing major abdominal surgery

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)

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Clinical Practice

CLINICAL PRACTICE

Post-discharge impact and cost-consequence analysis of prehabilitation in high-risk patients undergoing major abdominal surgery: secondary results from a randomised controlled trial

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Abstract

Background: Prehabilitation may reduce postoperative complications, but sustainability of its health benefits and impact on costs needs further evaluation. Our aim was to assess the midterm clinical impact and costs from a hospital perspective of an endurance-exercise-training-based prehabilitation programme in high-risk patients undergoing major digestive surgery.

Methods: A cost-consequence analysis was performed using secondary data from a randomised, blinded clinical trial. The main outcomes assessed were (i) 30 day hospital readmissions, (ii) endurance time (ET) during an exercise testing, and (iii) physical activity by the Yale Physical Activity Survey (YPAS). Healthcare use for the cost analysis included costs of the prehabilitation programme, hospitalisation, and 30-day emergency room visits and hospital readmissions.

Results: We included 125 patients in an intention-to-treat analysis. Prehabilitation showed a protective effect for 30-day hospital readmissions (relative risk: 6.4; 95% confidence interval [CI]: 1.4–30.0). Prehabilitation-induced enhancement of ET and YPAS remained statistically significant between groups at the end of the 3 and 6 month follow-up periods, respectively (ΔET 205 [151] s; P=0.048) (ΔYPAS 7 [2]; P=0.016). The mean cost of the programme was €389 per patient and did not increment the total costs of the surgical process (€812; CI: 95% −878 − 2642; P=0.365).

Conclusions: Prehabilitation may result in health value generation. Moreover, it appears to be a protective intervention for 30-day hospital readmissions, and its effects on aerobic capacity and physical activity may show sustainability at midterm.

Clinical trial registration: NCT02024776.

Keywords: cost-consequence analysis; exercise therapy; postoperative complications; preoperative care

Editorial decision: 16 May 2019; **Accepted:** 16 May 2019

Editor's key points

- Optimisation before major surgery (prehabilitation) is intuitively appealing.
- Additional investigations and introducing interventions to maximise prehabilitation add cost to healthcare, but these should be offset by reduced complications and shorter hospital stay.
- This study demonstrated the cost-effectiveness of prehabilitation for major abdominal surgery.

Major surgical procedures are frequently associated with postoperative complications that have a marked deleterious impact on health-related quality of life, morbidity/mortality, and costs.[1–4] On average, 20% of patients have major postoperative complications that it is estimated to account for 50% of operational costs.[5] Therefore, the design and implementation of innovative preventive interventions aiming at reducing postoperative complications constitute a relevant milestone with potential positive implications on health outcomes, patient's experience of care, and cost savings for both healthcare providers and third-party payers, allowing for a more efficient resource reallocation.

Prehabilitation is emerging as a preoperative intervention aiming at improving patient's aerobic capacity, nutritional balance, and psychological status. Its ultimate aim is to enhance patients' functional capacity in order to minimise postoperative morbidity and accelerate post-surgical recovery.[6] Several RCTs assessing prehabilitation programmes have shown positive effects of the intervention on aerobic capacity and physical activity, resulting in a significant reduction of both postoperative complications and length of hospital stay.[7–9] However, the impact of prehabilitation on healthcare costs and service sustainability has been insufficiently analysed.

The current research draws upon the secondary results of a recent RCT exploring the effects of prehabilitation in high-risk candidates for major digestive surgery at the Hospital Clínic de Barcelona (Catalonia),[7] and presents a cost-consequence analysis (CCA). CCA is a form of evaluation of healthcare programmes, in which costs and impacts of the intervention are presented separately.[10] Accordingly, firstly, we explored the effects of the intervention on postoperative recovery during a 6 month period after hospital discharge. Secondly, we evaluated the impact of the prehabilitation service on direct healthcare costs and the midterm sustainability of its clinical benefits.

Methods

Study design

The current study reports a CCA of a prehabilitation programme, with secondary outcomes from a previously published RCT carried out at the Hospital Clínic de Barcelona (Catalonia).[7] The Ethics Committee for Clinical Research of the centre approved the study (CEIC 2013/8579), for which the protocol was registered at ClinicalTrials.gov (NCT02024776) and it is currently closed. Specific amendments to the original public protocol can be found at https://clinicaltrials.gov/ct2/show/NCT02024776.

