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Optimizing patient active role with a user-centered eHealth platform (CONCERTO+) in chronic diseases management: A study protocol for a pilot cluster randomized controlled trial

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Abstract

Introduction Multimorbidity increases care needs and primary care use among people with chronic disease. The Concerto Health Program (CHP) has been developed to optimize chronic disease management in primary care services. However, in its current version, the CHP primarily targets clinicians and does not aim to answer directly patients' and their informal caregivers' needs for chronic disease management. Various studies have shown that interventions that increase patient activation level are associated with better health outcomes. Furthermore, educational tools must be adapted to patients and caregivers in terms of health literacy and usability. This project aims to develop, implement and evaluate a user-centered, multifunctional and personalized eHealth platform (CONCERTO+) to promote a more active patient role in chronic disease management and decision-making.

Methods and analysis This project uses a collaborative research approach, aiming at the personalization of CHP through 3 phases: 1) the development of one module of an eHealth platform combining scientific evidence and user-centered design; 2) a feasibility study of CONCERTO+ through a pilot cluster randomized controlled trial where patients with chronic disease from a primary healthcare practice will receive CONCERTO+ during 6 months and be compared to patients from a control practice receiving usual care; and 3) an analysis of CONCERTO+ potential for scaling up. To do so, we will conduct two focus groups with patients and informal caregivers and individual interviews with health professionals at the two study sites, as well as health care managers, information officers and representatives of the Ministry of Health.

Ethics and dissemination This study has ethical approval from Ethics Committee of Université Laval. The findings will be used to inform the effectiveness of

CONCERTO+ to improve management care in chronic disease. We will disseminate findings through presentations in scientific conferences and publication in peer reviewed journals.

Trial registration: Clinicaltrials.gov ID: NCT03628963

Keywords: Chronic disease management, Multimorbidity, eHealth, Patient and caregiver engagement, Health Literacy, User-centered design.

Strengths and limitations of this study

- The design of a user-centered technological solution is adapted to

chronic disease patients' needs and their literacy level.

- The inclusion of the caregivers in the use of CONCERTO+ is a novelty.
- The pilot test will provide data for feasibility, acceptability and usefulness of CONCERTO+.
- Good potential for sustainability given that it will be implemented in the real context of primary care practice with the collaboration of clinical teams.
- As a limitation, this project seems ambitious for its entire achievement in two years.

Introduction

Background

Chronic diseases are the number one cause of mortality in the world, and account for nearly 70% of deaths [1]. In Canada and around the world, multimorbidity, which means people who have more than two chronic diseases, is increasing [2]. In addition to often making like more difficult for the people living with these conditions, such the rise in cases is putting pressure on the Canadian healthcare system and causing over-consumption of care and services [3]. In the Province of Quebec, 45% of people aged 20 and over have more than two chronic diseases [4], and 80% of chronic disease consultations are done in primary health care services [5]. Multimorbidity increases care needs as well as the complexity of

health care services required in primary care, especially when it comes to applying recommendations for good clinical practices [5]. The total cost of the six most common chronic diseases in Quebec (ischemic heart disease, cerebrovascular disease, chronic obstructive pulmonary disease, cancer, hypertension and diabetes) has been estimated at 8, 1 billion, and this may rise up to $13 billion in 2030 if no substantial change is made [6].

In Quebec, primary care services have the main responsibility to support people with chronic diseases and their informal caregivers, jointly with other stakeholders of the local health network [7, 8]. However, primary care services suffer from many challenges and organizational constraints, in particular, the difficulty of access – with a large proportion of Quebeckers without a family doctor – and the wait times that are among the longest in Canada [9, 10]. Furthermore, the fragmentation of health care processes and the gaps in information transfer are recognized sources of inefficiency, that make critical the integration and continuity of care for chronic

diseases [7, 11]. To overcome these issues, many approaches linking healthcare providers, patients, caregivers and the organization of health care services are promoted [12]. The central role of patients in the management of their disease, which depends on their active involvement, is recognized as a key component in chronic disease management [13].

Active patient involvement requires that patients have the knowledge, skills and self-confidence to manage their health and healthcare [14]. Various studies have shown that interventions increasing patient activation level are associated with better health outcomes [15-22] and decreased costs [23]. However, active patient involvement and the quality of the interactions with health providers will partially depend on patient's knowledge of the disease and the needed care, in addition to their interpersonal skills as well as their ability to communicate their expectations, needs and preferences to their healthcare team [24, 25]. It is therefore important to offer patients and caregivers relevant information adapted to their health literacy

level. According the following definition, “Health literacy is linked to literacy and entails people’s knowledge, motivation and competences to access, understand, appraise and apply health information in order to make judgements and take decisions in everyday life concerning health care, disease prevention and health promotion to maintain or improve quality of life during the life course” [26]. For their part, health professionals must also have the communicational and interpersonal skills required to work in a team and share information appropriately with patients in order to support their active involvement [24]. Thus, it becomes important to act in advance by supporting patients’ autonomy and involvement in the care dynamic, and by promoting informational and educational relationships in disease management [25-27]. Therefore, it is crucial that information and educational tools are adapted to patients and caregivers in terms of literacy level and presentation [28-30].

eHealth technologies offer a potential to support chronic disease management. Some studies have shown positive effects on clinical processes (better adhesion to care protocol, reduced errors and improved monitoring and callback rates), on quality of care and effectiveness, and on patient outcomes [31-36].

Systematic reviews support the role of electronic personal health records and electronic portals allowing patient access to their health records in order to promote their active participation in their care [37-39]. However, to achieve expected outcomes, eHealth technologies first should be adopted and used in an appropriate manner by patients and health professionals [40]. Therefore, end-user involvement in the development of eHealth solutions is an imperative [41]. Moreover, eHealth literacy, which is inspired by the health literacy concept but focuses specifically on optimal eHealth solutions use, should be considered in order to ensure that the solutions are adapted to the capabilities of targeted users [30, 42]. While the number of eHealth solutions continues to increase, with more than 325,000 mobile

health applications in 2017 [43], the majority of them (53%) are used by less than 5,000 people and are often abandoned after a short trial period [44-46]. User involvement – including patients, informal caregivers and health professionals – is identified to be among the issues to ensure that eHealth solutions have a real impact, all the stakeholders must be promoted throughout the different stages of technology development, from conception to assessment [47]. Based on efficient chronic care models, high-potential technologies and patient involvement as active partner of their care, we suggest to develop an innovative and mobilizing project in order to improve patient care and experience.

Methods and analysis:

The following methods adhere to the Standard Protocol Items Recommendations for Interventional Trials (SPIRIT) guidelines for the reporting of study protocols.

This project is a collaborative work involving IT developers from CHP, designers, clinicians, technological partners and patient representatives. The aim is to develop, implement and evaluate a module of a multifunctional and personalized eHealth platform, CONCERTO+, through a pilot study for optimizing patient active role in medical follow-up, decision-making, satisfaction towards healthcare services and quality of life. The specific objectives are to: 1) develop a module of a multifunctional and personalized eHealth platform integrated to the CHP for patients and caregivers allowing them to engage in the follow-up and management of their chronic diseases; 2) test the integration of CONCERTO+ in monitoring care pathways of three frequent co-existing chronic diseases (diabetes, hypertension, dyslipidemia) and assess the usefulness and acceptability of the solution for patients with chronic diseases and their caregivers; 3) assess the scalability of the CONCERTO+ solution.

Phase 1: Development of the eHealth solution module

We will conduct a rapid literature review on the effects of eHealth interventions for supporting active involvement of patients with chronic diseases in their primary care team. For this purpose, we will follow the rapid review method suggested by Lawani et al. [48] and consider the latest evidence on eHealth interventions for chronical diseases monitoring and care. We will consider the following “Problem, Intervention, Comparison, Outcomes (PICO)” elements: (P): three targeted chronic diseases (diabetes, high blood pressure, dyslipidemia), alone or combined; (I) all eHealth interventions implemented in primary care and that directly involve patients (e.g. Electronic Medical Records, patient diary, patient portal, specific computerized monitoring for a chronic disease and technological interventions focused on lifestyle modifications; (C): routine follow–up; (O): Health outcomes specific to the disease (e.g. HbA1c for diabetes), generic health outcomes (e.g. mortality, quality of life), patient outcomes (e.g. involvement, personal efficacy) and practices and process outcomes (e.g. test numbers, emergency visits,

hospitalizations). First, we will start to consult existing systematic reviews, in particular that of Irizarry et al. [38], and a review of reviews that we have already completed [49]. We will also document issues relating to needs, expectations and concerns in terms of eHealth solutions for patients, their informal caregivers, and health care providers. This information will provide evidence summaries describing each eHealth solution associated with each targeted health issues, as well as information on the risks and benefits of these solutions. We will then use the methods suggested by Giguère et al. [50] to develop Decision Boxes to involve patients and their informal caregivers in the choice of functionalities and contents to develop in the CONCERTO+ solution, in line with an integrated care system (**Fig. 1**).

A first prototype will be developed by the design and technology teams, in close collaboration with researchers, health professionals and patient representatives who will identify the functionalities to include in the CONCERTO+ solution. Given

the time limit of the project, we will classify the required functionalities in 3 types: 1) essential and priority; 2) important but not priority; 3) required in the future.

For the development of the eHealth platform module, a user-centered approach will be used, based on three cycles with users. Iterative testing sessions will take place at the usability laboratory of UL lead by HW, providing all the equipment needed to conduct usability studies. Students in graphic and interaction design, under the direction of three experts from the School of Design of UL (EK, FLP, JR), will participate in the development of the platform's visual environment. An expert in eHealth literacy (CD) will ensure that contents of the clinical monitoring tools already integrated in the CHP are adapted to a general audience according to recommendations of the Health Literacy Guide [51], in addition of tools that provide understandable information (e.g link to a popular glossary of medical terms: https://publications.santemontreal.qc.ca/uploads/tx_asssmpublications/litteratie_v9.pdf).

The integration of the CONCERTO+ solution with the CHP will be ensured by the Concerto Health Group team who will work closely with the designers and researchers. Health professionals in primary care services from the sites participating in the pilot project will also be consulted to validate the match between the CONCERTO + solution and care pathways for professionals offered by the CHP.

Patient and Public Involvement

How was the development of the research question and outcome measures informed by patients' priorities, experience, and preferences?

A patient partner (informal caregiver) is involved as research partner at key stages of the study. His experience in caring of a patient with diabetes informed us on needs of patients, research focus, methods for collecting data for the study and dissemination strategy through patient and citizen groups associations.

How did you involve patients in the design of this study?

Our patient partner is invited at each research team meeting to make sure that the research questions are aligned with patients' needs. He gives his input in refining the focus of the research questions. He made valuable contributions in the design of the study.

Were patients involved in the recruitment to and conduct of the study?

In the first step of the study, the development of the first prototype, our patient partner helped us to recruit patients by sharing the invitation through his personal contacts and network and gave feedback for the pros and cons of the prototype development. He was also invited to contribute in editing the paper and is considered as a coauthor.

How will the results be disseminated to study participants?

To develop our dissemination strategy, we will review the results with the patient partner and integrate his feedback to ensure that we presented the results in the most effective way for the general populations. We will send a summary of the

research results to study participants who have provided their mailing address in the consent form and we will also organise events for patients and citizen groups and associations, such as outreach communications and scientific café.

For randomised controlled trials, was the burden of the intervention assessed by patients themselves?

For this part of the study, participants will assess the burden of the intervention by participating in focus groups.

Phase 2: Pilot cluster randomized clinical trial

The Phase 2 of the project will consist in a feasibility study based on a pilot cluster randomized clinical trial (c-RCT). Given the nature of the intervention, patients with chronic diseases are followed by a small team of primary care clinicians.

Study setting

The study will be conducted in two Family Medicine Groups (FMG) from the same health region (in the province of Quebec) but covering distinct areas, they have been selected as the clusters.

Eligibility criteria

Patients with two or more targeted chronic diseases (diabetes, hypertension, dyslipidemia) and who had three or more visits in the last 12 months will be eligible. Majors whose incapacity has been recognized judicially are in exclusion criteria.

Intervention

The intervention is the device CONCERTO+, a user-centered, multifunctional and personalized eHealth platform. Both groups, Experimental and control have the same features with regard to participants eligibility. Experimental group from FMG 1 will use CONCERTO+ application during 6 months. The Control group from FMG 2 will not use the application CONCERTO+ but continue to receive usual care. The

objective is to assess the feasibility, acceptability and potential effectiveness of the device CONCERTO+.

Outcomes

The involvement of patients following the use of CONCERTO+ will be our primary outcome of interest. We will use Patient Activation Measure (PAM) [52] which is built on patient knowledge, skills and confidence that are directly targeted by the intervention.

The score of the activation level obtained (between 0 and 100) shows the degree of ability to manage their health with confidence according to the following scale ranges: strongly disagree = 1; disagree = 2; agree = 3; strongly agree = 4. Patients who are more activated have better health outcomes. Patients answer to a survey of 13 questions with the following scoring for each answer:

1. Not believing that activation is important (≤ 47)

2. Lack of knowledge or confidence to take action (47.1 - 55.1)

3. Beginning to take action (55.2 - 67)

4. Taking action (≥ 67.1).

The PAM 13 questionnaire has been validated in French (see **Supplementary File 3**). We will ask a license to use, which is free for up to 250 patients in an academic research context [53]. The survey will be completed by participants of the two groups at baseline, and six months later. This period of CONCERTO+ use is enough to achieve the intended outcomes.

