CONNECARE

WP6 – DEPLOYMENT OF CLINICAL STUDIES

D6.1: STUDY RELEASE FEASIBILITY FOR THE CLINICAL STUDIES

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

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Abstract	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. The current document clearly complements the first two deliverables of WP7; that is, *D7.1- Evaluation plan for the entire project* and *D7.2- Evaluation results of the initial co-design phase until Study Release* indicating key specificities of the project assessment.

Table of contents

Glossary

AISBE	Integrated Care Area of Barcelona-Esquerra
CCP	Complex Chronic Patients
CDSS	Clinical Decision Support Systems
COPD	Chronic obstructive pulmonary disease
GMA	Adjusted Morbidity Groups
HR	Heart Rate
ICT	Information and Communication Technologies
IDIBAPS	Institut d'Investigacions Biomèdiques August Pi i Sunyer
IRBLL	Biomedical Research Institute of Lleida
MAST	Method for Assessment of Telemedicine applications
PDSA	Plan, Do, Study, Act
SACM	Smart Adaptive Case Management
SMS	Self-Management System
StaRI	Standards for Reporting Implementation Studies
UEQ	User Experience Questionnaire
UMCG	University Medical Centre Groningen

Executive Summary

The content of the document is the end result of a tight alignment of WP2, WP6 and WP7 teams with productive iterations between the clinical and the technological teams. To this end, ***D6.1: Study Release feasibility for the implementation studies*** in each of the CONNECARE sites has been conceived as an operational document, structured in five concise sections and nine schematic appendices, aimed at supporting the implementation studies. In the process of the elaboration of D6.1, the contributors have been asked to avoid repetition of concepts and information already described in previous deliverables.

The current document aims to be a practical guide for deployment of the implementation studies. It should contribute to fulfilment of expected outcomes in the five dimensions of CONNECARE described in detail in ***D7.2 Evaluation results of the initial co-design phase until Study Release***. Moreover, the document explicitly includes the identification of current risks, as well as the plans for contingency actions in order to ensure the final success of CONNECARE at M42.

Section 1: Final features of the implementation studies at site level briefly reports the version of the implementation studies, before deployment, at site level. The section also identifies areas of potential risk and proposes specific actions in order to overcome potential limiting factors.

Section 2: Data analytics at project level addresses the heterogeneities of the implementation sites. The section indicates the methodologies adopted for the comparability analysis among the four sites and addresses the characteristics of the joint analysis of two main areas following the StaRI approach[1] (**Appendix VII**), that is: i) Quadruple aim analysis of the implementation, and, ii) Assessment of the implementation strategies. Moreover, the section also refers to appendices III-VI to illustrate the specificities of the analysis carried out at site level.

Section 3: Log-book for follow-up of events. This section contains an agreed upon log file for documenting non-technical events (problems, issues, solutions) that occur in each

[1] Pinnock H, Barwick M, Carpenter CR, Eldridge S, Grandes G, Griffiths CJ, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor SJC, StaRI Group. Standards for Reporting Implementation Studies (StaRI): explanation and elaboration document. BMJ Open [Internet] BMJ Publishing Group; 2017 [cited 2017 Aug 17]; 7: e013318.

of the sites during the course of the deployment of the implementation studies., Technically-related incidences will be documented and tracked separately. The latter should facilitate interactions between implementation teams and technological partners simultaneously working on the refinement of the CONNECARE system in WP3-WP5.

Section 4: Logistics for data management and reporting deals with the characteristics and implementation strategies of the REDCap, as a shared tool for WP7 purposes, both at site level and at project level.. Information from Appendices I and II will be used at project level whereas the data from Appendices V-VIII will be only analysed at site level. It is of note that evaluation of two project outcomes, namely: i) ICT aspects (Appendix I); and, ii) Health risk assessment (Appendix II) will be mostly addressed at project level, but site specific outcomes will be considered. Finally, innovation on assessment methodologies, not included in the current document, will be considered only at project level and it will be addressed during the third period of the co-design process, from M36 to M42.

Finally, **Section 5: Roadmap for the implementation of the technology** briefly describes the current status of the ICT developments and the forecasted steps until implementation of the final CONNECARE system. In the current document, the section is considered separately because of the general consensus around the fact that release of robust technology to support the implementation studies constitutes the main bottleneck for a timely progress during the second period of the project.

The short-term calendar is as follows: i) Delivery and testing of the new version of the technological system (SMS and SACM) in late February 2018, ii) Initiation of the implementation studies by early March; and, iii) Set-up of REDCap (site level and general), as well as release of detailed evaluation strategy to be submitted in a peer review journal, during March 2018. Overall, the initiation of the second period of the project will have a three-month delay with a potential impact on the project outcomes.

1. Final features of the implementation studies at site level

The aim of this section is to provide a summary of the implementation studies at site level integrating the studies into the ongoing large scale deployment plans in each of the three areas: Catalonia with two complementary sites (ES), Groningen (NL) and Assuta (IL).

1.1 Catalonia (IDIBAPS)

The main characteristics of the implementation studies for the three case studies defined in the Description of Action (DoA) are displayed in **Figure 1**¡Error! No se encuentra el origen de la referencia. and briefly analyzed below. All of them are part of two large scale deployment integrated care programs carried out in the Integrated Care Area of Barcelona-Esquerra (AISBE) and in other healthcare sectors of Catalonia (ES): i) Management of Complex Chronic Patients (CCP) focusing on home hospitalization of acute patients & transitional care services; and, ii) Promotion of physical activity (PA) with focus on peri-surgical care in CONNECARE.

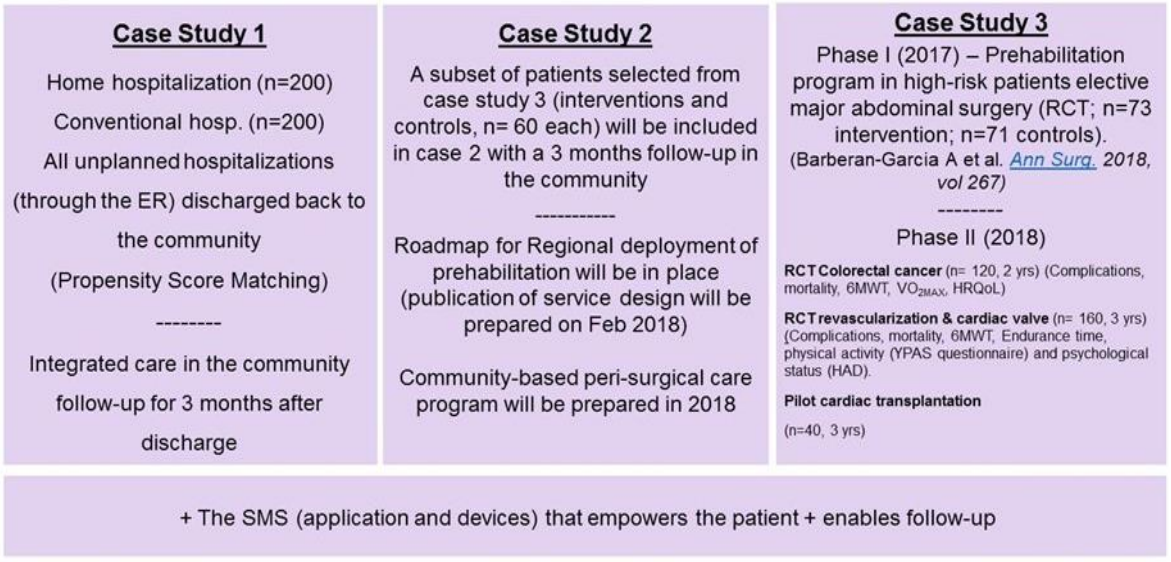


Figure 1 *- Characteristics of the three case studies implemented in Barcelona (IDIBAPS). Background information on the two scale-up programs supporting the implementation studies in CONNECARE, as well as, associated scientific literature, have been previously reported in D7.2 Evaluation results of the initial co-design phase until Study Release.*

CASE STUDY 1 – The study has a twofold aim: i) Assessment of the home hospitalization service for acute patients at Hospital Clinic, and, ii) Refinement of the transitional care services in AISBE, as indicated in **Figure 1** (left panel).

The design corresponds to an observational study wherein the intervention group (n= 200 patients, home hospitalization) and the control group (n= 200 patients, conventional hospitalization) are compared using propensity score matching considering: i) age, ii) sex, iii) population-based health risk assessment (adjusted morbidity groups, GMA scoring), iv) socioeconomic status; v) previous history of hospitalizations, and, vi) poly-pharmacy as matching variables.

The patients (intervention and control groups) will be sampled from among patients coming to the emergency room at Hospital Clinic and they will be followed-up until 90 days after discharge from hospitalization. The case study began early January and is planned to be completed at the end of December 2018 (M33). Follow-up of the patients will be done until the end of the CONNECARE project.

One additional aim within case study 1 is to refine the work done on predictive modelling during 2017.

CASE STUDY 3 – Efficacy, cost-effectiveness, as well as time-course of effects, of the prehabilitation service for high risk candidates to major abdominal surgery were demonstrated during 2017. The corresponding peer reviewed publications of the results of the initial randomized controlled trial (RCT) are either available *(Barberan-Garcia A et al Annals of Surgery 2018)* or ready for submission. Moreover, a co-design process for refinement of the service and analysis of its scalability was undertaken using a design-thinking approach during October-November 2017. The results of the three workshops support the deployment of prehabilitation as a main stream service at Hospital Clinic. Moreover, the entire design-thinking process is being prepared for submission to a peer-review journal before Easter 2018.