Over a 3 yr period (February 3, 2013 to June 13, 2016), a consecutive sample of patients undergoing elective major digestive surgery was included in the trial. The main inclusion criteria were high risk for surgical complications defined by age above 70 yr and ASA physical status 3/4.[11] Patients with a Duke Activity Status Index over 46 were not included in the trial.[12] A minimum waiting period allowing 4 weeks of programme was required as inclusion criterion. Subjects accepting to participate were blindly randomised (1:1 ratio) to control or intervention groups.

Control group

Patients included in the control group followed the standard preoperative protocol at Hospital Clínic de Barcelona. 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 i.v. iron, and in those at high risk of malnutrition (Malnutrition Universal Screening Tool ≥ 2[13]) 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 prehabilitation programme with two main objectives: (i) to increase aerobic capacity, and (ii) to enhance physical activity. The prehabilitation programme covered three main actions: (i) a motivational interview, (ii) a hospital-based high-intensity endurance-exercise training programme, and (iii) promotion of physical activity. A specialised physiotherapist was the case manager guiding the patients included in the intervention group throughout the prehabilitation programme. The length of the intervention depended on the waiting time to the surgery. A minimum waiting period allowing 4 weeks of programme was required as inclusion criterion. Patients attending the programme for less than 4 weeks were still included in the intention-to-treat analysis. The detailed characteristics of the trial have been reported previously.[7]

Clinical outcomes

The original trial design was powered for postoperative complications. Therefore, the following variables described were planned as secondary outcome variables. Endurance time (ET) measured by a cycling constant work-rate exercise testing at 80% of peak oxygen uptake[14] was assessed at baseline, presurgery, and at 3 months after surgery. Physical activity by the Yale Physical Activity Survey (YPAS),[15] self-perceived health status by the Short Form (36) Health Survey (SF-36),[16] and psychological status by the Hospital Anxiety and Depression Scale (HADS)[17] were assessed at baseline, presurgery, and at 30 days and 6 months after surgery. Moreover, all-cause mortality at 30 days and at 3 and 6 months was also registered.

Use of healthcare resources

Emergency room visits, hospital readmissions, and surgical reinterventions at 30 days for the same condition, 3 and 6 months into the follow-up period after surgery were also registered.