Secondary outcomes of interest are: 1) the impact of CONCERTO+ use on process indicators and care outcomes, measured with questions adapted from Glasgow et al. [54] and validated in the previous Concerto Health Program (CHP) assessment; Patients answer to a questionnaire after six months use of CONCERTO+. 5 scales based on the key components of CONCERTO+ are defined, and each scale include items: solving-problems/advices, delivery System design/decision support, goal setting/tailoring, follow-up / coordination, overall care. Items are scored on a

5-point scale ranging from 1 (Almost never) to 5 (Almost always), passing through subscales (Generally not); (Sometimes); Most of the time. Higher scores from the assessment survey have better effects in care outcomes.

2) The acceptability of the device CONCERTO+ will be assessed by patient and informal caregiver, at the end of the intervention with:

1. A short survey adapted from the Technology Acceptance Model [55] that includes 3 criteria (perceived ease of use, perceived usefulness, behavioral intention to use) with the following scoring: Strongly disagree = 1; Disagree = 2; Agree = 3; strongly agree = 4. Higher scores rates have a better acceptance of the use of CONCERTO+.

2. The use of CONCERTO+ that will be measured by logs (Tests numbers, emergency visits, and hospitalizations). (See **Supplementary File 1, 3**).

Participant timeline

Table 1 shows the distribution of outcomes measures through time. The first survey will be completed at baseline and six months after the use of CONCERTO+, in order to see the effects of the use of CONCERTO+ during the process care. The second survey will be completed six months after in order to assess the effects of

	Study period			
	Allocation	Post allocation		Close out
Time point	**-T1**	**T1** (at baseline)	**T2** (6 months after the use of Concerto+)	**T3**: During 3 months following the end of the intervention
	Enrolment - Eligibility screen - informed consent - Allocation			
Intervention group	✓	✓	✓	✓
Usual care group	✓			
Assessments				
Main outcome measure PAM measure		✓	✓	
Secondary outcome measure			✓	

Glasgow and al. Adapted survey				
Technology Acceptance Model			✓	
Logs measures			✓	
Two Focus groups				
Interviews				✓ ✓

the use and the third survey will be completed by patients and informal caregivers at the end of the intervention in order to assess the acceptability.

Table 1 Distribution of outcomes measures through time

Sample size calculation

Based on a similar study [56], a sample of 200 patients is enough to detect a difference of 2 points on the PAM score, with a power of 90% and an alpha of 0.05. Indeed, the assessment of online education intervention to chronical disease patients, showed a significant difference of 6 points on the PAM score in the experimental group (n = 58), whereas the difference was not significant in the control group (n = 68) [56]. Such a difference may be considered clinically significant because each additional point on the PAM score is associated with a 2% decrease in hospitalizations [53]. Considering an attrition rate of 15%, the sample size should remain relevant to detect a difference of at least 2 points on the PAM score, as differences reported in similar studies range from 2.5 to 6.5 points [14].

Recruitment strategy

For the first phase 1, the development of the eHealth solution module, we will recruit 7 to 10 patients and informal caregivers from convenience samples of volunteers joined through patient associations and mailing lists of our institution (Université Laval-UL). Eligible individuals will meet the following criteria: 1) Have two or more targeted chronic diseases (diabetes, hypertension, dyslipidemia) 2) had three or more visits in the last 12 months; 3) aged 18 years old and over and come from the greater Quebec area; 4) having in interest of technology; 5) be able to speak and read in French; 6) available to participate in three validation sessions. For the phase 2, the pilot cluster randomized clinical trial: a note will be added in the EMR (electronic Medical Record) of patients who had been preselected, and at their next visit at the FMG, the receptionist will give them an information sheet about the study to invite them to participate. Interested patients will be invited to call the research assistant using a toll free number or to leave their contact information to the receptionist who will forward them to the research assistant.

Then, patients will be contacted by the research assistant to validate their eligibility and confirm their interest. Recruitment will end when 100 patients are recruited from each site. We will ensure an equal distribution of participants according to their sex, and we will consider specific aspects in patient recruitment, particularly living alone, the presence of dependents and their literacy level. The recruitment chart is presented in **Fig. 2**

Allocation

Patient will be selected randomly with the help of the participating FMG by searching the local EMR system. A pre-selection of patients will be done by the four nurses involved in chronic disease care at the participating FMG. For each site, a sample of 200 patients (see sample size calculation) stratified by sex, age group and number of chronic diseases, will be randomly preselected by a statistician not involved in the team, using a computerized program. Then, the statistician will reveal group assignment through a call to the responsible of each

FMG in the presence of a research team member.

Blinding

The blinding will be single by the outcome assessor.

Phase 3: Scaling-up potential of the solution

For Phase 3, the analysis of CONCERTO+ potential for scaling-up will be done by documenting factors and conditions associated with the sustainability and scaling-up of the solution. To do so, we will conduct: 1) two focus groups with patients and informal caregivers who participated in the study (1 with the experimental group and 1 with the control group, each group gathering between 8 and 12 participants); 2) semi-structured individual interviews with health professionals as well as with health care managers, information officers, and representatives of the Ministry of Health and Social Services will be conducted at the two study sites two FMG of one region in the Province of Quebec). The number of interviews will be determined

according to the data saturation principle, but is estimated to be around 15 participants in total. Interviews with patients, informal caregivers and health professionals will include questions about factors facilitating or limiting sustained use of the CONCERTO+ solution by patients and informal caregivers, and the support of this use by health professionals, inspired by a recent study on personal electronic health record [58, 59]. Questions for managers and decision-makers will be based on Expand Net framework [60] that proposes 12 elements helping to appreciate the potential of innovation expansion at different time of its progress (see **Supplementary File 2,4**).

Data analysis plan

The study started in 2017 and will end in 2019. Data will be collected managed and analysed at each step of the project. For the phase 1, we started to collect data in October 2018; for the phase2, we will start in April 2019 and the phase 3 in November 2019. We will ensure that surveys are correctly completed in order to

avoid many missing data. Quantitative data will be analyzed using standard statistical model Anova, we will compare the scores test for repeated measurements, controlling the initial PAM score. We will also make tests according to sex, literacy level and comorbidity because these variables are associated with the PAM score [57]. Focus groups discussions and interviews will be recorded with participants' consent, and the content will be transcribed verbatim. The qualitative analysis will consist in a thematic-pragmatic content analysis [61] using the NVivo 10 software. We will use an inductive-deductive analysis, in an iteratively and flexible way, which allows a hybrid codification from the conceptual dimensions of the model and the emergent themes [62]. We will verify the role of the identified dimension in the literature as the initial basis for analysis, while remaining open to the advent of other context-specific aspects. Results from qualitative analyses will be cross with quantitative data to see commonalities among participants' characteristics. The investigators will compare intervention and control groups to

judge the effectiveness of CONCERTO+ and will inform if there is an effect in their health status. Participants will also be asked about the helpfulness of the device in supporting their disease self-management.

Monitoring

A Data Monitoring Committee is not required for this study due to low risk of adverse events. The principal investigator has the authority to suspend or terminate the study at any time if any big trouble occurs.

Ethics and dissemination

This study has ethical approval from the Research Ethics Committee of Université Laval; approval number: 2018-067 /01-06-2018 with all protocol modifications being mandatory to report (see **Supplementary Files 5, 6**). All participants will provide their consent following a procedure approved by the ethics board (see **Supplementary Files 7-9**) before enrollment in the study. We have to communicate

with the ethics committee if any change occurs to the protocol. All data will be anonymised and will be used only for statistical research and analysis. They will be securely stored on the server of Canadian Research Chair on Technologies and Practices in Health, we will never share it with third parties. Only the principal investigator or his nominee and eventually students who work in the project will have access on the list of participants in different phases of the project. Data from EMR will be also anonymised by a medical secretary or a research assistant who will sign a confidentiality agreement. In addition, all team members will sign a confidentiality agreement so that any personal information of participants will not be shared.

In keeping with our participative approach and inspired by frameworks of collaboration between researchers and knowledge users [63, 64], knowledge translation will be done in an integrated way throughout the project, with an emphasis on collaboration, shared outcomes, and feedback from stakeholders at

each step of the research. We will also share the outcomes through presentations in the networks and organizations of the team members, and through the production of dissemination tools for patient and citizen groups and associations. Ideally, these presentations will be done in tandem (patient-researcher; patient-clinician) in an interactive way, by taking the time for discussion and exchanges with the audience (e.g. lunch and learn, scientific café). The presentations will be supported with materials (brief reports, narrated slideshows, etc.) allowing a greater dissemination of the activities and outcomes. Knowledge translation activities at the end of project will consist of publishing outcomes in open access / peer reviewed journals. Presentations at national and international conferences in health informatics, chronic diseases, and patient engagement are also scheduled.

Study status

This is an ongoing study taking place from December 2017 until December 2019. At the time of writing, the prototype of the eHealth technology module was designed and the first usability test is done.

Discussion

This project shows a potential of success through the involvement of the technological partner who has a long collaborative experience with researchers. The eHealth solution is also likely to be acceptable because it will be adapted to patient's needs, based on our user-centered approach and the adaptation of the content to users' literacy level. Previous results associated with the use of the CHP solution for clinicians show promising preliminary outcomes based on validated measures that are relevant and sensitive to the proposed intervention. The solution has also a good potential for sustainability given that it will be implemented in the real context of primary care practice, with the collaboration of clinical teams. Finally, the project team is engaged in disseminating the results and pursuing the

development and adaptation of the CONCERTO+ solution in order to contribute to improving the health of people in Canada and internationally.

List of abbreviations

CHP: Concerto Health Program

c-RCT: cluster randomized clinical trial

EMR: Electronic Medical Record

FMG: Family medicine Group

IT: Information Technology

PAM: Patient activation measure

PICO: Problem, Intervention, Comparison-Outcomes

SPOR: Strategy of Patient-Oriented Research

UL: Université Laval

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knowledge translation between research and practice in clinical settings. Res Nurs Health. 2008; **31**:130-40.

Footnotes

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Competing interest: The authors declare that they have no competing interests.