The three additional RCT displayed in **Figure 1** (right panel) are scheduled to be completed during CONNECARE lifetime enriching the initial commitment indicated in the DoA.

CASE STUDY 2 – The results obtained so far in case study 3 are providing a robust background to undertake case study 2 (**Figure 1**, central panel) addressing peri-surgical care; that is: i) Personalized pre-habilitation; ii) In-patient care preventing peri-surgical complications; and, iii) Post-surgical care to speed-up functional recovery of the patients.

The implementation study to be carried out in CONNECARE will include 60 patients selected from the intervention group of three ongoing RCTs depicted in case 3 (**Figure 1**, right panel) and 60 paired patients selected from the control groups of the same RCTs. Propensity score matching will be used to refine comparability between the two groups.

One additional key issue in case 2 will be the consolidation of the integration of the CONNECARE's SMS with the health information systems at Hospital Clinic, as well as the adaptation of the SMS to the Catalan personal health folder (Cat@Salut La Meva Salut) such that ICT-support to the regional scalability of the service can be achieved. The timeframe for a robust technological support is estimated to be achieved on June 2018 and full evaluation of the setting by early Fall 2018. The final aim is to generate the roadmap for scalability of case studies 2 and 3 by the end of 2018 such that regional deployment can be planned during 2019. It includes three main items: i) Refined service workflow definition; ii) Regional ICT-support; and, iii) Consensus on metrics (Key Performance Indicators, KPI) for service assessment.

Case study 2 will be also used at Hospital Clinic to develop a site version of CONNECARE's SACM through the expansion of the current web-based functionality for digitalisation of clinical processes (IPA, Informatització de Processos Assistencials). The concepts being consolidated in the CONNECARE's SACM will be transferred in the local developments based on Camunda (https://camunda.org/).

Finally, case study 2 also aims to generate appropriate risk predictive modelling tools feeding clinical decisions support systems in order to personalize the community-based peri-surgical care program to the patient needs.

POTENTIAL LIMITING FACTORS – 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.

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.

1.2 Catalonia (IRBLL)

The main characteristics of the implementation studies for the two case studies indicated in the Description of Action (DoA) are displayed in **Figure 2¡Error! No se encuentra el origen de la referencia.** and briefly analyzed below. Both of them are part of the planned efforts to implement and consolidate integrated care in the health region of Lleida, and are aligned with ongoing integrated care programs in Catalonia.

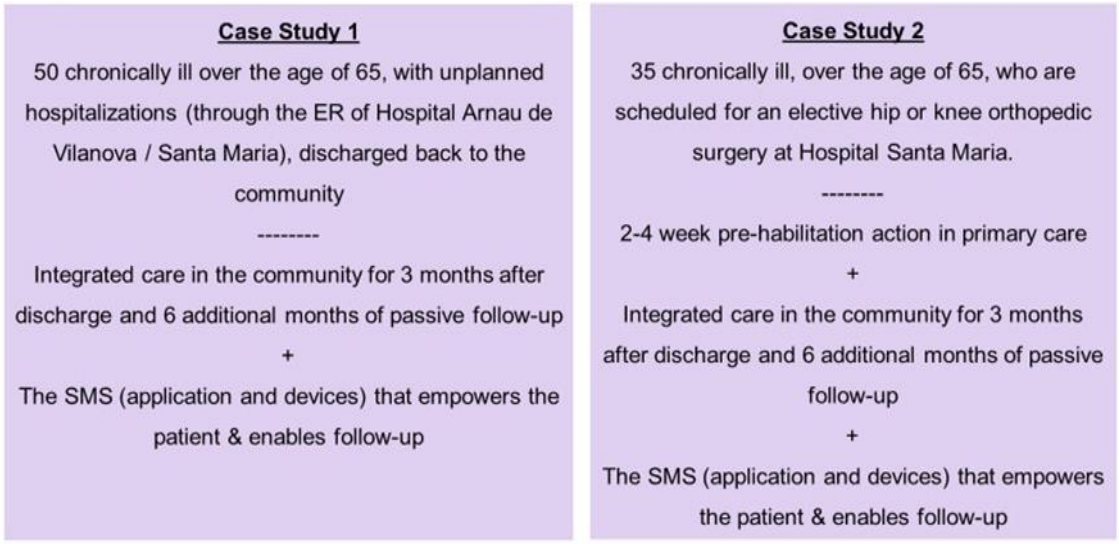


***Figure 2** - Characteristics of the case studies implemented in Lleida (IRBLLEIDA).*

CASE STUDY 1 – The study is the spearhead of formal community-based integrated care in the region of Lleida, wrapping-up several pre-existing initiatives into a single program, as indicated in **Figure 2** (left panel). Case study 1 will assess: (i) the effectiveness of joint/integrated discharge planning of hospitalized complex patients; (ii) the effectiveness of integrated transitional care in the community post-discharge; and, (iii) the added value of a self-management system app.

The design corresponds to an observational study wherein the intervention group (n= 50 patients, undergoing the CONNECARE program) and the control group (n= 50 patients, conventional management) are matched on: age, sex, population-based health risk assessment (adjusted morbidity groups, GMA scoring), and comorbidities (Charlson index). All patients (intervention and control groups) will be recruited from the emergency room at Hospital Arnau de Vilanova / Hospital Santa Maria, Lleida, before hospital discharge. Briefly, the Hospital case manager will be in charge of obtaining informed

consent and recruiting all participants. After discharge, patients in the control group will follow standard management in primary care, while patients on the intervention group will embrace the CONNECARE program benefitting of a SMS app during 90 days post discharge. All patients regardless of study arm will have a 6-months passive follow-up after the initial 90 days standard/CONNECARE management.

CASE STUDY 2 – The objective of case study 2 (**Figure 2**, right panel) is to assess the effectiveness of the integrated care process as described above for Case Study 1, focusing on complex patients who undergo major elective hip or knee arthroplasty surgery. A major additional element will be the assessment of the effectiveness of prehabilitation (pre-surgery) and rehabilitation (post-surgery) programs for this patient group.

The design corresponds to an observational study wherein the intervention group (n= 35 patients, undergoing the CONNECARE program) and the control group (n= 35 patients, conventional management) are matched on: age, sex, type of surgery (hip/knee), population-based health risk assessment (adjusted morbidity groups, GMA scoring), and comorbidities (Charlson index). All patients (intervention and control groups) will be recruited from Hospital Santa Maria, Lleida, at the time of surgery scheduling. Briefly, the Hospital team will be in charge of obtaining informed consent and recruiting all participants, and designing a pre-habilitation plan to be monitored from primary care, if needed. After surgery and during hospitalization, patients in the CONNECARE program will be provided a SMS app, a physical assessment and rehabilitation plan, and a pain control plan. All patients will undergo a 1-month standard / CONNECARE close follow-up in the community coordinated by the hospital team, and 2 additional months of standard / CONNECARE follow-up coordinated by the primary care team. All patients regardless of study arm will have a 6-months passive follow-up after the initial 90 days standard/CONNECARE management.

POTENTIAL LIMITING FACTORS

Two categories of risk factors limiting the outcomes of the implementation studies in Lleida have been identified: (i) the readiness and the robustness of the technological developments implemented in the project. The start date of the implementation studies is

dependent on the first release of the SACM and the SMS and the integration between them. In addition, the first release of the SACM and the SMS will not contain all of the functionalities that will be added gradually in subsequent releases throughout the course of the implementation studies; and (ii) the lack of integration of SACM & SMS with either Lleida's Electronic Health Records and the Catalan personal health folder (Cat@Salut La Meva Salut) will require double entry of data throughout the implementation studies, burdening professionals and potentially hampering their engagement towards the newly implemented technology.

1.3 Israel (Assuta)

The main characteristics of the implementation studies for the two case studies in Assuta indicated in the Description of Action (DoA) are displayed in **Figure 3** and briefly analysed below. Both of the case studies are an essential component of the integrated Care System currently being implemented in the City of Ashdod, spearheaded by Assuta Ashdod hospital and in collaboration with the four Health Plans and the Municipality.