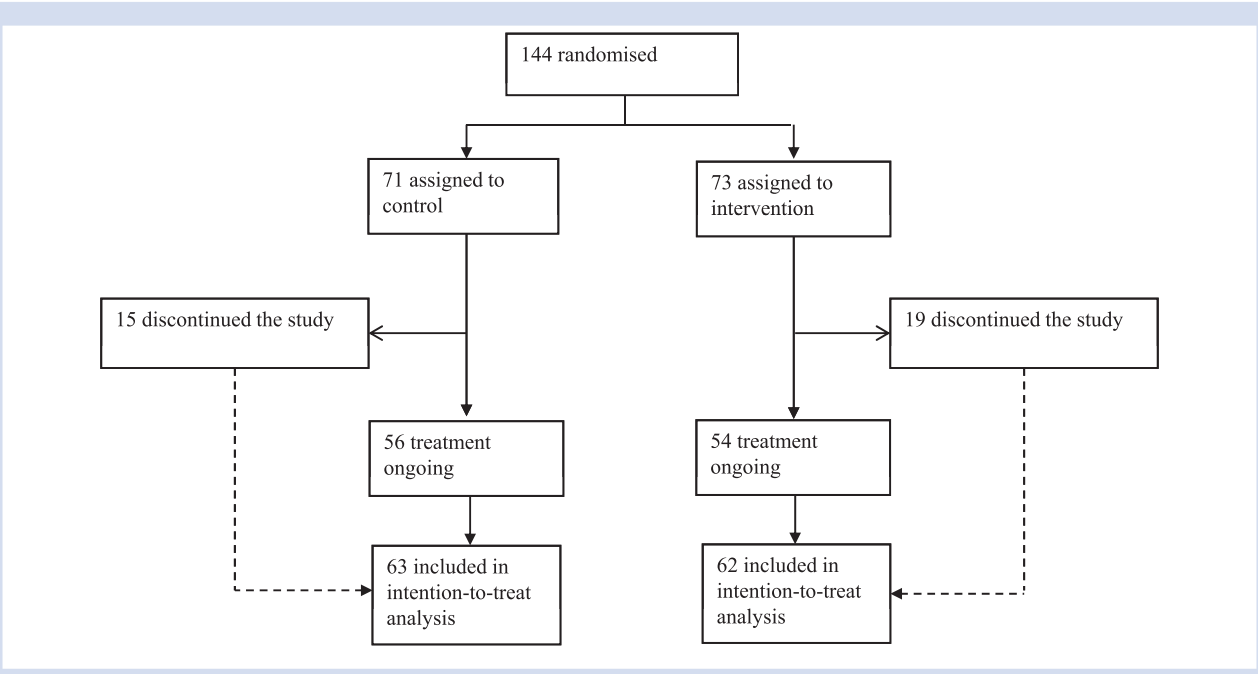

Fig 1. Flow chart of the study.

Costs

Total individual costs were prospectively obtained for each group from the hospital perspective, so the cost analysis was restricted to direct healthcare costs. Hospital patient-level data were collected to analyse the impact of the programme on hospital care costs. A combination of diagnostic-related-group-based hospital fees and micro-costing was used to identify and measure the cost allocation. Hospital fees used are specific of the Hospital Clínic de Barcelona, and micro-costing implied direct cost imputation according to individual consumption at a patient level.

The costs of the prehabilitation programme and those from the follow-up period were estimated. Prehabilitation programme costs included (i) a cardiopulmonary exercise testing, (ii) the physiotherapist fees, and (iii) a pedometer device. Follow-up included hospitalisation after surgery, hospital readmissions, surgical re-interventions, and emergency room visit costs at 30 days after hospital discharge. Follow-up postoperative costs included (i) inpatient services (hospital-specific fees), (ii) emergency room visits (hospital-specific fee), (iii) diagnostic procedures (hospital-specific fees), (iv) pharmaceutical consumption (micro-costing), (v) blood products consumption (micro-costing), and (vi) structural costs (hospital-specific fee). Costs are expressed in Euro (€) 2017. No discount rate was used given the short time period used in this study.

Statistical analysis

Data are presented as mean (standard deviation [SD]) or 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 χ^2 or Fisher's exact tests for categorical variables, respectively. A *P*-value <0.05 was considered statistically significant.

For costs, the mean and 95% CI of difference in per-patient costs between the two groups were computed (control-group costs minus prehabilitation-group costs), so that positive values should be interpreted as a savings of the prehabilitation programme. We had to deal with a highly skewed distribution, which is typical of cost data. Right-sided asymmetric distribution appears when some patients incur in high costs, in our case, mainly because of major medical complications. To deal with this, a non-parametric approach (bootstrapping [1000 replications])[18] was used. Bootstrap analysis yields more robust when dealing with skewed cost data compared with non-parametric tests (such as Mann–Whitney).[10]

Results

Of the initial sample of 144 patients randomised, 19 did not undergo surgery and were excluded from all analyses. Thus, a sample of 125 patients (71 [11] yr; 75% male; adjusted Charlson comorbidity index 7 [9]) was included in an intention-to-treat analysis, as depicted in Fig. 1.

Use of healthcare resources after hospital discharge

Readmission and emergency room visits are presented in Supplementary Table S1. The percentage of patients being readmitted at 30 days after hospital discharge, or still hospitalised during that period, was 10% of the overall sample. It is of note that the prehabilitation group showed a lower rate of 30 day hospital readmissions compared with the usual care group (18% *vs* 3%; *P*=0.009). Accordingly, prehabilitation showed to have a protective role for 30 day hospital readmissions with an estimated relative risk (RR) of 6.4 (95% CI: 1.4–30.0). No other significant differences in healthcare use were found during the 6 month follow-up period.