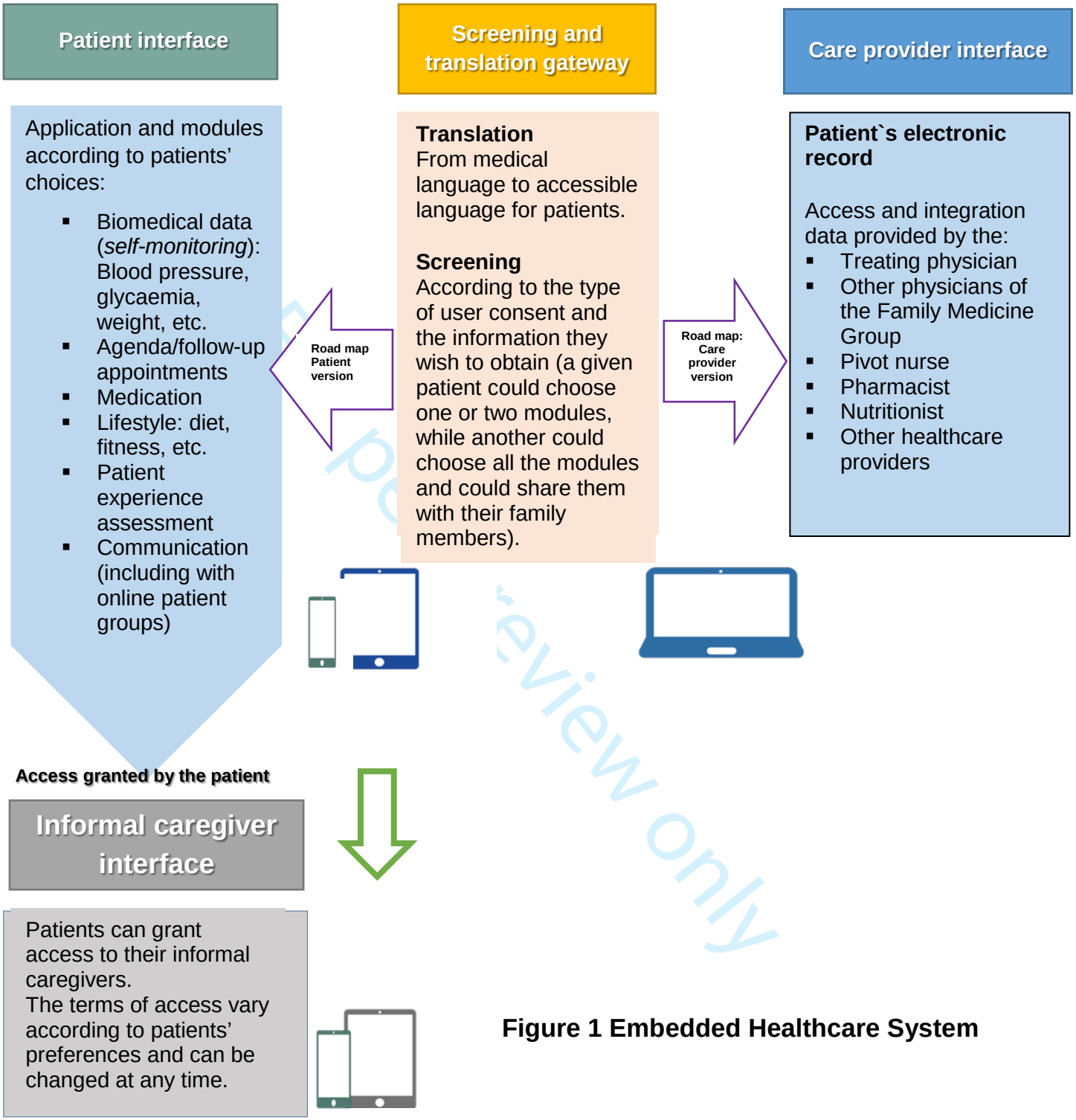

Figure 1 Embedded Healthcare System

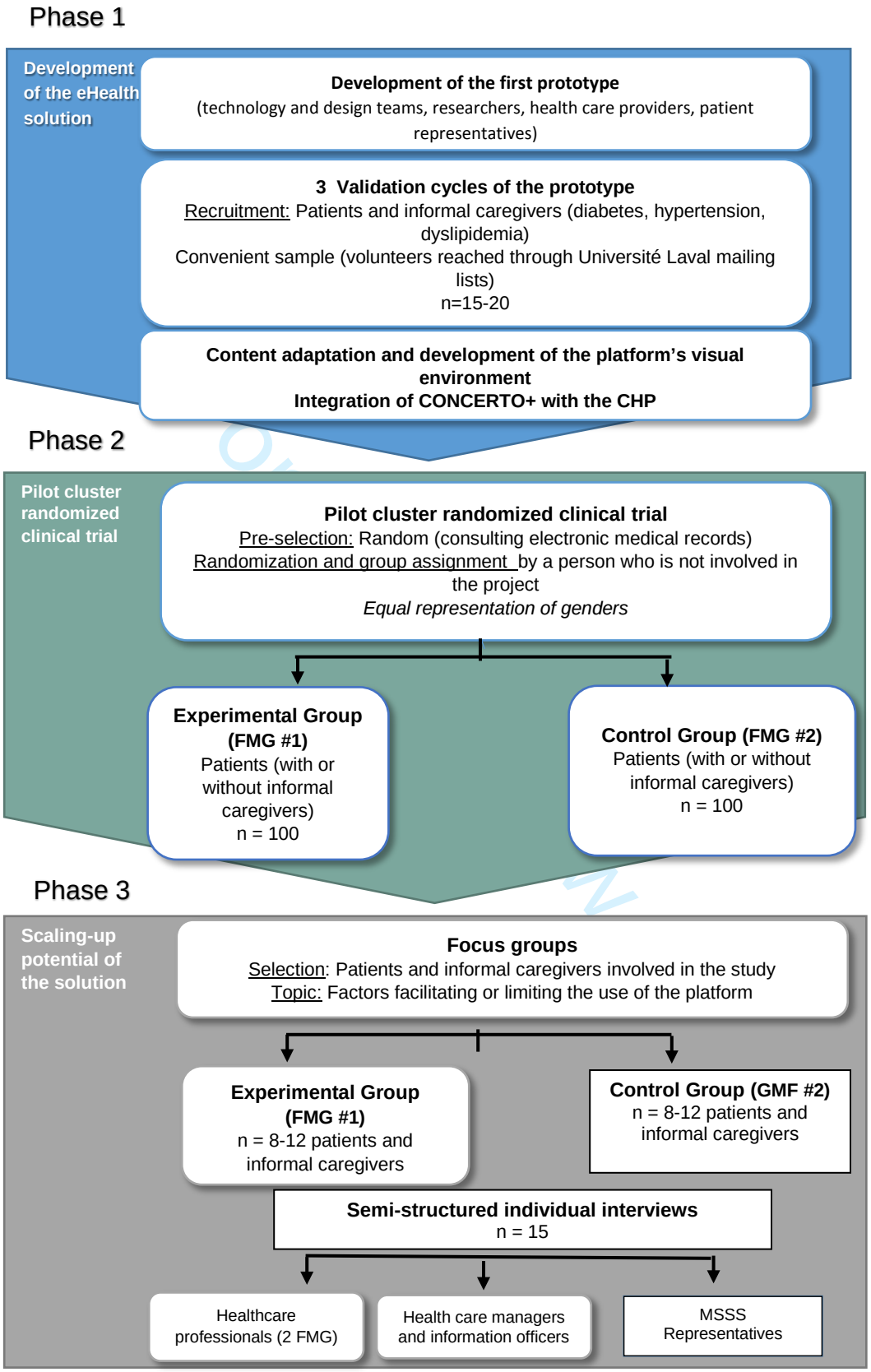

Figure 2 Recruitment flowchart

Supplementary File 1: Outcome measures and items (original English version)

1. Patient Activation
Tool used
Patient Activation Measure-PAM-13
Criteria[1]
1. When all is said and done, I am the person who is responsible for managing my health condition. 2. Taking an active role in my own healthcare is the most important factor in determining my health and ability to function. 3. I am confident that I can take actions that will help prevent or minimize some symptoms or problems associated with my health condition. 4. I know what each of my prescribed medications does. 5. I am confident I can tell when I need to go get medical care and when I can handle a health problem. 6. I am confident I can tell my health provider the concerns I have even when he or she does not ask. 7. I am confident I can follow through on the medical treatment I need to do at home. 8. I understand the nature and causes of my health condition. 9. I know the different medical treatment options available for my health condition. 10. I have been able to maintain the lifestyle changes I have made for my health. 11. I know how to prevent further problems with my health condition. 12. I am confident I can find a solution when new situations or problems arise with my health condition. 13. I am confident I can maintain lifestyles changes, like diet and exercise, even during times of stress.
Results measurement
Scoring (for each criteria)**:** ▪ Strongly disagree = 1 ▪ Disagree = 2 ▪ Agree = 3 ▪ Strongly agree = 4 **Activation level** (converted into a score of 100)**:** **1.** Not believing that activation is important (≤ 47) **2.** Lack of knowledge or confidence to take action (47.1-55.1) **3.** Beginning to take action (55.2-67) **4.** Taking action (≥ 67.1)

[1] Adapted from: Moljord I E O, Lara-Cabrera ML. Perestelo-Pérez L, Rivero-Santana A, Eriksen L, Linaker OM. Psychometric properties of Patient Activation Measure-13 among out-patients waiting for mental health treatment: a validation study in Norway. *Patient education and counseling*. 2015*98*(11):1410-1417.

2. Impacts of the use of CONCERTO+
Tool used
Survey used for the assessment of the CHP pilot
Criteria[1]
Problem-solving/Advice 1. Have you been asked how your illness affects your life? 2. Have you been helped in planning ahead to take care of your illness even in hard times? 3. Did your care providers ask about your values and traditions when they recommended treatment? 4. Have you been helped in drawing up a treatment plan that you could follow in your daily life? **Delivery system design/Decision support** 1. Have you been asked about your health habits? 2. Have you been encouraged to go to a specific group or class to help you cope with your chronic illness? 3. Have you been given a copy of your treatment plan? **Goal-setting/Tailoring** 1. Have you been asked to talk about your goals in the context of receiving care for your chronic condition? 2. Have you been helped in setting specific goals to improve your diet or fitness? 3. Have you been given a written list of things you should do to improve your health? 4. Have you been shown how taking proper care of your illness influenced your condition? 5. Are you satisfied that your care was well organized? **Follow-up/Coordination** 1. Have you been referred to a dietitian, health educator, or counselor? 2. Have you been told how your visits with other doctors were going? 3. Have you been told how your visits with other types of doctors, such as a specialist or a surgeon, helped in your treatment? 4. Have you been asked how your visits with other doctors were going? 5. Have you been contacted after a visit to see how things were going? **Overall care[2]** Since you began using CONCERTO+ 1. Have you had an appointment with a professional from the clinic? 2. Have you received help when you were in need? 3. Have you had a follow-up appointment for your health condition? 4. Have you been helped through contact with a professional from the team or by receiving an answer from one of the team members after a phone call? 5. Have you had the feeling that your nurse coordinates all of your care? 6. Have you had the feeling that your health problems are being taken into account by the Program team? 7. Have you noticed that your visits with other health professionals are being taken into account by the Program team? 8. Have you been helped in understanding your test results (e.g. laboratory test, pressure tap, etc.)? 9. Have you received an answer in emergency situations?

[1] These criteria were originally developed and validated by Glasgow RE, Wagner EW, Schaefer J, Mahoney LD, Reid RJ, Greene SM. 2005. Development and validation of the patient assessment of chronic illness care (PACIC). Medical Care. 43, 5: 436–444.

[2] Adapted from McIntosh, CN. Examen de la validité factorielle de certains modules de l'Enquête canadienne sur l'expérience des soins de santé primaires. Statistique Canada, Division de l'information et de la recherche sur la santé. July 2008.

3. Acceptance of CONCERTO+
Tool used
Survey based on the *Technology Acceptance Model*
Criteria
Perceived ease of use 1. My interaction with CONCERTO+ is clearer and more comprehensive. 2. I find it is easy to get CONCERTO+ to do what I want it to do. 3. The use of CONCERTO+ will improve my follow-up. 4. The use of CONCERTO+ will improve the effectiveness of my care. **Perceived usefulness** 1. The use of CONCERTO+ will improve my health condition. 2. I find CONCERTO+ to be a useful tool for the follow-up of my health condition. 3. The use of CONCERTO+ is interesting. 4. I like to use a smart phone or a tablet to look for health information. 5. I'm eager to use technology to manage my health condition. **Behavioural intention to use** 1. I'm going to use CONCERTO+ in the future. 2. Using CONCERTO+ is part of my plan.
4. The use of CONCERTO+
Tool used
CONCERTO+ logs use
Criteria
Logs

Supplementary File 2: ExpandNet recommendations for scaling up (WHO, 2013) Original English version

1. Engage in a participatory process involving key stakeholders.
2. Ensure the relevance of the proposed innovation.
3. Reach a consensus on expectations for scale up.
4. Tailor the innovation to the socio-cultural and institutional settings.
5. Keep the innovation as simple as possible.
6. Test the innovation in the variety of socio-cultural and institutional settings where it will be scaled up.
7. Test the innovation under routine operating conditions and existing resource constraints of the health system.
8. Develop plans to assess and document the process of implementation.
9. Advocate with donors and other sources of funding for financial support beyond the pilot stage.
10. Prepare to advocate for necessary changes in policies, regulations, and other health systems components.
11. Develop plans for how to promote learning and disseminate information.
12. Plan on being cautious about initiating scale up before the required evidence is available.

Supplementary File 3: Mesure d'activation du patient (PAM-13) French translation

1. Activation du patient
Outil utilisé
Mesure d'activation du patient (*Patient Activation Measure-PAM-13*)
Critères [1]
1. En fin de compte, je suis la personne qui est responsable de gérer ma condition de santé **2.** Prendre un rôle actif dans mes soins de santé et le facteur le plus important pour déterminer ma santé et mon habileté pour fonctionner **3.** Je suis confiant que je peux prendre des actions qui m'aideront à prévenir ou minimiser certains symptômes ou problèmes associés avec ma condition de santé **4.** Je sais quels sont les effets de tous mes médicaments prescrits **5.** Je suis persuadé que je peux savoir quand j'ai besoin de soins médicaux et quand je peux gérer mes problèmes de santé par moi-même **6.** Je suis persuadé que je peux exprimer à mon professionnel de la santé mes préoccupations même quand il ou elle ne le demande pas **7.** Je suis convaincu que je peux appliquer les traitements médicaux dont j'ai besoin à la maison **8.** Je comprends la nature et les causes de ma condition de santé **9.** Je connais les différentes options de traitements médicaux qui sont disponibles pour ma condition de santé **10.** J'ai été capable de maintenir des changements de style de vie que j'ai adopté pour ma santé **11.** Je sais comment prévenir des problèmes ultérieurs en lien avec ma condition de santé **12.** Je suis confiant que je peux trouver des solutions quand des nouvelles situations ou problèmes apparaissent en lien avec ma condition de santé **13.** Je suis persuadé que je peux maintenant des changements de style de vie comme une diète et de l'exercice même durant des périodes de stress
Mesure des résultats
Notation (pour chaque critère) **:** ▪ Fortement en désaccord (1 point) ▪ En désaccord (2 points) ▪ En accord (3 points) ▪ Fortement en accord (4 points) **Niveaux d'activation** (selon la conversion des résultats sur un score de 100) **:** 1. Ne croit pas que l'activation est important (≤ 47) 2. Manque de savoir ou de confiance pour agir (47.1-55.1) 3. Commence à agir (55.2-67) 4. Agit (≥ 67.1)

[1] Adapté de: Moljord I E O, Lara-Cabrera ML. Perestelo-Pérez L, Rivero-Santana A, Eriksen L, Linaker OM. Psychometric properties of Patient Activation Measure-13 among out-patients waiting for mental health treatment: a validation study in Norway. *Patient education and counseling*. 2015*98*(11):1410-1417.