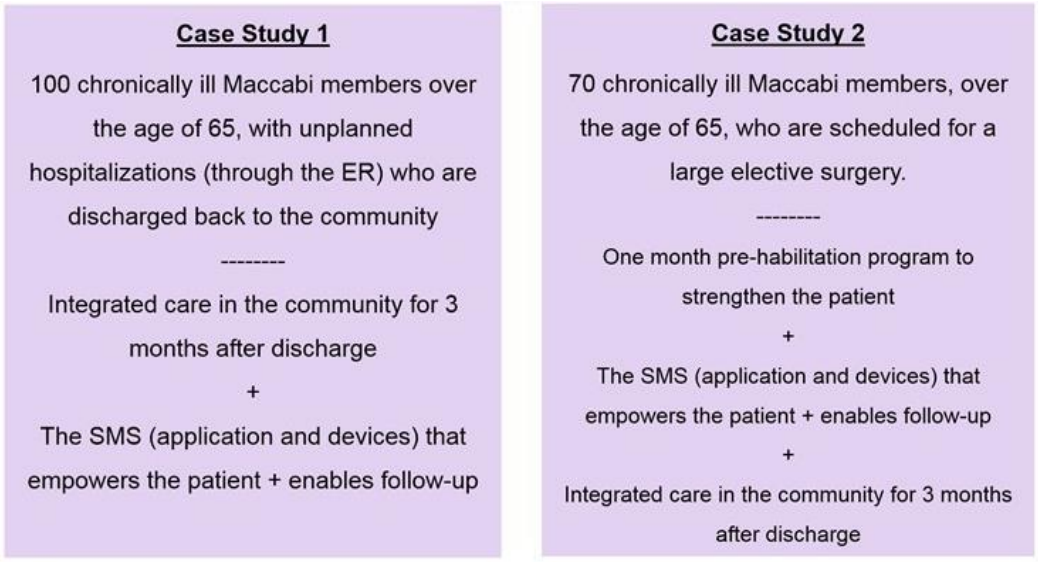


Figure 3 *- Characteristics of the two case studies to be implemented in Israel (ASSUTA)*

CASE STUDY 1 – The objective of case study 1 is to assess four elements:

1. The effectiveness of case management of complex patients in the hospital

2. The effectiveness of joint/integrated discharge planning for complex patients
3. The effectiveness of integrated transitional care in the community post-discharge
4. The effectiveness and added value of the self-management system app

The design of Case study 1 is a matched control observational study comparing 100 patients in the intervention group with 100 patients in the control group using propensity score statistical analysis. The two groups will be matched for the following characteristics:

- Age
- Sex
- Diagnoses
- History of previous hospitalizations
- Poly-pharmacy (number and type of medication)
- Date of admission to the hospital
- Date of discharge from the hospital
- Socioeconomic status
- Situation of dwelling (not in an institution)
- User name and password to the Maccabi patient portal
- Population based Risk assessment as determined by patient's inclusion in the Maccabi complex patient registry

The patients in the intervention group will be Maccabi members 65+ admitted to Assuta Ashdod hospital from the emergency room who met the CONNECARE inclusion criteria that identify the patient as a complex patient, and are discharged home with close follow up and care coordination of the Maccabi Case manager and the CONNECARE SMS app for 90 days post discharge. The control group will be selected retrospectively from the Maccabi database from among patients with the same characteristics (as defined above) who were hospitalized in the same time period in a different hospital.

CASE STUDY 2 - The objective of case study 2 is to assess the effectiveness of the integrated care process as described above for Case Study 1 focusing on complex patients who undergo major elective surgery. A major additional element will be the assessment of the effectiveness of the pre-habilitation program for this patient group. Thus, for case 2, additional characteristics for comparison between the intervention and control group will be:

- Type of surgery
- Date of surgery

As in Case 1, Case 2 is a matched control group study with an intervention group of 70 patients that undergo major elective surgery in Assuta Ashdod hospital and who have at least one month of pre-habilitation prior to surgery. The control group of 70 patients will be selected retrospectively from the Maccabi data base, who match the intervention group for all of the characteristics delineated for Case 1 as well as for the type and date of surgery and who undergo the same surgery in another hospital at about the same time.

Case 1 and Case 2 will be implemented at the beginning of March 2018 following the first release of the SACM and the SMS, initially with 10 patients to identify major bugs in the technologies, and followed, as soon as possible but no later than the beginning of April, with full recruitment activities. Assuming that the pace of recruitment is as anticipated, the implementation studies will continue until the end of June 2019, allowing for at least 3 months for evaluation and preparation of the final deliverables.

The following tables describe in detail the implementation process for both case studies:

Case Study 1:

What	Where	When	Who
Identification and recruitment of patients	Inpatient Department	During hospitalization / close to discharge	Assuta Ashdod's CMs
Patient assessment in the SACM	In hospital	During hospitalization / close to discharge	Maccabi's integration nurse
Providing the SMS and devices to the patient (and his or her family) with training	In hospital	During hospitalization / prior to discharge	Maccabi's integration nurse
- Input of the discharge and treatment plan to the SACM - Coordinating all services in the community - Monitor data from the SMS - Changes in the treatment plan according to need	In the community	During 3 months after discharge	Maccabi's integration nurse

- Coordination with the CM in Assuta in case of re-hospitalization			
Patient's discharge from the project including a final assessment	In the community	Three months after discharge	Maccabi's integration nurse

Case Study 2:

What	Where	When	Who
Identification and recruitment of patients	Surgical clinic	After scheduling surgery	Assuta Ashdod's research nurse
Patient assessment in the SACM	hospital outpatient	One month before the surgery	Assuta Ashdod's research nurse
- Physiotherapist assessment in the SACM - Pre-habilitation plan - Input Pre-habilitation plan into the SACM	hospital physical therapy institute	One month before the surgery	Hospital physiotherapist
Providing the SMS devices to the patient (and his or her family) with training	Hospital outpatient	One month before the surgery	Assuta Ashdod's research nurse
- Monitor data from the SMS - Changes in the treatment plan according to need - One hour training, one-three times a week in the hospital's physiotherapy institute	hospital physical therapy institute	For one month up until the surgery	Assuta Ashdod's research nurse + Hospital physiotherapist
Checking that the patient still meets the criteria for continued participation in the study	Inpatient Department	During hospitalization / close to discharge	Maccabi's integration nurse
Second patient assessment in the SACM	In hospital	During hospitalization / close to discharge	Maccabi's integration nurse
Refreshing the use of the SMS for the patient (and his or her family)	In hospital	During hospitalization / prior to discharge	Maccabi's integration nurse

Input the discharge and treatment plan to the SACM Coordinating all services in the community Monitor data from the SMS Changes in the treatment plan according to need Coordination with the CM in Assuta in case of re-hospitalization	In the community	During 3 months after discharge	Maccabi's integration nurse
Patient's discharge from the project including a final assessment	In the community	Three months after discharge	Maccabi's integration nurse
Checking that the patient still meets the criteria for continued participation in the study	Inpatient Department	During hospitalization / close to discharge	Maccabi's integration nurse

POTENTIAL LIMITING FACTORS

Two categories of risk factors limiting the outcomes of the implementation studies in Assuta have been identified:

1. The readiness and the robustness of the technological developments implemented in the project. The start date of the implementation studies is dependent on the first release of the SACM and the SMS and the integration between them. In addition, the first release of the SACM and the SMS will not contain all of the functionalities that will be added gradually in subsequent releases throughout the course of the implementation studies. On one hand, this is part of the co-design and PDSA cycles that is an inherent part of the project. On the other hand, this is a challenge to implementation as it may require additional training for patients. This will also be a challenge to the logistics of evaluation of the SMS as the evaluation will need to address the differences between the various cohorts of patients according to each release.
2. In Assuta and Maccabi, the SACM and SMS will not be integrated with the Electronic Medical Records systems and Maccabi Patient Portal. At the start of the implementation studies, there will also not be the ability to electronically transfer information between the EMRs and the SACM. This means that there will be

double entry of data throughout the implementation studies. Moreover, those entering data and those performing the follow-up on the PROMs from the SMS – will need to access the SACM via a link in the EMR that will take them to an external site. While it is expected that this will not limit follow up by Case managers, it may well affect the extent to which other clinicians (including family doctors) enter the SACM.

1.4 Groningen (UMCG)

The main characteristics of the implementation studies for the two case studies indicated in the Description of Action (DoA) are displayed in **Figure 4** and briefly analysed below.

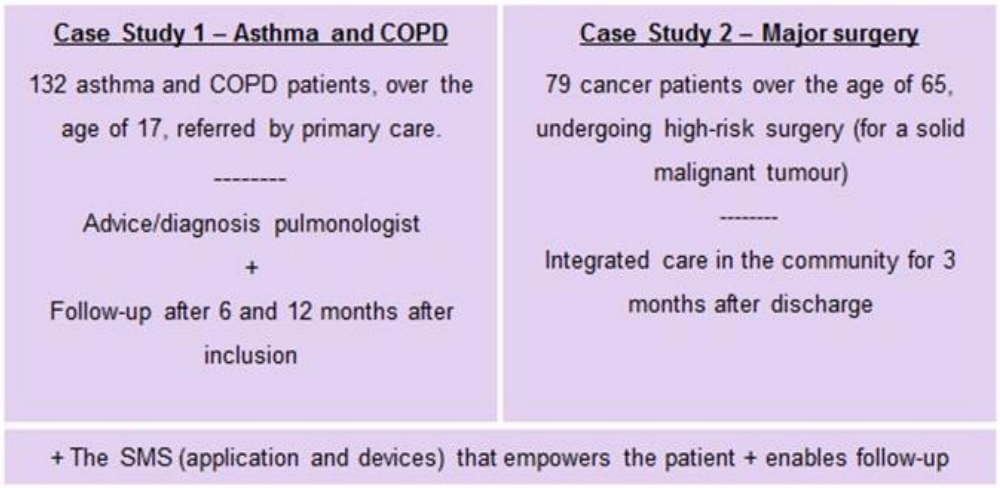


Figure 4 *- Characteristics of the two case studies implemented in The Netherlands (UMCG). Background information on the two scale-up programs supporting the implementation studies in CONNECARE, as well as, associated scientific literature, have been previously reported in D7.2 Evaluation results of the initial co-design phase until Study Release.*

CASE STUDY 1 – The CONNECARE SMS will be implemented in an existing well implemented integrated care service for asthma and COPD patients in the North of the Netherlands. In this service, primary care physicians refer patients with respiratory complaints or a diagnosis of asthma / COPD for assessment. Patients receive lung function assessment, evaluation of burden of disease, medication evaluation and other diagnostics. All collected data is transferred through the Internet to pulmonologist in a local hospital. The pulmonologist assesses the data and sends diagnosis and treatment

advice to the general practitioner. This process might be optimised with the CONNECARE SMS because the patient will be directly involved.