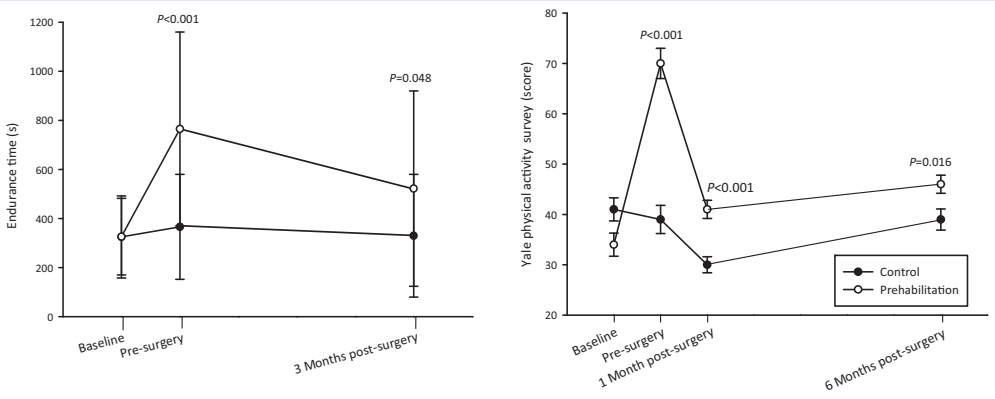

Fig 2. Midterm effects of prehabilitation on aerobic capacity and physical activity.

Postoperative functional recovery

Supplementary Table S2 shows the clinical outcomes during the overall study period. Prehabilitation-induced enhancement of aerobic capacity (ET) at Month 3 of the postoperative follow-up period remained significantly higher as compared with the usual care group (Fig. 2, left panel). Moreover, the ET of the intervention group assessed at 3 month follow-up was significantly higher to the measured at baseline (325 [151] *vs* 535 [401] s in ET; P=0.010).

Likewise, the prehabilitation-induced increase of physical activity levels (YPAS index) remained significantly higher at 6 month follow-up as compared with controls (Fig. 2, right panel). Likewise, the YPAS index at Month 6 of the follow-up period is significantly above the baseline values in the intervention group (34 [16] *vs* 46 [13] YPAS index values; P<0.001).

Consistently, the prehabilitation group also showed a higher score in the physical component of the SF-36 questionnaire at 30 days and 6 months of follow-up, compared with usual care (Supplementary Table S2). On the other hand, no differences between groups were found in the SF-36 mental component.

In terms of psychological status, the intervention group showed lower anxiety and depression levels (HADS score) at 30 days after surgery, as compared with the usual care group (9 [7] *vs* 6 [5] HADS score; P=0.008). No other significant differences in clinical outcomes were found between the study groups (Supplementary Table S2).

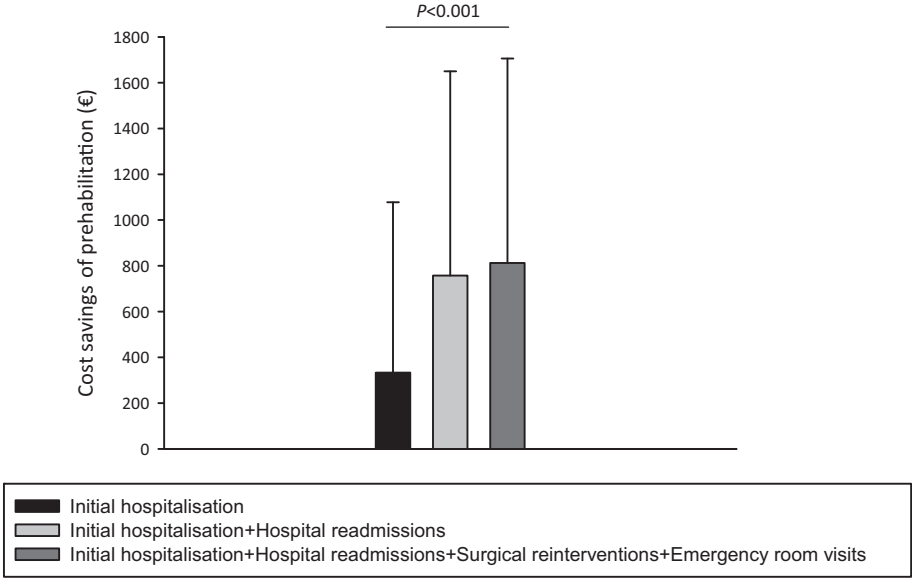

Fig 3. Cost savings of prehabilitation according to different healthcare interactions.