Traduction libre

2. Impacts de l'utilisation de CONCERTO+
Outil utilisé
Questionnaire utilisé lors de l'évaluation de la phase pilote du Programme de santé Concerto [1]
Critères [2]
Résolution de problèmes/conseils : 1. Vous a-t-on demandé quels étaient les effets de votre maladie sur votre vie ? 2. Vous a-t-on aidé à planifier afin de pouvoir prendre soin de votre état de santé même en des moments difficiles ? 3. Vos fournisseurs de soins tenaient-ils compte de vos valeurs et de vos traditions au moment de vous recommander un traitement ? 4. Vous a-t-on aidé à élaborer un plan de traitement que vous pourriez mettre en pratique dans votre vie quotidienne ? **Prestation de soins/aide à la décision :** 1. Vous a-t-on posé des questions sur vos habitudes de santé ? 2. Vous a-t-on encouragé à faire partie d'un groupe ou d'une classe, comme une session d'information éducative, pour vous aider à vivre avec votre état de santé chronique ? 3. Vous a-t-on remis une copie de votre plan de traitement ? **Établissement des objectifs/personnalisation :** 1. Vous a-t-on demandé de parler de vos objectifs en ce qui concerne la manière de prendre soin de votre condition chronique ? 2. Vous a-t-on aidé à fixer des objectifs spécifiques pour améliorer votre alimentation ou votre activité physique ? 3. Vous a-t-on montré comment ce que vous avez fait pour prendre soins de vous-même a influencé votre condition chronique ? 4. Vous a-t-on remis une liste écrite des choses que vous devriez faire pour améliorer votre santé ? 5. Étiez-vous satisfait de la manière dont vos soins étaient organisés ? **Coordination des soins :** 1. Vous a-t-on dirigé vers un diététiste, un éducateur en matière de santé ou un conseiller ? 2. Vous a-t-on dit comment vos visites chez d'autres genres de médecins (p. ex., spécialiste, chirurgien) contribuaient à votre traitement ? 3. Vous a-t-on demandé comment se passaient vos visites chez les autres médecins ? 4. A-t-on communiqué avec vous après une visite pour savoir comment les choses se passaient ? **Globalité des soins :** Depuis que vous utilisez CONCERTO+, avez-vous… 1. Pu obtenir un rendez-vous avec un professionnel de la clinique ? 2. Été aidé(e) lorsque vous en aviez besoin ? 3. Obtenu un rendez-vous de suivi de votre condition de santé ? 4. Eu besoin d'entrer en contact avec un professionnel de l'équipe ou reçu une réponse de l'un d'entre eux à la suite de votre appel téléphonique ? 5. L'impression que votre infirmière coordonne l'ensemble de vos soins ?

[1] Adapté de : McIntosh, CN. Examen de la validité factorielle de certains modules de l'Enquête canadienne sur l'expérience des soins de santé primaires. Statistique Canada, Division de l'information et de la recherche sur la santé. Juillet 2008.

[2] Ces critères ont été développés initialement et validés par Glasgow et collaborateurs : Glasgow RE, Wagner EW, Schaefer J, MahoneyLD, Reid RJ, Greene SM. 2005. Development and validation of the patient assessment of chronic illness care (PACIC). Medical Care. 43, 5: 436–444.

6. Le sentiment que l'équipe du Programme a tenu compte de votre problème de santé ? 7. Pu constater que l'on a tenu compte de vos consultations avec d'autres professionnels de la santé que ceux de l'équipe du Programme ? 8. Pu vous faire aider à comprendre vos résultats de tests (par exemple : test de laboratoire, prise de pression, etc.) ? 9. Obtenu une réponse lors d'une situation urgente pour vous ?

3. Acceptation de CONCERTO+
Outils utilisé
Questionnaire basé sur le Modèle d'acceptation de la technologie
Critères
Facilité d'utilisation perçue : 1. Mon interaction avec le système CONCERTO+ est claire et compréhensible 2. Je trouve qu'il est facile de demander au système CONCERTO+ de faire ce que je veux 3. L'utilisation de CONCERTO+ améliorera mon suivi 4. L'utilisation de CONCERTO+ améliorera mon efficacité à me prendre en charge **Utilité perçue :** 1. L'utilisation de CONCERTO+ améliorera mon état de santé 2. Je trouve que CONCERTO + est un outil utile pour le suivi de mon état de santé 3. L'utilisation de CONCERTO + plus intéressant. 4. J'aime travailler avec l'ordinateur. 5. Je cherche des aspects de mon métier qui demande d'utiliser l'ordinateur **Intention comportementale d'utiliser :** 1. Je vais utiliser CONCERTO+ dans le futur. 2. J'établis un plan pour utiliser CONCERTO+
4. Utilisation de CONCERTO+
Outil utilisé
Registres d'utilisation de CONCERTO+
Critères
Registres (*Logs*)

Supplementary File 4: Recommandations d'ExpandNet pour le passage à l'échelle (OMS, 2013) (French translation)

1. Engager un processus participatif impliquant les principales parties prenantes
2. Assurer la pertinence de l'innovation proposée
3. Trouver un consensus sur les attentes à propos du passage à grande échelle
4. Ajuster l'innovation aux cadres socioculturels et institutionnels
5. Garder l'innovation aussi simple que possible
6. Tester l'innovation dans la variété de cadres socioculturels et institutionnels où elle passera à grande échelle
7. Tester l'innovation dans les conditions de fonctionnement de routine et sous les contraintes de ressource actuelles du système de santé
8. Planifier l'évaluation et la documentation du processus de mise en œuvre
9. Plaider auprès des bailleurs de fonds et autres sources de financement pour un soutien financier au-delà de la phase pilote
10. Se préparer à plaider pour des changements nécessaires dans les politiques, règlements et autres composantes des systèmes de santé
11. Planifier la façon de promouvoir l'apprentissage et la diffusion de l'information
12. Se préparer à la prudence quant au lancement du passage à grande échelle avant l'obtention des preuves requises

Supplementary File 5: Ethical and funding approval (English translation)

ETHICS APPROVAL

Research project involving human beings or the consultation of personal information

This research project is reviewed in accordance with the
ethical procedures management of research with human beings of Université Laval
by the sectorial committee of research ethics in health science

Project title	Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare
Researcher's name	Marie-Pierre Gagnon
Approval number	2018-067 / 01-06-2018
Decision date	June 1, 2018
Approval expiration date	July 1, 2019

After reviewing the information and documents it has been provided, the committee notes that the project respects ethical principles of research with human beings. It takes note of the written confirmation of the researcher that she is aware of the follow-up actions[1] associated with ethical approval of this project and that she has agreed to apply them. Therefore, the committee approves this project for one year.

June 6, 2018

Mahmoud Rouabhia, Chair of the
Research Ethics Committee in
Health Sciences

[1] Follow-up action reminder on the next page.

Follow-up actions associated with ethics approval

For the project entitled **Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare** (file number: 2018-067)

1. Notify the Committee in writing without undue delay (independent of its statutory meeting agenda) in the following situations:

   - Any changes to the project, as approved this day, that would include changes to the choice of participants, to recruitment, to the obtention of consent, to the collection of data, and/or to the incurred risks or disadvantages before the application of any such changes (the template of the letter requesting an amendment is available on the CÉRUL website).

   - Any changes to the instrument used for recruitment (ads, posters, or other instruments), to the confirmation of consent (consent form, information sheet, or other forms of confirmation), or to the collection of data (survey, interview grid, or other data collection mechanisms) by providing the latest version of the document under consideration, where changes will be highlighted, before its use.

   - Any unexpected and serious event (e.g. psychological distress of a participant, threat against a person, unexpected or side effects of a product, a drug or a test) that may occur in the course of the current project and would involve a participant, by completing the VRR-EI form available on the CÉRUL website.

   - Any early termination of this research for any reason, be it funded or not, including reasons due to suspension or cancellation on the part of the granting agency.

2. Until the project is finished, and not only for recruitment, submit an annual renewal request for approval by providing a report on research progress, the number of recruited participants, and the difficulties encountered along the way, by using the VRR-107 form. The renewal request must be sent to the committee at least 30 days before the end date of the approval, independent of the statutory meeting agenda.

I, the undersigned, Marie-Pierre Gagnon, declare that I **have read and understood the above follow-up actions associated with ethics approval** and agree to apply them during the entire research project for which I am the principal researcher.

Signature of the principal researcher:_____ Date: 2018-06-04

Supplementary File 6: Ethical approval (original French version)

UNIVERSITÉ LAVAL

Vice-rectorat à la recherche et à la création
Comité d'éthique de la recherche

APPROBATION DE L'ÉTHIQUE

Projet de recherche impliquant des êtres humains ou
la consultation de renseignements personnels

Ce projet de recherche a été examiné en conformité avec les
Modalités de gestion de l'éthique de la recherche sur des êtres humains de l'Université Laval,
par le Comité sectoriel d'éthique de la recherche en sciences de la santé

Projet intitulé :	Personnaliser CONCERTO : L'expérience patient optimisée pour des soins intégrés, coordonnés et efficients
Nom du chercheur :	Madame Marie-Pierre Gagnon
Numéro d'approbation :	2018-067 / 01-06-2018
Date de décision :	1er juin 2018
Date d'expiration de l'approbation :	1er juillet 2019

Après examen des informations et des documents qui lui ont été transmis, le Comité a constaté que ce projet respecte les principes d'éthique de la recherche avec des êtres humains. Il prend acte de la confirmation écrite de la chercheure à l'effet qu'elle a pris connaissance des mesures de suivi[1] associées à l'émission de l'approbation éthique de son projet et qu'elle accepte de les appliquer. Par conséquent, le Comité approuve ce projet pour un an.

B. Rouabhia — 6 juin 2018

Mahmoud Rouabhia, président
Comité d'éthique de la recherche en sciences de la santé

Date

[1] Rappel des mesures de suivi au verso

Maison Michael-John-Brophy
2241, chemin Sainte-Foy
Québec (Québec) G1V 0A6
CANADA

418 656-2131, poste 4506
Télécopieur : 418 656-2840
cer@vrr.ulaval.ca
www.cerul.ulaval.ca

UNIVERSITÉ LAVAL

Vice-rectorat à la recherche et à la création
Comité d'éthique de la recherche

Mesures de suivi associées à l'approbation éthique

Pour le projet intitulé : **Personnaliser CONCERTO : L'expérience patient optimisée pour des soins intégrés, coordonnés et efficients** (numéro de dossier : 2018-067)

1. Informer le Comité par écrit et dans les meilleurs délais (indépendamment du calendrier de ses réunions statutaires) des situations suivantes si elles se présentent :
   - de **toute modification au projet,** comme il a été approuvé en ce jour, qui comporterait des changements dans le choix des participants, dans le recrutement, dans la manière d'obtenir leur consentement, de réaliser la collecte des données ou encore, dans les risques ou inconvénients encourus par la participation, et ce, préalablement à l'application de ce changement (modèle de lettre de demande d'amendement disponible sur le site Internet des CÉRUL) ;
   - de **toute modification** qui serait apportée à un **instrument utilisé pour le recrutement** (annonces, affiches, etc.), pour confirmer le **consentement** (formulaire de consentement, feuillet d'information, etc.) ou pour effectuer la **collecte** des données (questionnaire, grille d'entrevue, etc.) en fournissant la nouvelle version du document concerné, où les modifications auront été mises en évidence, préalablement à son utilisation ;
   - de **tout événement imprévu et sérieux** (ex. : détresse psychologique d'un participant, menace proférée à l'égard d'une personne, effets secondaires ou imprévus ou indésirables d'un produit, d'un médicament ou d'un test, etc.) qui surviendrait dans le déroulement d'une activité du présent projet et qui impliquerait un participant, en complétant le formulaire VRR-EI disponible sur le site Internet des CÉRUL ;
   - de l'**interruption prématurée de ce projet de recherche** pour une raison quelconque qu'il soit financé ou non, y compris en raison de la suspension ou de l'annulation de l'approbation d'un organisme subventionnaire.
2. Tant que le projet ne sera pas terminé, et non seulement le recrutement, présenter annuellement une **demande de renouvellement** de l'approbation, en fournissant un rapport sur le déroulement de la recherche, le nombre de participants recrutés et, le cas échéant, sur les difficultés rencontrées en cours de réalisation, à l'aide du formulaire VRR-107. La demande de renouvellement doit être transmise au Comité dans un délai de 30 jours avant la date de fin de l'approbation, indépendamment du calendrier des réunions statutaires.

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cer@vrr.ulaval.ca
www.cerul.ulaval.ca

Research title: Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare

Supplementary File 7: Consent form for validation cycles

This research entitled "Optimizing patient usability experience with an eHealth platform for embedded, coordinated and efficient healthcare" is conducted by Marie-Pierre Gagnon, from faculty of nursing at Université Laval.

Before you agree to take part in this research project, please take the time to read and understand the following information. This document will explain you the aim of this research project, his process, advantages, risks and disadvantages. We invite you to ask all questions you may deem necessary to the research staff. You can find their contact details at the end of the form.