A pragmatic randomised controlled trial will be set up with 66 patients in the control group and 66 patients in the intervention group. Both groups will be accessed at baseline, after three months and after six months with different questionnaires. The intervention group receives the CONNECARE SMS including activity tracker. Our hypothesis is that patients who have received the CONNECARE SMS are able to manage their asthma or COPD more effectively compared to patients in the control group. Therefore the COPD health status or asthma control is expected to be higher in the intervention group in the follow-up phase.

Patients will be included from the Asthma/COPD-service and randomly divided in control or intervention group. We will start with a pilot of 10 patients in March 2018. The start of the intervention will be in spring 2018. Last patient in will be September 2018. Last patient out will be April 2019.

POTENTIAL LIMITING FACTORS

- Attrition is a risk factor because if too many patients stop filling in the questionnaires that power will drop. However we took into account a 10% attrition rate.
- Preliminary test studies with the CONNECARE SMS showed that the application can be difficult to use especially for elderly. Therefore it is important to develop the CONNECARE SMS according to the comments of the patients. We plan to train patients in using the application before the start of the study.
- Time is another limiting factor because the start date of the study has been postponed for six months. We have therefore less time to include patients.

CASE STUDY 2 – The aim of the current study is to co-design, develop, and evaluate a novel smart, adaptive self-support integrated care system for care management of the elderly oncological patients in the postoperative period. This will improve postoperative outcome in the elderly patients, improve quality of the perioperative care after hospital

discharge, will possibly avoid unnecessary medical consumption and lead to earlier detection of complications post-discharge, rather than scheduled hospital follow-up.

The design corresponds to a prospective observational cohort study. The study population will consist of 79 consecutive cancer patients aged 65 years and older, undergoing a high-risk surgical procedure for a solid malignant tumour in the operative centre of the University Medical Centre Groningen (UMCG). The study group (n = 79) will be compared with a historical control group (n= 150 patients, care as usual), using i) age, ii) sex, iii) Groningen Frailty Indicator.

The patients (study group) will be included from the outpatient clinic of the department of surgery and they will be followed-up until 90 days (3 months) after discharge from hospitalisation. The case study will begin early March 2018 and is planned to be completed at the end of December 2018 (if the inclusion number is reached), otherwise the study period will be prolonged.

POTENTIAL LIMITING FACTORS

- Categories of risk factors limiting the outcomes of the implementation studies in Groningen (UMCG) 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.
- A second limiting factor is the remaining time period to perform the case studies. A known bottleneck of comparable studies in elderly patients is the inclusion rate, as also indicated in the description of case study 1.
- A third limiting factor is the experience with integrated care in the UMCG, which is little. The case studies function as proof-of-concept studies, to investigate the usefulness of the integrated care system and if implementation on a larger scale is possible in the future.

2. Data analytics at project level

As described in ***D7.2: Evaluation of results of the initial co-design phase until study release***, the following five items will be considered in the evaluation of the implementation studies:

i) **Baseline comparability of the study groups, by case study, among sites**.

ii) **Effectiveness (using a "Quadruple Aim" approach) & operational costs analyses of the interventions by site** *(Appendices III-VI)*.

iii) **Implementation strategies analyses by site,** reported following the StaRI recommendations (Appendix VII).

iv) **Comparisons between the study groups of the implementation studies and the study groups of the ongoing scale-up at site level** in order to assess representativeness of the implementation studies in each site.

v) **Joint analysis of the results of the implementation studies, effectiveness and implementation strategies, for the entire CONNECARE project.**

The current deliverable, ***D6.1: Study Release feasibility for the three implementation studies***, provides the key information (see Appendices III to VII) needed to define the REDCap customization both at site level and at project level. Also, the current document, together with D7.2, defines the detail of the CONNECARE evaluation for periods 2 (implementation studies) and 3 (recommendations and transferability) of the project. The developments associated with both REDCap customization and evaluation strategies will be decided during the period February-March 2018. While the detailed evaluation of the implementation studies will carried out at site level, the commonalities of the implementation studies and the other dimensions of the project: i) overall cost-effectiveness analysis and the programs, ii) implementation strategies; iii) ICT developments; iv) health risk assessment; and, v) innovation on evaluation approaches will be done at project level and coordinated by WP7 leadership.

The next two tables for case studies 1 and 2, respectively, compare the characteristics of the implementation studies among the four sites. These tables facilitate the identification of a core group of common variables (see Appendices III to VI) allowing the analysis of the effects of the interventions at project level. We are planning to generate conclusions at project level for each category of the Quadruple aim approach and also for the implementation strategies. The latter should allow identification between general and site specific factors modulating large scale deployment of integrated care.

CASE STUDY 1 – Comparison among sites

	IDIBAPS	LLEIDA	ASSUTA	GRONINGEN
Study Design	Observational study with a matched active control group	Observational study with a matched active control group	Matched intervention – retrospective control group study	Pragmatic randomized controlled trial
N	200	50	100	132
Study Description	Unplanned admission to hospital, discharge to home hospitalization, as well as direct admission to home hospitalization from ER	Unplanned admission to hospital, discharge to home with integrated follow up	Unplanned admission to hospital, discharge to home with home care or integrated follow up	Unplanned admission to primary care, advice/diagnosis, return home with integrated follow-up
Inclusion Criteria	• Acute or exacerbated chronic patients including surgical patients • Living at home • Carer 24/7 • Having phone at home	• Hospitalized patients • Moderate to high risk of early hospital related event (GMA/LACE>7) • Living at home • Having phone at home	• Hospitalized Maccabi members • Age > 65 • Moderate to high risk of early readmission (LACE>7) • Living at home • 3 of the following; Regular use > 4 medications, at least 1 non-elective hospitalizations or ER visits during the past year, Malnutrition, elements of dependency/socioeconomic status • Have WIFI or cellular network at home and able to use a smart phone or tablet	• Adults referred to the AC-service above the age of 17 • Participants should own a tablet or smart phone • Comprehension of the Dutch language (reading and writing) • Willing to sign informed consent and answered the questionnaire's that are provided

CASE STUDY 2– Comparisons among sites

	IDIBAPS - Case 3	LLEIDA	ASSUTA	GRONINGEN
Study Design	Pragmatic randomized controlled trial, randomization 1:1	Pragmatic randomized controlled trial, randomization 1:1	Matched intervention – control group study	Prospective observational cohort study (comparison with historical cohort)
N	60	35	70	79
Study Description	Prehabilitation service for high risk candidates to major abdominal surgery following a three month integrated follow up in the community, post discharge supported by the Connecare Digital platform	Prehabilitation service for hip or knee orthopaedic surgery followed by a three month integrated follow up in the community, post discharge supported by the Connecare Digital platform	Prehabilitation service for Maccabi members candidate for major surgery followed by a three month integrated follow up in the community, post discharge supported by the Connecare Digital platform	A three month integrated follow up in the community, post discharge for elderly cancer patients candidate for elective surgery supported by the CONNECARE Digital platform

Surgical procedures	Esophagectomy, gastrectomy, colorectal major surgery, Whipple surgery or major pancreatic resection, hepatic resection, or bariatric surgery	Orthopaedic patients, including Hip and Knee arthroplasty patients	All major elective surgical procedures- general surgery, orthopaedic, gynaecological or urological	Elderly patients candidate for elective surgery for the removal a solid tumour under general anaesthesia
Inclusion Criteria	• Candidate for Major surgery • Age > 65 • ASA class III or IV • Living at home • Have WIFI or cellular network at home able to use a smart phone or tablet	• Candidate for Major surgery • Age > 65 • ASA class II or III • Living at home • Have WIFI or cellular network at home able to use a smart phone or tablet	• Maccabi members candidate for Major surgery • Age > 65 • ASA class II or III • At least one chronic illness • Living at home • Have WIFI or cellular network at home able to use a smart phone or tablet	• Candidate for elective surgery for a solid tumor • Age > 65 • ASA class II or III • Have WIFI or cellular network at home able to use a smart phone or tablet

3. Logbook for follow-up of non-technical issues

CONNECARE sites will use a "logbook" to record the non- technical issues – or the issues involved in the implementation process – whereas the JIRA tool will continue to be used for the management of the technical tasks/issues.

However, there will be some overlap – for example difficulties in using the SACM and/or SMS. Some difficulties may have to do with problems in training, or blocks on the part of older people in using the SMS, or difficulties experienced by clinicians in using the SACM (such issues will be recorded using the logbook), but others will be bugs in the technology that need to be fixed by the technical partners (these issues will be recorded in the JIRA tool).

The basic structure of the logbook (for each case study) will be the following:

Issue Log										
Issue (Step in the process)	Case Study	Site	Description	Priority (H, M, L)	Category	Reported By (role and name)	Assigned To (role and name)	Status	Date Resolved	Resolution/ Comments

Each CONNECRE site will decide whether to use the logbook as a local Excel file or in the cloud (e.g., Google Spreadsheet), however, periodically the implementation process will be revised to identify common issues, which should be the basis for discussion among the partners and brainstorming solutions.