Cost analysis

Both study groups showed a marked skewness in the distribution of costs, as reported in Supplementary Table S3. Moreover, the control group presented two outliers (common cut-off of 3 SD from the mean was used) incurring in high costs (Supplementary Fig. S1). Therefore, in order to provide a robust analysis, we performed the assessment of costs with and without outliers separately. In addition, a bootstrapping approach (1000 replications) was done to calculate the means and 95% CI of the difference in per-patient costs between the two groups.

The mean cost of the prehabilitation programme was €389 per patient, including €230 cardiopulmonary exercise testing, €41 motivational interview, €22 pedometer device, and €96 group endurance-exercise training sessions.

The average cost savings of prehabilitation (Fig. 3) increased by including healthcare use at 30 day follow-up compared with considering only the initial hospitalisation (€333 [745] *vs* €812 [894]; $P<0.001$). However, the prehabilitation programme did not show statistically significant cost savings at 30 days, as presented in Supplementary Table S4 (€812; CI 95% −878 − 2642; $P=0.365$). Similarly, no statistically significant differences on costs between study groups were found when stratifying by level of surgical aggression or surgical risk (Supplementary Table S5).

Discussion

To our knowledge, this is the first study evaluating midterm clinical impact (3 and 6 months post-surgery) and costs of prehabilitation in patients undergoing intra-cavity surgery. The main findings of this randomised trial are (i) a prehabilitation programme, including hospital-based high-intensity endurance-exercise training and promotion of physical activity, was a protective factor for 30-day hospital readmission in high-risk patients undergoing major digestive surgery; (ii) the prehabilitation-induced benefits on aerobic capacity and physical activity showed sustainability at 3 and 6 months after surgery, respectively; and (iii) prehabilitation fosters health value, as it reduces perioperative complications (RR: 0.5; 95% CI: 0.3–0.8)[7] without increasing direct healthcare costs, which may be interpreted as evidence of higher value for money (cost-effective intervention).

The impact of exercise training on healthcare use and medical costs in chronic stable patients has been widely assessed within the context of cardiopulmonary rehabilitation programmes, reporting significant reductions in the number of hospital admissions, emergency room visits, and direct costs.[19–23] However, the rehabilitation-induced enhancement of aerobic capacity, in stable pulmonary and cardiac patients and in the absence of any maintenance strategy, appears to diminish over 6–12 months after programme discharge.[19,24–26] Consistently, the current trial demonstrated a high protective role of prehabilitation for 30 day hospital readmissions (RR: 6.4; 95% CI: 1.4–30.0) in elderly multimorbid patients (mean [SD] age-adjusted Charlson index 7 [9]).[7] Moreover, the prehabilitation-induced effects on aerobic capacity and physical activity showed sustainability at 3 and 6 months post-surgery, respectively. End follow-up ET and YPAS score were lower than preoperative assessments (Fig. 2), but still higher than the baseline measurements. One can speculate that the main reasons of prehabilitation-induced-benefit decline may be the impact of the surgical process, the postoperative co-adjuvant treatment, the progression of the underlying co-morbidities, and patients' lower adherence to physical activity. Therefore, we strongly believe that there is a need to implement sustainable and modular postoperative programmes in order to (i) optimise the postoperative time required for hospital discharge and functional recovery, and (ii) empower patients and provide long-term support on self-management strategies within an integrated care approach (e.g. promotion of physical activity, nutritional advising, and psychological and disease management).[27,28] From our point of view, there is a need of robust perioperative studies assessing both the optimal interventions to be performed and the best duration for the programmes in different subsets of patients. The final outcome would be a sort of modular and patient-oriented programme tailored mainly in terms of type of surgery and patients' surgical risk.