Type of study

This research project aims to develop, implement and evaluate a user-centered, multifunctional and personalized eHealth platform (CONCERTO+) to promote a more active patient role in chronic disease management and decision-making, satisfaction towards healthcare services and quality of life. Specific objectives are to:

1) develop a module of a multifunctional and personalized eHealth platform integrated to the CHP (Concerto Health Program) for patients and caregivers allowing them to engage in the follow-up and management of their chronic diseases;

2) test the integration of CONCERTO+ in monitoring care pathways of three frequent co-existing chronic diseases (diabetes, hypertension, dyslipidemia) and assess the usefulness and acceptability of the solution for patients with chronic diseases and their caregivers;

3) assess the scalability of the CONCERTO+ solution.

The course of the participation:

Validation of the prototype of the application CONCERTO+

Your participation in this research will consist in validating the prototype of the application CONCERTO+. In practical terms, you should go to the usability laboratory of Université Laval lead by Dr Holly Witteman. The validation of the application will be done either on a smartphone or a digital tablet. The aim is to collect your input in visual presentation, content, usability of the application, the pros and cons and any consideration of the application developed. Iterative testing via three validation sessions will be organized. If you agree to participate to the validation cycles, your participation may have incur parking and travel expenses. In addition, the participation in each validation cycle requires approximately one and a half hour of your time.

Project approved by the sectorial committee of research ethics in health science of Université Laval (Approval number 2018-067), June 1st 2018. MPG

Research title: Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare

Potential benefits and risks or disadvantages related to your participation

There are no direct benefits for the participants. However, this research enables improve the adaptation and value of the CHP in order to provide a multifunctional and personalized eHealth platform, to promote a more active patient and informal care givers role in chronic disease management.

Compensation

If you participate in validation cycles, we can provide you a lump sum amount of 18 $ for the time you have allocated for this activity. This sum will be returned in each validation session.

Voluntary participation and right to withdraw

You are free to participate to this research project. You may voluntarily withdraw at any time without any justification and with no adverse consequences or without prejudice. However If you decide so, It is important to inform the research team whose contact details are included at the end of the document. All your personal information will be destroyed.

Confidentiality and data management

The following measures will be applied to ensure your private information stays private:

•Your name will not be mentioned in any report;

•The various documents will be codified and only the investigator and his team will have access to the list of names and codes;

• Your individual results will never be shared;

• In the interest of scientific rigor, the electronic data will be kept in a folder with a password on the web server of the Canada Research Chair on Technology and Practices in Health at Université Laval. They will be destroyed only five years after the end of the research, in December 2024;

• This research will be publicated in scientific reviews and no one can able to identify you;

• A short summary of the research results will be sent to you if requested by indicating the address where you would like to receive the document, just after the blank space provided for your signature.

Acknowledgment

Your collaboration is useful to achieve this study, thank you for your participation.

Additional information

If you have any question on the research, the involvement of your participation or if you want to withdraw from this research, please contact: Mame Awa Ndiaye, research coordinator, Amélie Lampron, research coordinator or Marie-Pierre Gagnon, principal investigator at the following coordinates:

• Mame Awa Ndiaye: mame-awa.ndiaye.ciussscn@ssss.gouv.qc.ca

• Amélie Lampron: amelie.lampron2.ciussscn@ssss.gouv.qc.ca

• Marie-Pierre Gagnon: marie-pierre.gagnon@fsi.ulaval.ca

Complaints and criticism

Any complaint and criticism related to this research project will be addressed to the Ombudsman office at Université Laval:

Pavillon Alphonse-Desjardins, bureau 3320
2325, rue de l'Université
Université Laval
Québec (Québec) G1V 0A6
Information - Secretariat : (418) 656-3081

Project approved by the sectorial committee of research ethics in health science of Université Laval (Approval number 2018-067), June 1st 2018. MPG

Research title: Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare

Toll-free line: 1-866-323-2271
Email: info@ombudsman.ulaval.ca

Signatures

I, the undersigned _____freely consent to participate to the research entitled: «Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare». I have read and understood the aim, type, advantages, risks and disadvantages of the research project. I' m satisfied with the explanations, further details and responses received from the investigator, where appropriate, about my participation to this project.

_____ _____

Participant signature Date

A short summary of the search results will be sent to you if requested by indicating the address where you would like to receive the document. The results will not be available before December 20th. If your address changes by that date, you are invited to inform the research team, the new address you wish to receive the document.

I wish receive a short summary ☐ No, I would prefer not to receive summary ☐

I would like to receive the summary at the following email address or mailing address:

_____

_____

I explained the aim, type of the study, advantages, risks and disadvantages of the research project I have answered to the best of my knowledge the questions asked and have verified the understanding of the participant.

_____ _____

Investigator or research coordinator signature Date

Copy of the participant.

Project approved by the sectorial committee of research ethics in health science of Université Laval (Approval number 2018-067), June 1st 2018. MPG

Research title: Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare

List of the team members/ Names of project partners	Role in the project
Marie-Pierre Gagnon	Specialist of patient engagement and eHealth technology assessment
Christian Chabot	Patient partner, co-designer of the project
Guylaine Chabot, Alain Larouche	Technological partners
France Légaré, Anik Giguère, Annie LeBlanc	Experts in shared decision making
Samira Rahimi Abbasgholizadeh	Expert in decision aids tools
Jean-Paul Fortin, Aude Motulsky, Claude Sicotte	Experts in evaluation of health information systems
Holly Witteman	Expert in adaptation of user-centered technologies
Ronald Buyl	Expert in medical informatics and biostatistics
Carole Délétroz	Expert in health literacy
Erik Kavanagh, Frédéric Lépinay, Jacynthe Roberge	Specialists in application development and design
Amélie Lampron, Mame Awa Ndiaye	Research coordinators

Project approved by the sectorial committee of research ethics in health science of Université Laval (Approval number 2018-067), June 1st 2018. MPG

Research title: Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare

Supplementary File 8: Consent form (patients and informal caregivers) 2a

This research entitled "Optimizing patient usability experience with an eHealth platform for embedded, coordinated and efficient healthcare" is conducted by Marie-Pierre Gagnon, from faculty of nursing at Université Laval.

Before you agree to take part in this research project, please take the time to read and understand the following information. This document will explain you the aim of this research project, his process, advantages, risks and disadvantages. We invite you to ask all questions you may deem necessary to the research staff. You can find their contact details at the end of the form.

Type of study

This research project aims to develop, implement and evaluate a user-centered, multifunctional and personalized eHealth platform (CONCERTO+) to promote a more active patient role in chronic disease management and decision-making, satisfaction towards healthcare services and quality of life. Specific objectives are to:

1) develop a module of a multifunctional and personalized eHealth platform integrated to the CHP (Concerto Health Program) for patients and caregivers allowing them to engage in the follow-up and management of their chronic diseases;

2) test the integration of CONCERTO+ in monitoring care pathways of three frequent co-existing chronic diseases (diabetes, hypertension, dyslipidemia) and assess the usefulness and acceptability of the solution for patients with chronic diseases and their caregivers;

3) assess the scalability of the CONCERTO+ solution.

The course of the participation:

1) Validation of the prototype of the application CONCERTO+

Your participation in this research will consist in using the application CONCERTO+ (intervention group) or to continue your usual health follow-up (control group). For the participants of the intervention group, the use of the application will be explained to you by the members of the research team. You will complete a short questionnaire at the beginning and at the end of a six months period use, which will focus on the following points:

- Health management
- Feelings in competency and self confidence in health management
- Impacts of CONCERTO+ use
- The use of CONCERTO+

2) Focus group

Your participation in this research consists in participating in a focus group composed of 8 -12 people. The discussion will last approximately two hours and will focus on conditions and factors related to the wide-scale dissemination of the solution CONCERTO+.

Project approved by the sectorial committee of research ethics in health science of Université Laval (Approval number 2018-067), June 1st 2018. MPG

Research title: Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare

Potential benefits and risks or disadvantages related to your participation

There are no direct benefits for the participants. However, participating in this research enables improve the adaptation and value of the CHP in order to provide a multifunctional and personalized eHealth platform, to promote a more active patient and informal care givers role in chronic disease management.

Compensation

If you accept to participate, a lump sum of 50 $ will be offered to you for the time you have allocated for this activity. This sum will be returned to you during the focus group discussion.

Voluntary participation and right to withdraw

You are free to participate to this research project. You may voluntarily withdraw at any time without any justification and with no adverse consequences or without prejudice. However If you decide so, It is important to inform the research team whose contact details are included at the end of the document. All your personal information will be destroyed.

Confidentiality and data management

The following measures will be applied to ensure your private information stays private:

•Your name will not be mentioned in any report;

•The various documents will be codified and only the investigator and his team will have access to the list of names and codes;

• Your individual results will never be shared;

• In the interest of scientific rigor, the electronic data will be kept in a folder with a password on the web server of the Canada Research Chair on Technology and Practices in Health at Université Laval. They will be destroyed only five years after the end of the research, in December 2024;

• This research will be publicated in scientific reviews and no one can able to identify you;

• A short summary of the research results will be sent to you if requested by indicating the address where you would like to receive the document, just after the blank space provided for your signature.

Acknowledgment

Your collaboration is useful to achieve this study, thank you for your participation.

Additional information

If you have any question on the research, the involvement of your participation or if you want to withdraw from this research, please contact: Mame Awa Ndiaye, research coordinator, Amélie Lampron, research coordinator or Marie-Pierre Gagnon, principal investigator at the following coordinates:

• Mame Awa Ndiaye: mame-awa.ndiaye.ciussscn@ssss.gouv.qc.ca

• Amélie Lampron: amelie.lampron2.ciussscn@ssss.gouv.qc.ca

• Marie-Pierre Gagnon: marie-pierre.gagnon@fsi.ulaval.ca

Complaints and criticism

Any complaint and criticism related to this research project will be addressed to the Ombudsman office at Université Laval:

Pavillon Alphonse-Desjardins, bureau 3320

2325, rue de l'Université

Université Laval

Québec (Québec) G1V 0A6

Information - Secretariat : (418) 656-3081

Project approved by the sectorial committee of research ethics in health science of Université Laval (Approval number 2018-067), June 1st 2018. MPG

Research title: Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare

Toll-free line: 1-866-323-2271
Email: info@ombudsman.ulaval.ca

Signatures

I, the undersigned _____freely consent to participate to the research entitled: «Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare». I have read and understood the aim, type, advantages, risks and disadvantages of the research project. I' m satisfied with the explanations, further details and responses received from the investigator, where appropriate, about my participation to this project.

_____ _____
Participant signature Date

Do you wish to participate in the first step of this research involving the use of application CONCERTO+ and the completion of two questionnaires on the active involvement?

Yes, i accept to participate ☐ No, i would prefer not to participate ☐

Do you wish to participate in the second step of the project involving the participation in a focus group on factors and conditions related to the wide-scale dissemination of the solution CONCERTO+?

Yes, i accept to participate ☐ No, i would prefer not to participate ☐

A short summary of the search results will be sent to you if requested by indicating the address where you would like to receive the document. The results will not be available before December 20th. If your address changes by that date, you are invited to inform the research team, the new address you wish to receive the document.

I wish receive a short summary ☐ No, I would prefer not to receive summary ☐

I would like to receive the summary at the following email address or mailing address:

_____

_____

I explained the aim, type of the study, advantages, risks and disadvantages of the research project I have answered to the best of my knowledge the questions asked and have verified the understanding of the participant.

_____ _____
Investigator or research coordinator signature Date

Copy of the participant.

Project approved by the sectorial committee of research ethics in health science of Université Laval (Approval number 2018-067), June 1st 2018. MPG

Research title: Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare

Supplementary File 9: Consent form (interviews)

This research entitled "Optimizing patient usability experience with an eHealth platform for embedded, coordinated and efficient healthcare" is conducted by Marie-Pierre Gagnon, from faculty of nursing at Université Laval.

Before you agree to take part in this research project, please take the time to read and understand the following information. This document will explain you the aim of this research project, his process, advantages, risks and disadvantages. We invite you to ask all questions you may deem necessary to the research staff. You can find their contact details at the end of the form.

Type of study

This research project aims to develop, implement and evaluate a user-centered, multifunctional and personalized eHealth platform (CONCERTO+) to promote a more active patient role in chronic disease management and decision-making, satisfaction towards healthcare services and quality of life. Specific objectives are to:

1) develop a module of a multifunctional and personalized eHealth platform integrated to the CHP (Concerto Health Program) for patients and caregivers allowing them to engage in the follow-up and management of their chronic diseases;

2) test the integration of CONCERTO+ in monitoring care pathways of three frequent co-existing chronic diseases (diabetes, hypertension, dyslipidemia) and assess the usefulness and acceptability of the solution for patients with chronic diseases and their caregivers;

3) assess the scalability of the CONCERTO+ solution.

The course of the participation:

Your participation to this research consists in participating in one-on-one semi-structured interview with a member of the team. This interview will last approximately 30 minutes and will focus on the following points:

- Factors facilitating the use of CONCERTO+
- Factors limiting the use of CONCERTO+
- Support to the use of CONCERTO+ by health professionals
- Expansion of CONCERTO+

Project approved by the sectorial committee of research ethics in health science of Université Laval (Approval number 2018-067), June 1st 2018. MPG

Research title: Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare

Potential benefits and risks or disadvantages related to your participation

There are no direct benefits for the participants. However, participating in this research enables improve the adaptation and value of the CHP in order to provide a multifunctional and personalized eHealth platform, to promote a more active patient and informal care givers role in chronic disease management.