4. Logistics for data management and reporting

4.1 REDCap – the tool

REDCap[2] is a secure web application that can be used to collect virtually any type of data (including 21 CFR Part 11[3], FISMA[4], and HIPAA-compliant environments[5]) because it is an open-source Electronic Case Report Form (eCRF) specifically geared to support online or offline data capture for research studies and operations. The REDCap Consortium, a vast support network of collaborators, is composed of thousands of active institutional partners in over one hundred countries who utilize and support REDCap in various ways (e.g., 478k projects, 635k users and 4460 articles).

Once the CONNECARE research team decided that both **co-design and evaluation data will be collected by means of several eCRF implemented in REDCap**, EURECAT, as project coordinator, deployed a centralized version of REDCap 8.0.1 (**Figure 5**) in a secure Amazon (Amazon EC2) Virtual Private Server: https://redcap.connecare.eu. *Deliverable 9.1 – POPD – Requirement No. 5*, in its Annex **¡Error! No se encuentra el origen de la referencia.** details CONNECARE specific infrastructure that will be used to host REDCap, data storage model, user privileges, authentication options, logging and audit trails, data interoperability options with other systems, protective security measures, and general best practices for hosting REDCap.

[2] https://www.project-redcap.org/

[3] Title 21 CFR Part 11 is the part of Title 21 of the Code of Federal Regulations that establishes the United States Food and Drug Administration (FDA) regulations on electronic records and electronic signatures (ERES). 21 CFR Part 11 defines the criteria under which electronic records and electronic signatures are considered trustworthy, reliable, and equivalent to paper records.

[4] The Federal Information Security Management Act of 2002 (FISMA) is a United States federal law that recognizes the importance of information security to protecting information and information systems from unauthorized access, use, disclosure, disruption, modification, or destruction in order to provide integrity, confidentiality and availability.

[5] HIPAA, the Health Insurance Portability and Accountability Act of 1996 is a United States law that sets the standard for protecting sensitive patient data. Any company that deals with protected health information must ensure that all the required physical, network, and process security measures are in place and followed.

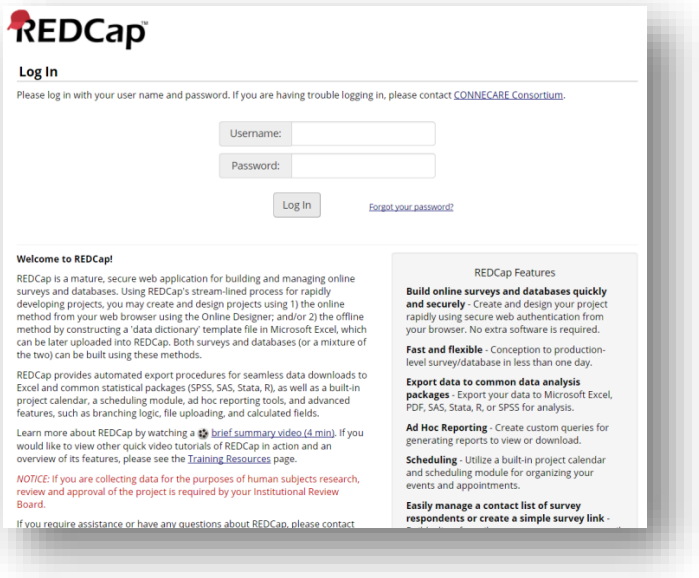


***Figure 5** – Main page of the CONNECARE REDCap instance accessible at https://redcap.connecare.eu.*

A responsible person from one partner of each site (IRBLL, IDIAPS, Assuta and UMCG), plus EURECAT as project coordinator, has been granted administration privileges (see **Figure 6**). Therefore, each site-specific administrator is responsible for granting REDCap access to every new user at site level.

eurecat**admin** (Eurecat **admin**) - juanmanuel.fernandez@eurecat.org
site_**admin** (Eurecat **admin**) - juanmanuel.fernandez@eurecat.org
assuta_**admin** (Rachelle Kaye) - rachellek@assuta.co.il
idibaps_**admin** (Isaac Cano) - isaaccf@gmail.com
irbll_**admin** (Jordi de Batlle) - jordidebatlle@gmail.com
umcg_**admin** (Maarten Lahr) - m.m.h.lahr@umcg.nl

***Figure 6** – List of REDCap administrators.*

To facilitate getting started with REDCap, a number of short training video resources are available at https://redcap.connecare.eu/index.php?action=training. Moreover, the whole process of project design and data collection is facilitated with in-line text and videos (by clicking on the question mark icon [?]). The following sections summarises the main implementation steps and supporting REDCap tools.

4.2 Implementation of an Electronic Case Report Form in REDCap

Once the research team has decided the data to be collected and the design to know how it has to be collected, the implementation of the eCRF in REDCap software platform can be performed. As depicted in **Figure 7**, the first step is the creation of the project defining its name and purpose. By

default, new projects use the 'classic' data collection format, which is the best option if all data collection instruments will only need to be used once for each record in the project. If some instruments need to be utilized repeatedly a specific finite number of times (e.g., using an instrument named 'Visit Data' over ten visits for the same subject), then 'longitudinal' data collection will likely be best. Additionally, the longitudinal format also allows one to utilize the scheduling module, if needed. As a second step, the instruments or forms can be implemented and will be tested continuously. The forms can be implemented using the data dictionary (offline method) or the online designer (online REDCap interface). Finally, once the implementation of the instruments has been completed, the user rights can be set. In the case that a longitudinal database has been designed, the study events to collect the data can be defined and then the database can be moved to production status to start the data collection.

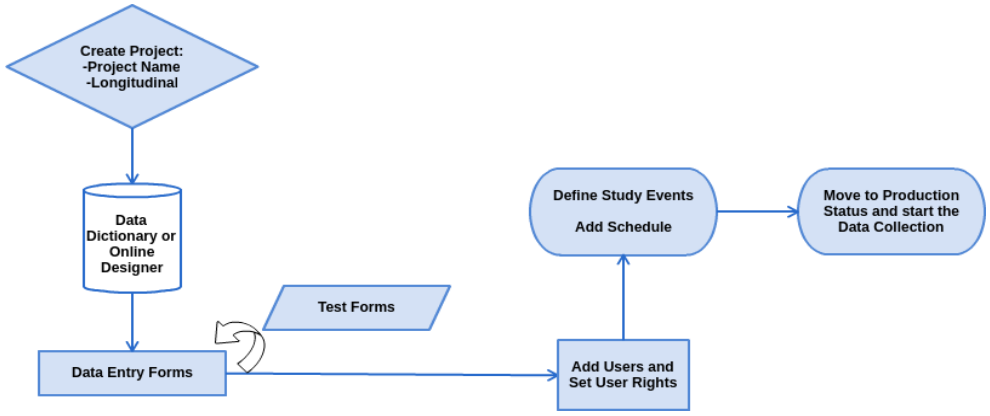
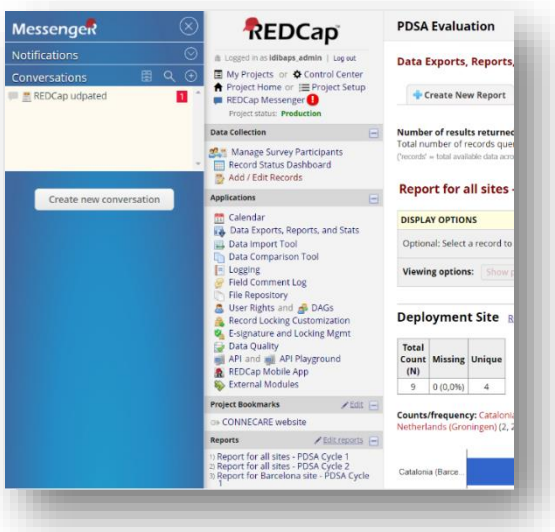


Figure 7 *- Schema of all steps in REDCap to implement an Electronic Case Report Form.*

4.3 Communicating and sharing documents with other REDCap users.

REDCap Messenger is a communication platform built directly into REDCap. It allows REDCap users to communicate easily and efficiently with each other in a secure manner. At its core, REDCap Messenger is a chat application that enables REDCap users to send one-on-one direct messages or to organize group conversations with other REDCap users. REDCap Messenger is also the best and easiest way to share documents with other REDCap users, in which you can upload documents and embed pictures inside any given conversation.



4.4 Complementary REDCap Applications

Once the implementation of the eCRF has been done following the study protocols, the applications provided by REDCap can be used in order to increase the quality, security and consistency of the database.

Schedule

The data collectors can schedule events in a longitudinal project. Hence, events are then added to the project calendar to help the research team and the patient who can receive an email reminding appointment. Moreover, the forms that are associated with that event can be opened from the calendar.

User Rights

Depending on the user's profile (Administrator, Data Collector, Data Analyst, etc.) the rights of each user who is granted access to the project can be defined individually. Alternatively, predefined user roles can be useful when many users with the same privileges are involved in the same project.

Data Exports, Reports and Stats

This module allows the users to easily view reports of the data, inspect plots and descriptive statistics of the data, as well as export the data to Microsoft Excel, SAS, Stata, R, or SPSS for analysis (if the user has such privileges). The "entire" data set or only specific instruments (or events) can be exported or view them as a report, depending on the task. You may also create your own custom reports in which you can filter the report to specific fields, records, or events using a vast array of filtering tools.

Data Import Tool

This module is used for importing data into this project from a CSV (comma delimited) file, following a Data Import Template. This functionality can be very useful if part of the data will not be entered manually into the eCRF but imported from a different source instead.