It is important to highlight that all patients underwent surgery within an enhanced recovery after surgery (ERAS) in-house programme. ERAS was adopted in our hospital more than a decade ago; a dedicated multidisciplinary team collaborates to promote a large number of elements of pre-, intra-, and postoperative care (evidence based) to reduce the physiological and psychological stress of surgery with the aim of improving patient outcome. Our compliance with ERAS recommendations,[29] although the number of ERAS elements depends on the type of surgery, is over 70%, and no patients are excluded from the programme. In this context, we believe that our results should prompt taking prehabilitation programmes into major consideration as an intervention to be included in the ERAS pathway for high-risk patients undergoing major elective surgery.

Our randomised trial presents different design strengths discussed in detail in Barberan-Garcia and colleagues,[7] such as (i) prospective recruitment of patients, reinforcing external validity of the results; (ii) blinding of clinicians collecting perioperative outcomes; (iii) absence of contamination amongst groups, as two different informed consents were used; and (iv) absence of missing data in the exhaustive costs and healthcare use register. However, we acknowledge the fact that the analysis used secondary outcomes of an RCT, which renders the results of the current investigation as 'hypothesis generating'. Other study limitations to take into account are the lack of assessment of indirect (societal) costs, the possible lack of statistical power to prove the potential cost-saving effect of prehabilitation, the particular characteristics of the population, and the lack of generalisability of the results because it was a single-centre study. We want to point out that costs at 3 and 6 months have not been reported because of the lack of differences on healthcare use between groups during this period of the follow-up (Supplementary Table S1).

From our understanding, future studies should focus on the evaluation, not only of the clinical and economic impact, but also on the implementation practicalities of real-life deployment experiences on prehabilitation, tackling aspects, such as (i) assessment of sustainability and coverage of the service, (ii) identification of factors modulating implementation success and key performance indicators[30] to track the service, and (iii) generation of recommendations for service transferability to other sites, amongst others. In that sense, prehabilitation programmes basing their supervised sessions in the community setting are postulated as interesting strategies to increase accessibility whilst reducing total costs.

We report highly valuable and promising information, which can guide future studies on the topic whilst supporting

the efficacy and cost-effectiveness of a prehabilitation programme.

Authors' contributions

Study design: AB-G, MU, RR, JF, JB, AML, JP-J, JR, GM-P.
Data collection: AB-G, MU, RR, JF.
Data interpretation: all authors.
Intervention: AB-G.
Statistical analysis: AB-G, NP-A.
Writing of first draft: AB-G, MU.
Approval of final version: all authors.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.bja.2019.05.032.

Declaration of interest

The authors declare that they have no conflicts of interest.