Compensation

If you accept to participate, a lump sum of 50 $ will be offered to you for the time you have allocated for this activity. This sum will be returned to you during the focus group discussion.

Voluntary participation and right to withdraw

You are free to participate to this research project. You may voluntarily withdraw at any time without any justification and with no adverse consequences or without prejudice. However If you decide so, It is important to inform the research team whose contact details are included at the end of the document. All your personal information will be destroyed.

Confidentiality and data management

The following measures will be applied to ensure your private information stays private:

•Your name will not be mentioned in any report;

•The various documents will be codified and only the investigator and his team will have access to the list of names and codes;

• Your individual results will never be shared;

• In the interest of scientific rigor, the electronic data will be kept in a folder with a password on the web server of the Canada Research Chair on Technology and Practices in Health at Université Laval. They will be destroyed only five years after the end of the research, in December 2024;

• This research will be publicated in scientific reviews and no one can able to identify you;

• A short summary of the research results will be sent to you if requested by indicating the address where you would like to receive the document, just after the blank space provided for your signature.

Acknowledgment

Your collaboration is useful to achieve this study, thank you for your participation.

Additional information

If you have any question on the research, the involvement of your participation or if you want to withdraw from this research, please contact: Mame Awa Ndiaye, research coordinator, Amélie Lampron, research coordinator or Marie-Pierre Gagnon, principal investigator at the following coordinates:

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• Amélie Lampron: amelie.lampron2.ciussscn@ssss.gouv.qc.ca

• Marie-Pierre Gagnon: marie-pierre.gagnon@fsi.ulaval.ca

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Project approved by the sectorial committee of research ethics in health science of Université Laval (Approval number 2018-067), June 1st 2018. MPG

Research title: Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare

Toll-free line: 1-866-323-2271
Email: info@ombudsman.ulaval.ca

Signatures

I, the undersigned _____freely consent to participate to the research entitled: «Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare». I have read and understood the aim, type, advantages, risks and disadvantages of the research project. I' m satisfied with the explanations, further details and responses received from the investigator, where appropriate, about my participation to this project.

_____ _____
Participant signature Date

A short summary of the search results will be sent to you if requested by indicating the address where you would like to receive the document. The results will not be available before December 20th. If your address changes by that date, you are invited to inform the research team, the new address you wish to receive the document.

I wish receive a short summary ☐ No, I would prefer not to receive summary ☐

I would like to receive the summary at the following email address or mailing address:

_____

_____

I explained the aim, type of the study, advantages, risks and disadvantages of the research project I have answered to the best of my knowledge the questions asked and have verified the understanding of the participant.

_____ _____
Investigator or research coordinator signature Date

Copy of the participant.

Project approved by the sectorial committee of research ethics in health science of Université Laval (Approval number 2018-067), June 1st 2018. MPG

Supplementary File 10: Funding

Canadian Institutes of Health Research / Instituts de recherche en santé du Canada

AUTHORIZATION FOR FUNDING

CIHR (Canadian Institutes of Health Research) has approved funding as detailed below. Subject to the approbation of funding by Parliament, these funds will be made available to the business officer at the indicated institution for disbursement.

AUTORISATION DE FINANCEMENT

IRSC (Instituts de recherche en santé du Canada) vous accorde les fonds tel qu'indiqué ci-dessous. Suivant l'affectation des crédits par le Parlement du Canada, les fonds seront mis à la disposition du trésorier de l'établissement indiqué qui s'occupera des versements.

201706PCG-385330-PCG-CFBA-111141

20/12/2017

Institution Paid/Établissement chargé d'administrer les fonds:
Université Laval

Recipient(s)/Bénéficiaire(s):
Gagnon, Marie-Pierre
CHU de Québec

Program/Programme:
Subvention catalyseur: Subventions Catalyseur sur la santé personnalisée
Nouvelle subvention

In Partnership with/En partenariat avec : IRSC - Grandes initiatives #2; IRSC - Institut du Cancer; IRSC - Inst santé femmes et hommes; IRSC - Inst services politq de santé; IRSC - Institut de génétique; IRSC - Institut du vieillissement

Primary Institute/Institut principal: Services et politiques de la santé

Project Title/Titre du projet:
Personnaliser CONCERTO: L'expérience patient optimisée pour des soins intégrés, coordonnés et efficients

Co-Investigator(s) & Associates/Supervisor(s)/Host/Co-chercheur(s)/Directeur(s) de recherche/Hôte:
Dr. Samira Abbasgholizadeh Rahimi, Prof. Ronald Buyl, Mr. Christian Chabot, Docteur Jean-Paul Fortin, et coll.

PAYMENT DETAILS/DÉTAILS DES VERSEMENTS

Funding Reference Number/ No. de Référence du financement: **PCG — 155469**

Period / Période	Type	Amount by Type / Montant par type	Total by Fiscal Year / Total par exercice	
01/09/2017 à 31/03/2018	Fonctionnement	$58,080	$58,080	2017-18
01/04/2018 à 31/03/2019	Fonctionnement	$99,681	$99,681	2018-19
01/04/2019 à 31/08/2019	Fonctionnement	$41,568	$41,568	2019-20

Progress Report Required: / Rapport des progrès réalisés requis: **Ne s'applique pas**

Application to Renew Funding Required: / Demande de renouvellement des fonds requis: **Non Renouvelable**

NOTES:

Les IRSC exigent que leur contribution à votre recherche soit reconnue dans toutes les présentations écrites et orales de vos résultats de recherche, qu'il s'agisse d'articles scientifiques, de communiqués, de conférences de presse, de conférences publiques ou d'entrevues avec les médias. Votre numéro de référence du financement (NRF), qui apparaît dans la section « Détails des paiements » ci-dessus, doit être précisé lorsqu'il est question d'articles scientifiques pour lesquels le soutien des IRSC est reconnu. Veuillez consulter les lignes directrices des IRSC ci-jointes en matière de communications publiques pour plus de détails sur les communications publiques et les exigences relatives à la reconnaissance du soutien.

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La présente est une subvention d'un terme de 2 ans qui sera payée dans les années financière 2017-18 à 2019-20 avec une date d'entrée en vigueur du 01/09/2017 couvrant la période jusqu'au 31/08/2019.

Les IRSC vous demanderont de soumettre un rapport final électronique pour cette subvention par le Système de rapports de recherche sur RechercheNet. Des instructions vous seront fournies par courrier électronique provenant de RechercheNet dès que l'activité deviendra disponible.

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SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

			Pages
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	6
	6b	Explanation for choice of comparators	
Objectives	7	Specific objectives or hypotheses	9
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	13
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	13
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	13
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	13-15

1Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	15
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	17
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	17
Methods: Assignment of interventions (for controlled trials)			
Allocation:			19
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	19
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	20
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	21
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	

	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	40
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	21-22
	31b	Authorship eligibility guidelines and any intended use of professional writers	
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary Files 6-8
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Optimizing patient active role with a user-centered eHealth platform (CONCERTO+) in chronic diseases management: A study protocol for a pilot cluster randomized controlled trial

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Optimizing patient active role with a user-centered eHealth platform (CONCERTO+) in chronic diseases management: A study protocol for a pilot cluster randomized controlled trial

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Abstract

Introduction Multimorbidity increases care needs and primary care use among people with chronic diseases. The Concerto Health Program (CHP) has been developed to optimize chronic disease management in primary care services. However, in its current version, the CHP primarily targets clinicians and does not aim to answer directly patients' and their informal caregivers' needs for chronic disease management. Various studies have shown that interventions that increase patient activation level are associated with better health outcomes. Furthermore, educational tools must be adapted to patients and caregivers in terms of health literacy and usability. This project aims to develop, implement and evaluate a user-centered, multifunctional and personalized eHealth platform (CONCERTO+) to promote a more active patient role in chronic disease management and decision-making.

Methods and analysis This project uses a collaborative research approach, aiming at the personalization of CHP through 3 phases: 1) the development of one module of an eHealth platform combining scientific evidence and user-centered design; 2) a feasibility study of CONCERTO+ through a pilot cluster randomized controlled trial where patients with chronic disease from a primary healthcare practice will receive CONCERTO+ during 6 months and be compared to patients from a control practice receiving usual care; and 3) an analysis of CONCERTO+ potential for scaling up. To do so, we will conduct two focus groups with patients and informal caregivers and individual interviews with health professionals at the two study sites, as well as health care managers, information officers and representatives of the Ministry of Health.

Ethics and dissemination This study received ethical approval from Ethics Committee of Université Laval. The findings will be used to inform the

effectiveness of CONCERTO+ to improve management care in chronic disease. We will disseminate findings through presentations in scientific conferences and publication in peer reviewed journals.

Trial registration: Clinicaltrials.gov ID: NCT03628963

Keywords: Chronic disease management, Multimorbidity, eHealth, Patient and caregiver engagement, Health literacy, User-centered design.

Strengths and limitations of this study

- The design of a user-centered technological solution is adapted to

chronic disease patients' needs and their literacy level.

- The inclusion of informal caregivers in the use of CONCERTO+ is a novelty.
- The pilot test will provide data for feasibility, acceptability and usefulness of CONCERTO+.
- Good potential for sustainability given that it will be implemented in the real context of primary care practice with the collaboration of clinical teams.
- As a limitation, this project seems ambitious for its entire achievement in two years.

Introduction

Background

Chronic diseases are the number one cause of mortality in the world, and account for nearly 70% of deaths [1]. In Canada and around the world, multimorbidity, which means people who have more than two chronic diseases, is increasing [2]. In addition to often making life more difficult for people living with these conditions, the rise in multimorbidity is putting pressure on the Canadian healthcare system and causing over-consumption of care and services [3]. In the Province of Quebec, 45% of people aged 20 and over have more than two chronic diseases [4], and 80% of chronic disease consultations are done in primary health care services [5].

Multimorbidity increases care needs as well as the complexity of health care services required in primary care, especially when it comes to applying recommendations for good clinical practices [5]. The total cost of the six most common chronic diseases in Quebec (ischemic heart disease, cerebrovascular disease, chronic obstructive pulmonary disease, cancer, hypertension and diabetes) has been estimated at 8, 1 billion Canadian dollars, and this may rise up to 13 billion in 2030 if no substantial change is made [6].

In Quebec, primary care services have the main responsibility to support people with chronic diseases and their informal caregivers, jointly with other stakeholders of the local health network [7, 8]. However, primary care services suffer from many challenges and organizational constraints, in particular, the difficulty of access – with a large proportion of Quebeckers without a family doctor – and the wait times that are among the longest in Canada [9, 10]. Furthermore, the fragmentation of health care processes and the gaps in information transfer are recognized sources

of inefficiency, that make critical the integration and continuity of care for chronic diseases [7, 11]. To overcome these issues, many approaches linking healthcare providers, patients, caregivers and the organization of health care services are promoted [12]. The central role of patients in the management of their disease, which depends on their active involvement, is recognized as a key component in chronic disease management [13].

Active patient involvement requires that patients have the knowledge, skills and self-confidence to manage their health and healthcare [14]. Various studies have shown that interventions increasing patient activation level are associated with better health outcomes [15-22] and decreased costs [23]. However, active patient involvement and the quality of the interactions with health providers will partially depend on patient's knowledge of the disease and the needed care, in addition to their interpersonal skills as well as their ability to communicate their expectations, needs and preferences to their healthcare team [24, 25]. It is therefore important

to offer patients and caregivers relevant information adapted to their health literacy level. According the following definition, “Health literacy is linked to literacy and entails people’s knowledge, motivation and competences to access, understand, appraise and apply health information in order to make judgements and take decisions in everyday life concerning health care, disease prevention and health promotion to maintain or improve quality of life during the life course” [26]. For their part, health professionals must also have the communicational and interpersonal skills required to work in a team and share information appropriately with patients in order to support their active involvement [24]. Thus, it becomes important to act in advance by supporting patients’ autonomy and involvement in the care dynamic, and by promoting informational and educational relationships in disease management [25-27]. Therefore, it is crucial that information and educational tools are adapted to patients and caregivers in terms of literacy level and presentation [28-30].

eHealth technologies offer a potential to support chronic disease management. Some studies have shown positive effects on clinical processes (better adhesion to care protocol, reduced errors and improved monitoring and callback rates), on quality of care and effectiveness, and on patient outcomes [31-36].