Data Quality

The REDCap Data Quality module provides the capability to perform a quality control verification on all the fields in a project. Pre-defined rules can be executed that allow members of the project to check for the following common discrepancies in your data: Missing values, Incorrect Data Type (Field Validation error), Values out of range (Field Validation error), Outliers for numerical fields, Hidden fields that contain values or multiple choice fields with invalid values.

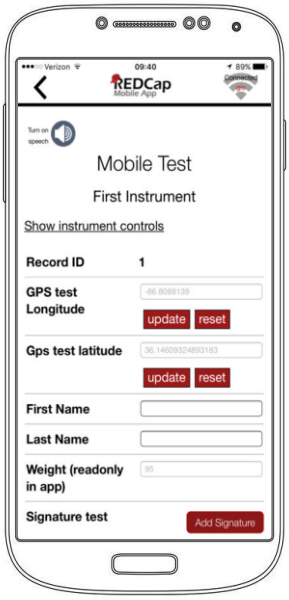
Data Comparison tool, Logging, Field Comment Log and File Repository

The Data comparison tool is used to compare two records in the project. The Logging provides information about who has changed the instrument, who has changed the data or who has accessed data when the events occurred. Moreover, the Field Comment Log is a capability that allows members of the project to leave comments on any field within a data entry form by clicking the view comment log icon ( ) to the left of any field. Finally, the File Repository is used as a general purpose location within REDCap for storing files. It is useful for storing files that are associated with a specific project, for storing files that are shared by others on the project and for maintaining a history of archived files.

REDCap mobile app

The REDCap mobile app supports the following features that contribute to the realization of the collection of data:

- The mobile app is ideal for data collection that needs to be performed in areas without any available internet access or in areas with sporadic internet access.
- The user interface allows multiple individuals to access the app on a single device via a secure login.
- Teams with multiple mobile devices have the capability to collect data for one project, or multiple projects simultaneously.
- Activity in the app is logged for auditing purposes.



4.5 Data management at site level

Each clinical institution participating in CONNECARE (i.e., Hospital Clinic, Hospital Arnau i Vilanova, Assuta medical center, and UMCG) can define and manage its own eCRF for the collection of outcome variables, while stating to the common design for data collection.

With respect to collection of issues regarding the implementation process (Logbook), as stated in Section 3, each CONNECRE site will decide whether to use the logbook as a local Excel file or in the cloud (e.g., Google Spreadsheet).

Finally, the selected instrument for assessing user experience (UEQ-5D) will be defined as a survey in REDCap by IDIBAPS and facilitated to all sites for its collection.

4.6 Data management at project level

IDIBAPS will manage a shared eCRF for the collection of outcome variables and data analytics at project level. At the end of the study, each project participant will have secured web access to the anonymised eCRF data.

5. Roadmap for implementation of the technology

The technology will be implemented in sequential versions. Each version will contain additional features and progress. The versions' scope was set according to the priorities that were agreed in the PB5 meeting (January 16th – 18th, 2018 – Tel Aviv). The following **Table** summarizes the scope of each version and the expected date of release. Unexpected delays delivering each version (and associated functionalities) and deviations from the planned Gantt are considered as main tools for assessment of ICT maturity.

Version number	Date	Scope
V1	**16.1.2018**	Current version
V2	**27.2.18**	1. CS2 2. work plan 3. summary page 4. Walking Activity + HR +Blood pressure (FITBIT +Charge HR) 5. Simple tasks (Raise your hands + Drugs prescriptions) (10 Patients in each site)
V3	**11.4.18**	1. CS1 in all sites 2. Questionnaires (decide common list of Questionnaires) E2E 3. Monitoring prescription: • Weight • Temperature • Glucose – only or Assuta • Sleep • Pulse (Oxygen saturation)
V4	**28.5.18**	1. Advices (manual advices) - E2E 2. Messages 3. Alerts (patient weight is too low – in the SACM) 4. Reminders (You need to walk 1000 steps – SMS) 5. Drugs prescriptions 6. Additional Questionnaires
V5	TBD	1. Recommendation System
V6	TBD	1. CDSS for risk
V7	TBD	2. More advanced features and requirements

6. Appendices

6.1 Appendix I – Assessment of ICT

This appendix provides information on three elements: i) High level description of the evaluation of ICT during the project lifetime (already described in **D7.2: Evaluation results of the initial co-design phase until study release**; ii) Assessment of ICT user experience; and, iii) Detailed Gantt for assessing maturity of ICT.

6.1.1 High level description of ICT assessment

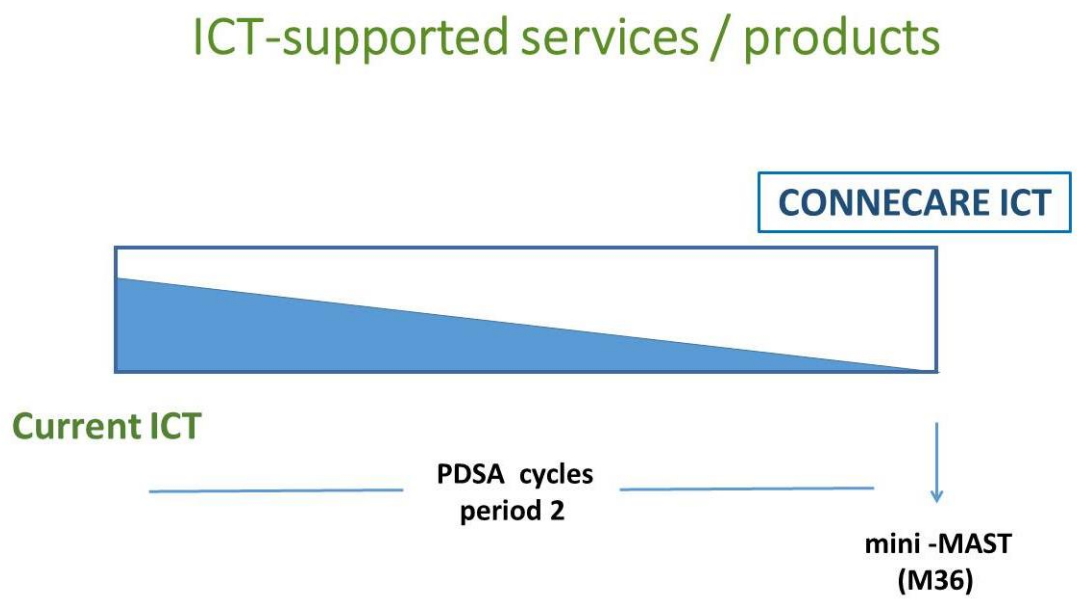


Figure 9 *- The figure provides a high level description of the evolution of ICT assessment during period 2 (implementation studies) and period 3 (generation of recommendations) of the project. The main ICT-supporting tools developed in CONNECARE are the SMS and SACM that will be used on top of existing technology that support the large scale deployment of integrated care in all sites with different degrees of maturity and sophistication. It is of note that while the SMS should be a transversal tool used in all sites with minor modifications, the SACM requires important site adaptions in order to achieve interoperability with existing ICT-systems and develop full functionality of the SMS. The figure indicates two key actions to be done during the second period of the project, namely: i) PDSA cycles to achieve progressive maturity and integration of the ICT tools at site level; and, ii) Evaluation of the CONNECARE system at the end of the second period (M36) using mini-MAST as assessment tool.*

6.1. 2. Assessment of user Experience

The CONNECARE instrument for assessing user experience (UEQ-5D) can be found in ***D7.2: Evaluation of results of the initial co-design phase until study release*** (Appendix II).

UEQ-5D in their different languages will be defined as a survey in REDCap by IDIBAPS and facilitated to all sites for its collection.

6.1.3. Assessing maturity of the ICT

The detailed plan for assessing maturity of the different versions of the ICT developments described in Section 5 of the current has been created and it is accessible in as a Microsoft Project GANTT chart.

6.2 Appendix II – Health risk assessment

The appendix formulates a high level description of the planned goals of the project regarding health risk assessment. The consortium as a whole will address three well-defined areas:

I. To explore the potential of population-based risk assessment to enhance clinical predictive modelling
II. To assess transferability of the population-based health-risk assessment tool used in Catalonia (Adjusted Morbidity Groups, GMA) to other sites: Netherlands & Israel
III. To develop specific predictive modelling tools at site level and assessment of transferability at project level

UNIMORE is currently implementing ICT developments that should facilitate achievement of the aims indicated for health risk assessment. Specific protocols are currently being prepared to address the specificities of the section. The analysis of datasets availability and working plan will be completed by the end of March 2018.

6.2.1. Current plans at site level

IDIBAPS & LLEIDA

Aim I – Assessment of the contribution of GMA to enhance clinical risk predictive modelling for management of complex chronic patients. Moreover, we are planning to use a similar approach for patients with Chronic Obstructive Pulmonary Disease (COPD).

Aim II – As described in Section 1, predictive modelling is planned for three types of patients: i) Subjects admitted in the home hospitalization program; ii) Complex chronic patients included in transitional care services; and, iii) Peri-surgical care program.

UMCG

The Asthma/COPD-service uses anonymous patient data for scientific reasons. At this moment data from 17,000 asthma and COPD patients is used for data analysis. A proposal will be written for the Asthma/COPD-service committee to request data to develop a risk model for CONNECARE. The database from the Asthma/COPD-service can be used as framework for other sides, as is done in for example the UNLOCK study.