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References

1. Pearse RM, Moreno RP, Bauer P, et al. Mortality after surgery in Europe: a 7 day cohort study. *Lancet* 2012; **380**: 1059–65
2. Schilling PL, Dimick JB, Birkmeyer JD. Prioritizing quality improvement in general surgery. *J Am Coll Surg* 2008; **207**: 698–704
3. Christensen T, Kehlet H. Postoperative fatigue. *World J Surg* 1993; **17**: 220–5
4. Vonlanthen R, Slankamenac K, Breitenstein S, et al. The impact of complications on costs of major surgical procedures: a cost analysis of 1200 patients. *Ann Surg* 2011; **254**: 907–13
5. Straatman J, Cuesta MA, de Lange-de Klerk ES, et al. Hospital cost-analysis of complications after major abdominal surgery. *Dig Surg* 2015; **32**: 150–6
6. Carli F, Zavorsky GS. Optimizing functional exercise capacity in the elderly surgical population. *Curr Opin Clin Nutr Metab Care* 2005; **8**: 23–32
7. Barberan-Garcia A, Ubré M, Roca J, et al. Personalised prehabilitation in high-risk patients undergoing elective major abdominal surgery: a randomized blinded controlled trial. *Ann Surg* 2018; **267**: 50–6
8. Katsura M, Kuriyama A, Takeshima T, et al. Preoperative inspiratory muscle training for postoperative pulmonary complications in adults undergoing cardiac and major abdominal surgery. *Cochrane Database Syst Rev* 2015; **10**: CD010356
9. Arthur HM, Daniels C, McKelvie R, et al. Effect of a preoperative intervention on preoperative and postoperative outcomes in low-risk patients awaiting elective coronary artery bypass graft surgery. A randomized, controlled trial. *Ann Intern Med* 2000; **133**: 253–62
10. Gray AM, Clarke PM, Wolstenholme JL, Wordsworth S. *Applied Methods of cost-effectiveness Analysis in health care. Handbooks in health economic evaluation series*. Oxford: Oxford University Press; 2010
11. American Society of Anesthesiologists. *2016 relative value guide book: a guide for anesthesia values*. Washington: American Society of Anesthesiologists; 2015
12. Struthers R, Erasmus P, Holmes K, Warman P, Collingwood A, Sneyd JR. Assessing fitness for surgery: a comparison of questionnaire, incremental shuttle walk, and cardiopulmonary exercise testing in general surgical patients. *Br J Anaesth* 2008; **101**: 774–80
13. Malnutrition Advisory Group, a Standing Committee of BAPEN. *Malnutrition universal screening tool* May 2003 (review August 2011). Available from, http://www.bapen.org.uk/pdfs/must/must_full.pdf. [Accessed 16 November 2016]. accessed
14. Gimeno-Santos E, Rodriguez DA, Barberan-Garcia A, et al. Endurance exercise training improves heart rate recovery in patients with COPD. *COPD* 2014; **11**: 190–6
15. Donaire-Gonzalez D, Gimeno-Santos E, Serra I, et al. Validation of the Yale Physical Activity Survey in chronic obstructive pulmonary disease patients. *Arch Bronconeumol* 2011; **47**: 552–60
16. 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**: 771–6
17. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand* 1983; **67**: 361–70
18. Puig-Junoy J, Casas A, Font-Planells J, et al. The impact of home hospitalization on healthcare costs of exacerbations in COPD patients. *Eur J Health Econ* 2007; **8**: 325–32
19. Griffiths TL, Burr ML, Campbell IA, et al. Results at 1 year of outpatient multidisciplinary pulmonary rehabilitation: a randomized controlled trial. *Lancet* 2000; **355**: 362–8
20. Seymour JM, Moore L, Jolley CJ, et al. Outpatients pulmonary rehabilitation following acute exacerbations of COPD. *Thorax* 2010; **65**: 423–8
21. Hui KP, Hewit AB. A simple pulmonary rehabilitation program improves health outcomes and reduces hospital utilization in patients with COPD. *Chest* 2003; **124**: 94–7
22. Raskin J, Spiegler P, McCusker C, et al. The effect of pulmonary rehabilitation on healthcare utilization in chronic obstructive pulmonary disease: the Northeast Pulmonary Rehabilitation Consortium. *J Cardiopulm Rehabil* 2006; **26**: 231–6
23. Rasekaba TM, Williams E, Hsu-Hage B. Can a chronic disease management pulmonary rehabilitation program for COPD reduce acute rural hospitalization utilization? *Chron Respir Dis* 2009; **6**: 157–63
24. Foglio K, Bianchi L, Bruletti G, et al. Seven-year time course of lung function, symptoms, health-related quality

of life, and exercise tolerance in COPD patients undergoing pulmonary rehabilitation programs. *Respir Med* 2007; **101**: 1961–70
25. Spuit MA, Troosters T, Trappenburg JC, et al. Exercise training during rehabilitation of patients with COPD: a current perspective. *Patient Educ Couns* 2004; **52**: 243–8
26. Piepoli MF, Corrà U, Benzer W, et al. Secondary prevention through cardiac rehabilitation: from knowledge to implementation. A position paper from the cardiac rehabilitation section of the association of cardiovascular prevention and rehabilitation. *Eur Cardiovasc Prev Rehabil* 2010; **17**: 1–17
27. Barberan-Garcia A, Gimeno-Santos E, Blanco I, et al. Protocol for regional implementation of collaborative self-management services to promote physical activity. *BMC Health Serv Res* 2018; **18**: 560
28. Barberan-Garcia A, Martinez R, Cano I, et al. Role of design thinking for adoption of integrated care: scalability of a prehabilitation service. *Int J Integr Care* 2019 (Under review)
29. Ljungqvist O, Scott M, Fearon KC. Enhanced recovery after surgery: a review. *JAMA Surg* 2017; **152**: 292–8
30. Gu X, Itoh K. Performance indicators: healthcare professionals' views. *Int J Health Care Qual Assur* 2016; **29**: 801–15

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