Systematic reviews support the role of electronic personal health records and electronic portals allowing patient access to their health records in order to promote their active participation in their care [37-39]. However, to achieve expected outcomes, eHealth technologies should first be adopted and used in an appropriate manner by patients and health professionals [40]. Therefore, end-user involvement in the development of eHealth solutions is an imperative [41]. Moreover, eHealth literacy, which is inspired by the health literacy concept but focuses specifically on optimal eHealth solutions use, should be considered in order to ensure that the solutions are adapted to the capabilities of targeted users [30, 42]. While the number of eHealth solutions continues to increase, with more than 325,000 mobile

health applications in 2017 [43], the majority of them (53%) are used by less than 5,000 people and are often abandoned after a short trial period [44-46]. User involvement – including patients, informal caregivers and health professionals – is identified to be among the conditions to ensure that eHealth solutions have a real impact. Thus, all these stakeholders must be involved throughout the different stages of technology development, from conception to assessment [47]. Based on efficient chronic care models, high-potential technologies and patient involvement as active partner of their care, we suggest to develop an innovative and mobilizing project in order to improve patient care and experience.

Methods and analysis:

The following methods adhere to the Standard Protocol Items Recommendations for Interventional Trials (SPIRIT) guidelines for the reporting of study protocols.

This project is a collaborative work involving IT developers from CHP, designers, clinicians, technological partners and patient representatives. The aim is to develop, implement and evaluate a module of a multifunctional and personalized eHealth platform, CONCERTO+, through a pilot study for optimizing patient active role in medical follow-up, decision-making, satisfaction towards healthcare services and quality of life. The specific objectives are to: 1) develop a module of a multifunctional and personalized eHealth platform integrated to the CHP for patients and caregivers allowing them to engage in the follow-up and management of their chronic diseases; 2) test the integration of CONCERTO+ in monitoring care pathways of three frequent co-existing chronic diseases (diabetes, hypertension, dyslipidemia) and assess the usefulness and acceptability of the solution for patients with chronic diseases and their caregivers; 3) assess the scalability of the CONCERTO+ solution.

Phase 1: Development of the eHealth solution module

We will conduct a rapid literature review on the effects of eHealth interventions for supporting active involvement of patients with chronic diseases in their primary care team. For this purpose, we will follow the rapid review method suggested by Lawani et al. [48] and consider the latest evidence on eHealth interventions for chronical diseases monitoring and care. We will consider the following “Problem, Intervention, Comparison, Outcomes (PICO)” elements: (P): three targeted chronic diseases (diabetes, high blood pressure, dyslipidemia), alone or combined; (I) all eHealth interventions implemented in primary care and that directly involve patients (e.g. Electronic Medical Records, patient diary, patient portal, specific computerized monitoring for a chronic disease and technological interventions focused on lifestyle modifications; (C): routine follow–up; (O): Health outcomes specific to the disease (e.g. HbA1c for diabetes), generic health outcomes (e.g. mortality, quality of life), patient outcomes (e.g. involvement, personal efficacy) and practices and process outcomes (e.g. test numbers, emergency visits,

hospitalizations). First, we will start to consult existing systematic reviews, in particular that of Irizarry et al. [38], and a review of reviews that we have already completed [49]. We will also document issues relating to needs, expectations and concerns in terms of eHealth solutions for patients, their informal caregivers, and health care providers. This information will provide evidence summaries describing each eHealth solution associated with each targeted health issues, as well as information on the risks and benefits of these solutions. We will then use the methods suggested by Giguère et al. [50] to develop Decision Boxes to involve patients and their informal caregivers in the choice of functionalities and contents to develop in the CONCERTO+ solution, in line with an integrated care system (**Fig. 1**).

A first prototype will be developed by the design and technology teams, in close collaboration with researchers, health professionals and patient representatives who will identify the functionalities to include in the CONCERTO+ solution. Given

the time limit of the project, we will classify the required functionalities in 3 types: 1) essential and priority; 2) important but not priority; 3) required in the future.

For the development of the eHealth platform module, a user-centered approach will be used, based on three cycles with users. Iterative testing sessions will take place at the usability laboratory of UL lead by HW, providing all the equipment needed to conduct usability studies. Students in graphic and interaction design, under the direction of three experts from the School of Design of UL (EK, FLP, JR), will participate in the development of the platform's visual environment. An expert in eHealth literacy (CD) will ensure that contents of the clinical monitoring tools already integrated in the CHP are adapted to a general audience according to recommendations of the Health Literacy Guide [51], in addition of tools that provide understandable information (e.g link to a popular glossary of medical terms: https://publications.santemontreal.qc.ca/uploads/tx_asssmpublications/litteratie_v9.pdf).

The integration of the CONCERTO+ solution with the CHP will be ensured by the Concerto Health Group team who will work closely with the designers and researchers. Health professionals in primary care services from the sites participating in the pilot project will also be consulted to validate the match between the CONCERTO + solution and care pathways for professionals offered by the CHP.

Patient and Public Involvement

A patient partner (informal caregiver) is involved as research partner at key stages of the study. His experience in caring of a patient with diabetes informed us on needs of patients, research focus, methods for collecting data for the study and dissemination strategy through patient and citizen groups associations.

Our patient partner is invited at each research team meeting to make sure that the research questions are aligned with patients' needs. He gives his input in refining

the focus of the research questions. He made valuable contributions in the design of the study.

In the first step of the study, the development of the first prototype, our patient partner helped us to recruit patients by sharing the invitation through his personal contacts and network and gave feedback for the pros and cons of the prototype development. He was also invited to contribute in editing the paper and is considered as a coauthor.

To develop our dissemination strategy, we will review the results with the patient partner and integrate his feedback to ensure that we presented the results in the most effective way for the general populations. We will send a summary of the research results to study participants who have provided their mailing address in the consent form and we will also organise events for patients and citizen groups and associations, such as outreach communications and scientific café.

In this study, participants will assess the burden of the intervention by participating in focus groups.

Phase 2: Pilot cluster randomized clinical trial

The Phase 2 of the project will consist in a feasibility study based on a pilot cluster randomized clinical trial (c-RCT). Given the nature of the intervention, patients with chronic diseases are followed by a small team of primary care clinicians.

Study setting

The study will be conducted in two Family Medicine Groups (FMG) from the same health region (in the province of Quebec) but covering distinct areas, they have been selected as the clusters.

Eligibility criteria

Patients with two or more targeted chronic diseases (diabetes, hypertension, dyslipidemia) and who had three or more visits in the last 12 months will be eligible. Adults whose legal incompetence has been established by a court are not eligible.

Intervention

The intervention is the device CONCERTO+, a user-centered, multifunctional and personalized eHealth platform. Both groups, experimental and control, have the same criteria with respect to participant eligibility. Experimental group from FMG 1 will use CONCERTO+ application during 6 months. Control group from FMG 2 will not use the application CONCERTO+ but continue to receive usual care. The objective is to assess the feasibility, acceptability and potential effectiveness of the device CONCERTO+.

Outcomes

Patient involvement in their care following the use of CONCERTO+ will be our primary outcome of interest. We will use Patient Activation Measure (PAM) [52]

which is built on patient knowledge, skills and confidence that are directly targeted by the intervention.

The score of the activation level obtained (between 0 and 100) shows the degree of ability to manage their health with confidence according to the following scale ranges: strongly disagree = 1; disagree = 2; agree = 3; strongly agree = 4. Patients with a higher activation level are likely to have better health outcomes. Patients answer to a survey of 13 questions with the following scoring for each answer:

1. Not believing that activation is important (≤ 47)
2. Lack of knowledge or confidence to take action (47.1 - 55.1)
3. Beginning to take action (55.2 - 67)
4. Taking action (≥ 67.1).

The PAM 13 questionnaire has been validated in French. We will ask a license to use, which is free for up to 250 patients in an academic research context [53]. The

survey will be completed by participants of the two groups at baseline, and six months later. This period of CONCERTO+ use is enough to achieve the intended outcomes.

Secondary outcomes of interest are: 1) Impacts of CONCERTO+ use on process indicators and care outcomes, measured with questions adapted from Glasgow et al. [54] and validated in the previous Concerto Health Program (CHP) assessment. To measure these outcomes, patients will answer to a questionnaire after six months use of CONCERTO+. This questionnaire comprises 5 scales based on the key components of CONCERTO+ and covering the following dimensions: solving-problems/advices, delivery system design/decision support, goal setting/tailoring, follow-up / coordination, overall care. Items are scored on a 5-point scale with the following values: 1 (Almost never); 2 (Generally not); 3 (Sometimes); 4 (Most of the time); 5 (Almost always). For each scale, higher scores are expected to be associated with better care outcomes.

2) The acceptability of the device CONCERTO+ will be assessed by patients and informal caregivers, at the end of the intervention with:

1. A short survey adapted from the Technology Acceptance Model [55] that includes 3 criteria (perceived ease of use, perceived usefulness, behavioral intention to use) with the following scoring: Strongly disagree = 1; Disagree = 2; Agree = 3; strongly agree = 4. Higher scores indicate a better acceptance of the use of CONCERTO+.

2. The use of CONCERTO+ that will be measured by logs (numbers of tests ordered, emergency visits, and hospitalizations). (See **Supplementary File 1, 2**).

Participant timeline

Table 1 shows the distribution of outcomes measures through time. The first survey will be completed at baseline and six months after the use of CONCERTO+, in

order to see the effects of the use of CONCERTO+ during the process of care. The second survey will be completed six months after in order to assess the effects of the use of CONCERTO+, and the third survey will be completed by patients and informal caregivers after the intervention in order to assess its acceptability.

Table 1 Distribution of outcomes measures through time

	Study period			
	Allocation	Post allocation		Close
	out			
Time point	**-T1**	**T1** (at baseline)	**T2** (6 months after the use of Concerto+)	**T3**: During 3 months following the end of the intervention
	Enrolment - Eligibility screen - informed consent - Allocation			
Intervention group	✓	✓	✓	✓
Usual care group	✓			
Assessments Main outcome measure: PAM measure		✓	✓	
Secondary outcome measure: Survey adapted from Glasgow and al.			✓	
Technology Acceptance Model			✓	

Logs measures			✓	
Focus groups				✓
Interviews				✓

Sample size calculation

Based on a similar study [56], a sample of 200 patients is enough to detect a difference of 2 points on the PAM score, with a power of 90% and an alpha of 0.05. Indeed, the assessment of online education intervention to chronical disease patients, showed a significant difference of 6 points on the PAM score in the experimental group (n = 58), whereas the difference was not significant in the control group (n = 68) [56]. Such a difference may be considered clinically significant because each additional point on the PAM score is associated with a 2% decrease in hospitalizations [53]. Considering an attrition rate of 15%, the sample size should remain relevant to detect a difference of at least 2 points on the PAM score, as differences reported in similar studies range from 2.5 to 6.5 points [14].

Recruitment strategy

For the Phase 1, the development of the eHealth solution module, we will recruit 7 to 10 patients and informal caregivers from convenience samples of volunteers joined through patient associations and mailing lists of our institution (Université Laval-UL). Eligible individuals will meet the following criteria: 1) have one or more targeted chronic diseases (diabetes, hypertension, dyslipidemia); 2) had three or more medical visits in the last 12 months; 3) are 18 years old and over; 4) reside in the greater Quebec area; 5) have an interest in technology; 6) are able to speak and read in French; 7) are available to participate in three validation sessions.

For the Phase 2, the pilot cluster randomized clinical trial, a note will be added in the EMR (electronic medical record) of patients who had been preselected, and at their next visit at the FMG, the receptionist will give them an information sheet about the study to invite them to participate. Interested patients will be invited to call the research assistant using a toll free number or to leave their contact information to the receptionist who will forward them to the research assistant. Then, patients will

be contacted by the research assistant to validate their eligibility and confirm their interest. Recruitment will end when 100 patients are recruited from each site. We will ensure an equal distribution of participants according to their sex, and we will consider specific aspects in patient recruitment, particularly living alone, the presence of dependents and their literacy level. The recruitment chart is presented in **Fig. 2**

Allocation

Patient will be selected randomly with the help of the participating FMG by searching the local EMR system. A pre-selection of patients will be done by the four nurses involved in chronic disease care at the participating FMG. For each site, a sample of 200 patients (see sample size calculation) stratified by sex, age group and number of chronic diseases, will be randomly preselected by a statistician not involved in the team, using a computerized program. Then, the statistician will reveal group assignment through a call to the responsible of each

FMG in the presence of a research team member.

Blinding

Given the nature of the intervention, participating patients and healthcare providers cannot be blinded, but the outcome assessor will be blinded to participant assignment.

Phase 3: Scaling-up potential of the solution

For Phase 3, the analysis of CONCERTO+ potential for scaling-up will be done by documenting factors and conditions associated with the sustainability and scaling-up of the solution. To do so, we will conduct: 1) two focus groups with patients and informal caregivers who participated in the study (1 with the experimental group and 1 with the control group, each group gathering between 8 and 12 participants); 2) semi-structured individual interviews with health professionals as well as with health care managers, information officers, and representatives of the Ministry of

Health and Social Services will be conducted at the two study sites two FMG of one region in the Province of Quebec). The number of interviews will be determined according to the data saturation principle, but is estimated to be around 15 participants in total. Interviews with patients, informal caregivers and health professionals will include questions about factors facilitating or limiting sustained use of the CONCERTO+ solution by patients and informal caregivers, and the support of this use by health professionals, inspired by a recent study on personal electronic health record [57, 58]. Questions for managers and decision-makers will be based on Expand Net framework [59] that proposes 12 elements helping to appreciate the potential of innovation expansion at different time of its progress (see **Supplementary File 3,4**).