The use of the EMBRACE dataset to enrich health risk assessment of complex chronic patients is being explored.

ASSUTA

The Assuta case studies will focus on patients of Maccabi Healthcare Services, the second largest Health Plan Israel with over 2 million patients nationwide. Maccabi has developed a Complex

Patient Registry that includes all Maccabi patients nationwide that are considered to be complex in accordance with an algorithm that takes into account: number of chronic diseases, functional status, cognitive level, poly-pharmacy, socioeconomic status and nutritional status, as well as age. Connecare will assess the contribution of the Complex Patient Registry to clinical risk predictive modelling for management of complex chronic patients as evidenced in the CONNECARE project.

ALL SITES will collaborate in Aim II – Assessment of transferability of GMA across sites.

6.2.2. ICT developments to facilitate health risk assessment

In the context of health risk assessment and predictive modelling, the CONNECARE CDSS is meant to complement the CONNECARE SACM –the CONNECARE case management system– exactly by providing, among other features, a predictive risk assessment functionality: given a patient health status, a set of predictions related to various risk indicators can be computed. Integration of the CDSS with the SACM is meant to make predictions readily available for patients enrolled in the CONNECARE program, thus to clinicians managing their case through the SACM. Nevertheless, having the CDSS as a standalone system may speed up creation of the risk prediction models, because each clinical partner within CONNECARE may exploit it using clinical and population data locally available without the need to have such data in the SACM, disclosing it.

For these reasons, the first prototype of the CDSS (see *D2.3: PATIENT-BASED HEALTH RISK ASSESSMENT AND STRATIFICATION* and *D3.2: FIRST SCREENING AND RISK STRATIFICATION DSS*) has been designed to work in a “plugin” mode: instead of building its own models for risk prediction based on CONNECARE data, it enables data scientists of the clinical partners to upload already trained models the CDSS can then apply on similar data. The second prototype will also enable the CDSS to train its own risk prediction models, exploiting any given machine learning algorithm, on data provided by the data scientist in the form of a dataset file. Although the standalone CDSS won’t be directly usable by the clinical staff – because it is still a Web Service meant to be integrated in the SACM – it can be used by data scientists or IT technicians assisting clinicians in building the risk prediction models to be later exploited within the SACM.

6.3 Appendix III – IDIBAPS: outcome variables

CASE STUDIES 1, 2 and 3

Assessment will be carried out following a Quadruple Aim approach, as indicated in Section 2 of the current document. Main variables considered in the analysis of case studies 1 and 2 (**Figure 1**, main text) are described in **Table 1** of the current appendix with the following specificities:

- Engagement of professionals and patients will be evaluated using the questionnaires proposed by the ACT@Scale project
- Case study 2 will include evaluation of aerobic capacity and peri-surgical complications
- Evaluation of case study 3 is defined by on-going RCTs described in **Figure 1** (main text). Protocols are available
- General characteristics of evaluation of implementation strategies are reported in Appendix VII
- Operational costs will be considered from a healthcare and social perspective measuring resource utilization for both intervention and control groups.

***Table 1** - Outcome variables, data source and measure instruments for CS1 & 2*

Outcome Variable	Data source	Measure Instrument
Clinical Data		
Socio-demographics	Catalan Health Surveillance System & Electronic Medical Records	---
Mortality	Catalan Health Surveillance System & Electronic Medical Records	---
Multi-morbidities	Catalan Health Surveillance System & Electronic Medical Records	---
Pharmacological and non-pharmacological therapies	Catalan Health Surveillance System & Electronic Medical Records	---
Healthy lifestyle (Tobacco/Nutrition/Alcohol/Physical Activity)	Electronic Medical Records	---
Home-based use of medical support devices (e.g. NIV, etc)	Electronic Medical Records	---
Cognitive state	Electronic Medical Records	Pfeiffer scale
Frailty risk	Electronic Medical Records	Tirs scale
Family function perception	Electronic Medical Records	Family Apgar scale
Activities of daily living (dependency)	Electronic Medical Records	Barthel scale
Emergency Department visits	Catalan Health Surveillance System	----
General Practitioner visits	Catalan Health Surveillance System	----
Cumulative days per year admitted in hospital	Catalan Health Surveillance System	---

Potentially avoidable hospitalizations	Catalan Health Surveillance System	----
Hospital readmissions	Catalan Health Surveillance System	---
Needs for social support	Catalan Health Surveillance System	---
Use of the Personal Health Folder	Catalan Health Surveillance System	---
Access to integrated care	Catalan Health Surveillance System	---
Costs		
Total health and social care cost	Catalan Health Surveillance System	---
Primary Care	Catalan Health Surveillance System	----
Hospital-related Care • Admissions • Emergency Room consultations • Outpatient specialized care	Catalan Health Surveillance System	---
Pharmacy	Catalan Health Surveillance System	---
Mental Health	Catalan Health Surveillance System	---
Socio-sanitary services	Catalan Health Surveillance System	---
Other costs • Respiratory therapies • Dialysis • Rehabilitation • Non-urgent patient transport	Catalan Health Surveillance System	----
Quadruple Aim		
Health-related quality of life	Auto-administered questionnaire	EuroQol-5D
Physical functioning	Auto-administered questionnaire	Short Form 36 (SF-36 - physical functioning domain)
Psychological well-being	Auto-administered questionnaire	Mental Health Inventory (MHI-5) of the Short Form 36
Social relationships & participation	Auto-administered questionnaire	Impact on Participation and Autonomy (IPA)
Enjoyment of life	Auto-administered questionnaire	Investigating Choice Experiments for the Preferences of Older People (ICECAP-O)
Resilience	Auto-administered questionnaire	Brief Resilience Scale (BRS)
Activation and engagement	Auto-administered questionnaire	Short form Patient Activation Measure (PAM-13)
Person centeredness	Auto-administered questionnaire	Person Centered Coordinated Care Experiences Questionnaire (P3CEQ)
Continuity of care	Auto-administered questionnaire	Nijmegen Continuity Questionnaire (NCQ)
Patient experience	Auto-administered questionnaire	Instrumento de Evaluación de la Experiencia del Paciente Crónico (IEXPAC)
Health-professional experience	Auto-administered questionnaire	ACT@Scale Questionnaire
Transitional Care		
Quality of healthcare transitions	Auto-administered questionnaire	Care Transitions Measure (CTM-15)®

6.4 Appendix IV – IRBLL: outcome variables

Outcome variables and sources for case studies 1 and 2

Aim	Outcome variables	Data source & Instrument	Comparison groups
Service utilization measures	Hospital admissions	Catalan Health Surveillance System / Electronic Medical Records	Between intervention and control group
	Length of hospital stay for current admission		
	Emergency Department visits		
	General Practitioner visits		
	Specialists visits		
	Diagnostic Tests (lab, imaging)		
	Mortality		
	Complications after surgery and duration of hospitalization (CS2 only)		
Health and well-being	Functional Status and Autonomy	Barthel Index of Activities of Daily Living	Before/after intervention
	Health-related quality of life and Social relations	EuroQoL Quality of Life Scale (EQ-5D) 12-Item Short Form Survey (SF-12)	
Experience with care	Person centeredness	Person Centred Coordinated Care Experiences Questionnaire (P3CEQ)	Only after intervention Only in the intervention group
	Continuity of care	Nijmegen Continuity Questionnaire (NCQ)	
	Patient satisfaction & engagement	ACT@Scale	
	Caregiver satisfaction & engagement	ACT@Scale	
Costs	Total health care cost	Catalan Health Surveillance System / Electronic Medical Records	Between intervention and control group
	Pharmacy costs		
	Hospital-related Care		

T2. Additional variables and sources

Topic	Variables	Data source & Instrument
Socio-demographic	Age & gender	Electronic Medical Records / collecting the information from the patient
	Anthropometric variables	
	Socioeconomic status level	

Health and well-being	Comorbidity & Diagnosis	LACE, ASA, WOMAC, Charlson, GMA & ICD-9 diagnoses
	Medications	List
	Anxiety & Depression / mood	Hospital Anxiety and Depression scale (HAD)
	Cognitive status	Pfeiffer
Healthcare barriers	Family support	Collecting the information from the patient
	Residence / Situation of dwelling	
	Social complexity	
	Self-care and capacity of the caregiver	
	Capacity to self-handle finances	
Healthy lifestyle	Smoking & alcohol	Collecting the information from the patient
	Sleep problems	To be agreed at Consortium level

6.5 Appendix V – Assuta: outcome variables

Pre-defined outcome variables for evaluation purposes in Assuta, Israel:

Aim	Outcome variables	Data source & Instrument	Comparison groups
Service utilization measures	Hospital admissions	Maccabi's Electronic Medical Records	Between intervention and control group
	Length of hospital stay for current admission		
	Emergency Department visits		
	General Practitioner visits		
	Specialists visits		
	Diagnostic Tests (lab, imaging)		
	Mortality		
	For CS2 Complications after surgery and duration of hospitalization		
Health and well-being	Functional Status and Autonomy	Barthel Index of Activities of Daily Living Lawton Instrumental Activities of Daily Living	Before and after intervention only in the intervention group
	Cognitive Status	Sweet 16 Questionnaire	
	Fall Risk	Downton Fall Risk Index	
	Health-related quality of life and Social relations	EuroQoL Quality of Life Scale (EQ-5D-5L) 12-Item Short Form Survey (SF-12)	
	Communication and Vision	InterRAI section D	
	Mood	Hospital Anxiety and Depression Scale (HADS)	
	Nutritional status	Malnutrition Universal Screening Tool (MUST)	
	Clinical status	Trend of test results e.g.HbA1c, LDL, Blood pressure etc.	
	Physical fitness	Timed up & go (TUG)	Before and after intervention only in CS2 intervention group
		Six Minute Walk Test (SMWT)	
		30-Second Seat to stand test (STS)	
		Baecke Physical Activity Questionnaire (BPAQ)	
Experience with care	Person centeredness	Person Centered Coordinated Care Experiences Questionnaire (P3CEQ)	Only after intervention only in the
	Continuity of care	Nijmegen Continuity Questionnaire	

		(NCQ)	intervention group
	Patient satisfaction & engagement	TBD	
	Caregiver satisfaction & engagement	TBD	
Costs	Total health care cost	Maccabi's and Assuta's Electronic Medical Records and administrative/financial systems	Between intervention and control group
	Pharmacy costs		
	Hospital-related Care		

Additional variables to be collected during the study:

Topic	Outcome variables	Data source & Instrument
Socioeconomic status	Demographic details of the patient • Birth year • Gender • Religious affiliation • Birth country • Immigration year • Years of education • Work status • Number of Kids • Nationality	Maccabi's Electronic Medical Records and by collecting the information from the patient
	Socioeconomic status level	
	Residence / Situation of dwelling	
	Social security subsidies	
Health and well-being	Comorbidity & Diagnosis	Lace, ASA, Charlson and ICD-9 list of diagnoses
	Medications	List
	Allergies	List
	Patient Clinical Data • Health assessment by Surgical Department and/or Anaesthesiologist • post-hospitalization Discharge Plan	
Healthy lifestyle	Smoking & alcohol	Collecting the information from the patient
	Sleep problems	A questionnaire identical to the entire Consortium, to be agreed

6.6 Appendix VI – UMCG: outcome variables

CASE STUDIES 1 and 2

For the assessment a Quadruple Aim approach will be followed, as outlined in Section 2 of the current document. Main variables considered in the analysis of case studies 1 and 2 (**Figure 1**, main text) are described in **Table 1** of the current appendix with the following specificities:

- The operational costs of the intervention will be calculated both from a healthcare and social (depend on age) perspective. Also resource utilization for both intervention and control groups are considered.
- Engagement of professionals and patients will be evaluated using the questionnaires proposed by the ACT@Scale project.
- General characteristics of evaluation of implementation strategies are reported in Appendix VI.

Table 1: Outcome variables, data source and measure instruments for CS1 & 2.

Outcome Variable	Data source	Measure Instrument
Clinical Data		
Case study 1	**Case study 1**	**Case study 1**
Socio-demographics	Certe electronical medical records	Data asthma/COPD-service
Working diagnosis	Certe electronical medical records	Remark laboratory assistant (categorical)
Disease severity	Certe electronical medical records	CCQ, CARAT
Medication	Certe electronical medical records	Remark laboratory assistant (categorical)
Inhaler technique	Certe electronical medical records	Remark laboratory assistant (categorical)
Lung function	Certe electronical medical records	Spirometry
Shortness of breath	Auto-administered questionnaire	MRC scale
Disease burden	Auto-administered questionnaire	ABC tool
Physical activity	Self-reported	1 question, results are used in the ABC tool
Case study 2	**Case study 2**	**Case study 2**
Socio-demographics	UMCG electronical medical records	---
Working diagnosis	UMCG electronical medical records	---
Disease severity	UMCG electronical medical records	---
Peri-operative details	UMCG electronical medical records	---
Frailty	Questionnaire	Groningen Frailty Indicator (GFI)
Mood	Auto-administered questionnaire	Hospital Anxiety and Depression Scale (HADS)

Physical performance	Questionnaire	Activities of Daily Living (ADL)
Physical performance	Questionnaire	Instrumental Activities of Daily Living (iADL)
Physical performance	Physical test	Handgrip strength
Physical performance	Physical test	(Timed up & Go) TUG
Quality of life	Auto-administered questionnaire	EORTC QLQ C-30
Quality of life	Auto-administered questionnaire	EORTC QLQ ELD-14
Physical activity	Auto-administered questionnaire	International Physical Activity Questionnaire (IPAQ)
Nutritional status	Questionnaire	Mini Nutritional Assessment-Short Form (MNA-SF)
Nutritional status	Questionnaire	Nutritional Risk Screening (NRS)
Cognitive functioning	Cognitive assessments	Cognitive test battery
Complications following surgery	UMCG electronical medical records	Clavien Dindo Complication Classification
Readmission – Short term	UMCG electronical medical records	Short-term readmission rate (30 days)
Readmission – Long term	UMCG electronical medical records	Long-term readmission rate (3 months)
Healthy lifestyle (Tobacco/Nutrition/Alcohol/Physical Activity)	UMCG electronical medical records	---
Costs		
Case study 1	**Case study 1**	**Case study 1**
General Practitioner visits	Auto-administered questionnaire	TiC-P
Emergency Department visits	Auto-administered questionnaire	TiC-P
Number of hospital admissions	Auto-administered questionnaire	TiC-P
Social care visits	Auto-administered questionnaire	TiC-P
Paramedic vists	Auto-administered questionnaire	TiC-P
Dietician visits	Auto-administered questionnaire	TiC-P
Psychological care (outpatient) visits	Auto-administered questionnaire	TiC-P
Psychological care (inpatient) visits	Auto-administered questionnaire	TiC-P
Home care visits	Auto-administered questionnaire	TiC-P
Number of hospital outpatient clinic visits	Auto-administered questionnaire	TiC-P
Number of daycare treatments	Auto-administered questionnaire	TiC-P
Length of hospital stay	Auto-administered questionnaire	TiC-P
Case study 2	**Case study 2**	**Case study 2**
Health care costs	Health care insurance company records	---
Emergency Department visits	UMCG electronical medical records	---
Number of readmission	UMCG electronical medical records	---

Length of hospital stay	UMCG electronical medical records	---
Quadruple Aim		
Case study 1	**Case study 1**	**Case study 1**
Health-related quality of life and Social relations	Auto-administered questionnaire	12-Item Short Form Survey (SF-12)
Cognitive representation of illness	Auto-administered questionnaire	Brief illness perception questionnaire
Patient experience	Auto-administered questionnaire	ACT@Scale Questionnaire
Health-professional experience	Auto-administered questionnaire	ACT@Scale Questionnaire
Case study 2	**Case study 2**	**Case study 2**
Health and well-being	Auto-administered questionnaire	12-Item Short Form Survey (SF-12)
Patient experience	Auto-administered questionnaire	ACT@Scale Questionnaire
Health-professional experience	Auto-administered questionnaire	ACT@Scale Questionnaire

6.7 Appendix VII – Reporting of the implementation strategies (StaRI)

Table 1| **Standards for Reporting Implementation Studies: the StaRI Checklist of items to be reported**

Checklist item		Implementation strategy	Intervention†
Title	1	Identification as an implementation study, and description of the methodology in the title and/or keywords	
Abstract	2	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes	
Introduction	3	Description of the problem, challenge, or deficiency in healthcare or public health that the intervention being implemented aims to address	
	4	The scientific background and rationale for the implementation strategy (including any underpinning theory, framework, or model, how it is expected to achieve its effects, and any pilot work)	The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects)
Aims and objectives	5	The aims of the study, differentiating between implementation objectives and any intervention objectives	
Methods: description	6	The design and key features of the evaluation (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons	
	7	The context in which the intervention was implemented (consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere)	
	8	The characteristics of the targeted "site(s)" (locations, personnel, resources, etc) for implementation and any eligibility criteria	The population targeted by the intervention and any eligibility criteria
	9	A description of the implementation strategy	A description of the intervention
	10	Any subgroups recruited for additional research tasks, and/or nested studies are described	
Methods: evaluation	11	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets	Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
	12	Process evaluation objectives and outcomes related to the mechanism(s) through which the strategy is expected to work	
	13	Methods for resource use, costs, economic outcomes, and analysis for the implementation strategy	Methods for resource use, costs, economic outcomes, and analysis for the intervention
	14	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)	
	15	Methods of analysis (with reasons for that choice)	
	16	Any a priori subgroup analyses (such as between different sites in a multicentre study, different clinical or demographic populations) and subgroups recruited to specific nested research tasks	
Results	17	Proportion recruited and characteristics of the recipient population for the implementation strategy	Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
	18	Primary and other outcome(s) of the implementation strategy	Primary and other outcome(s) of the intervention (if assessed)
	19	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work	
	20	Resource use, costs, economic outcomes, and analysis for the implementation strategy	Resource use, costs, economic outcomes, and analysis for the intervention
	21	Representativeness and outcomes of subgroups including those recruited to specific research tasks	
	22	Fidelity to implementation strategy as planned and adaptation to suit context and preferences	Fidelity to delivering the core components of intervention (where measured)
	23	Contextual changes (if any) which may have affected outcomes	
	24	All important harms or unintended effects in each group	
Discussion	25	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications	
	26	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)	Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)
General	27	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial or study registration (availability of protocol), funding, and conflicts of interest	

*Implementation strategy refers to how the intervention was implemented.

†Intervention refers to the healthcare or public health intervention that is being implemented.