Data analysis plan

The study started in 2017 and will end in 2019. Data will be collected managed and analysed at each step of the project. For the phase 1, we started to collect data in

October 2018; for the phase 2, we will start in April 2019 and the phase 3 will start in November 2019. We will ensure that surveys are correctly completed in order to avoid many missing data. Quantitative data will be analyzed using standard statistical tests such as ANOVA. We will compare the scores for repeated measurements between the two groups, controlling for the initial PAM score. We will also make tests according to sex, literacy level and comorbidity because these variables are associated with the PAM score [60]. Focus groups discussions and interviews will be recorded with participants' consent, and the content will be transcribed verbatim. The qualitative analysis will consist in a thematic-pragmatic content analysis [61] using the NVivo 10 software. We will use an inductive-deductive analysis, in an iteratively and flexible way, which allows a hybrid codification from the conceptual dimensions of the model and the emergent themes [62]. We will verify the role of the identified dimension in the literature as the initial basis for analysis, while remaining open to the advent of other context-specific

aspects. Findings from qualitative analyses will be triangulated with quantitative data to see commonalities among participants' characteristics. We will compare intervention and control groups to judge the potential effectiveness of CONCERTO+ using process and care outcomes, and these results will inform the relevance of conducting a definitive trial to assess the effectiveness of CONCERTO+ for improving health outcomes. Participants will also be asked about the usefulness of the CONCERTO+ solution in supporting their disease self-management.

Monitoring

A Data Monitoring Committee is not required for this study due to low risk of adverse events. The principal investigator has the authority to suspend or terminate the study at any time if any major problem occurs.

Ethics and dissemination

This study received ethical approval from the Research Ethics Committee of Université Laval; approval number: 2018-067 /01-06-2018 with all protocol modifications being mandatory to report (see **Supplementary Files 5, 6**). All participants will provide their informed consent following a procedure approved by the ethics board (see **Supplementary Files 7-9**) before enrollment in the study. All data will be anonymized and will be used only for statistical research and analysis. They will be securely stored on the server of Canadian Research Chair on Technologies and Practices in Health, we will never share it with third parties. Only the principal investigator, the research coordinator and eventually students who work on the project will have access on the list of participants in the different phases of the project. Data from EMR will be also anonymized by a medical secretary or a research assistant who will sign a confidentiality agreement. In addition, all team members will sign a confidentiality agreement so that any personal information of participants will not be shared.

In keeping with our participative approach and inspired by frameworks of collaboration between researchers and knowledge users [63, 64], knowledge translation will be done in an integrated way throughout the project, with an emphasis on collaboration, shared outcomes, and feedback from stakeholders at each step of the research. We will also share the outcomes through presentations in the networks and organizations of the team members, and through the production of dissemination tools for patient and citizen groups and associations. Ideally, these presentations will be done in tandem (patient-researcher; patient-clinician) in an interactive way, by taking the time for discussion and exchanges with the audience (e.g. lunch and learn, scientific café). The presentations will be supported with materials (brief reports, narrated slideshows, etc.) allowing a greater dissemination of the activities and outcomes. Knowledge translation activities at the end of project will consist of publishing outcomes in open access

peer reviewed journals. Presentations at national and international conferences in health informatics, chronic diseases, and patient engagement are also scheduled.

Study status

This is an ongoing study taking place from December 2017 until December 2019. At the time of writing, the prototype of the eHealth technology module was designed and the first usability test was done.

Discussion

This project shows a potential of success through the involvement of the technological partner who has a long collaborative experience with researchers. The eHealth solution is also likely to be acceptable because it will be adapted to patient's needs, based on our user-centered approach and the adaptation of the content to users' literacy level. Previous results associated with the use of the CHP

solution for clinicians show promising preliminary outcomes based on validated measures that are relevant and sensitive to the proposed intervention. The solution has also a good potential for sustainability given that it will be implemented in the real context of primary care practice, with the collaboration of clinical teams. Finally, the project team is engaged in disseminating the results and pursuing the development and adaptation of the CONCERTO+ solution in order to contribute to improving the health of people in Canada and internationally.

List of abbreviations

CHP: Concerto Health Program

c-RCT: cluster randomized clinical trial

EMR: Electronic Medical Record

FMG: Family medicine Group

IT: Information Technology

PAM: Patient activation measure

PICO: Problem, Intervention, Comparison-Outcomes

SPOR: Strategy of Patient-Oriented Research

UL: Université Laval

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Figure 1: Embedded healthcare system

Figure 2: Recruitment flowchart

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Footnotes

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Competing interest: The authors declare that they have no competing interests.

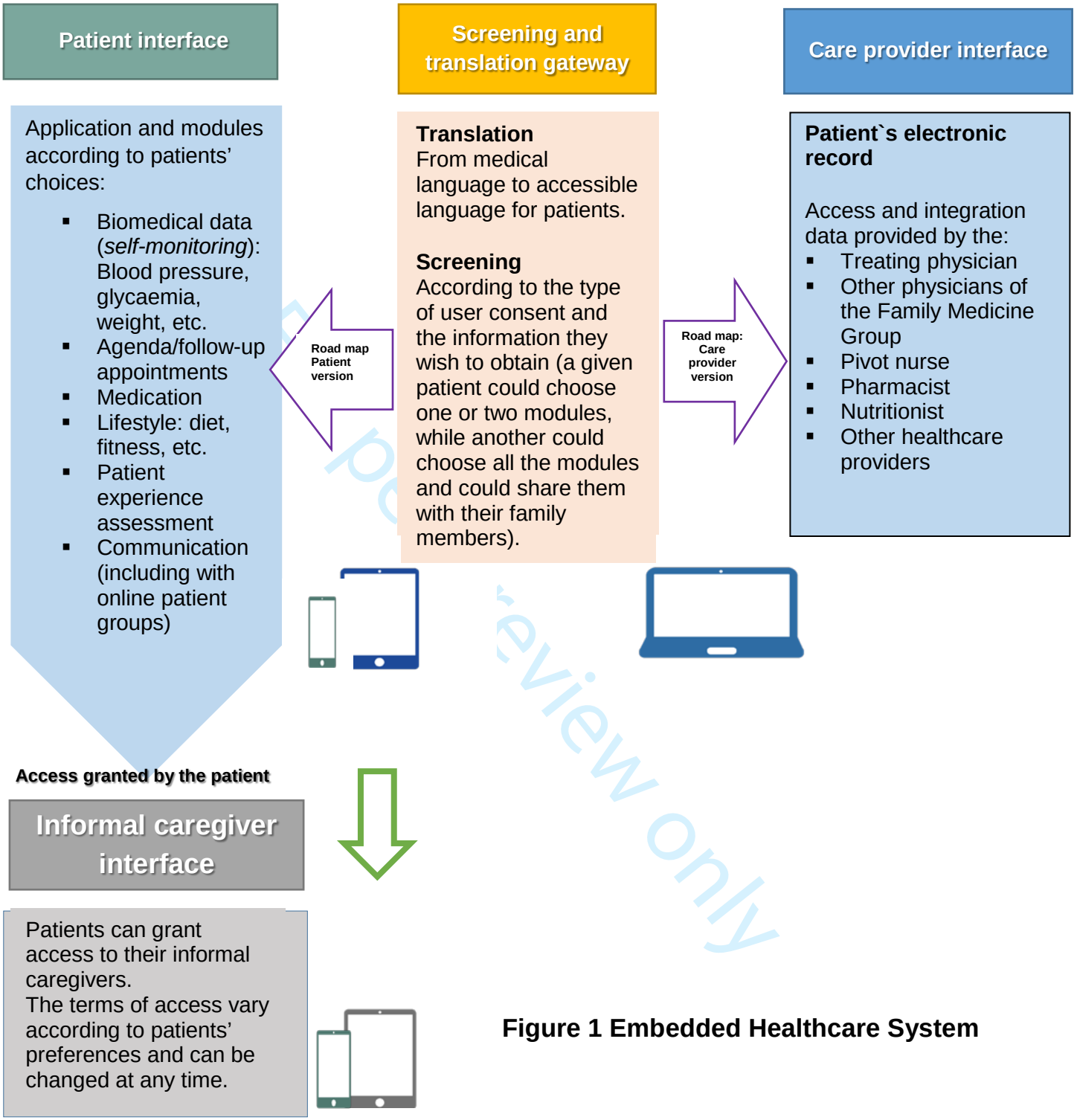

Figure 1 Embedded Healthcare System

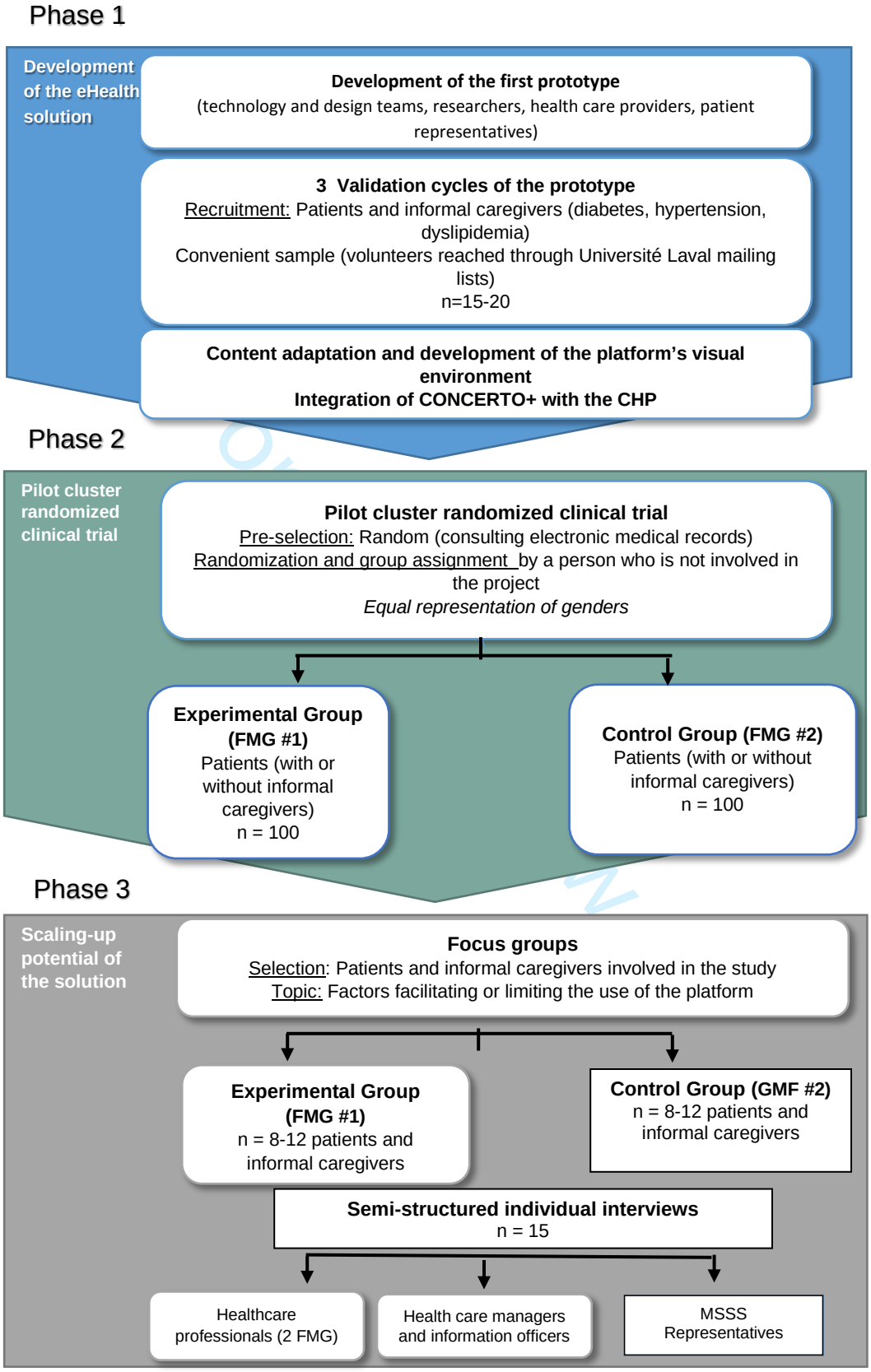

Figure 2 Recruitment flowchart

Supplementary File 1: Mesure d'activation du patient (PAM-13) French translation

1. Activation du patient
Outil utilisé
Mesure d'activation du patient (*Patient Activation Measure-PAM-13*)
Critères [1]
1. En fin de compte, je suis la personne qui est responsable de gérer ma condition de santé **2.** Prendre un rôle actif dans mes soins de santé et le facteur le plus important pour déterminer ma santé et mon habileté pour fonctionner **3.** Je suis confiant que je peux prendre des actions qui m'aideront à prévenir ou minimiser certains symptômes ou problèmes associés avec ma condition de santé **4.** Je sais quels sont les effets de tous mes médicaments prescrits **5.** Je suis persuadé que je peux savoir quand j'ai besoin de soins médicaux et quand je peux gérer mes problèmes de santé par moi-même **6.** Je suis persuadé que je peux exprimer à mon professionnel de la santé mes préoccupations même quand il ou elle ne le demande pas **7.** Je suis convaincu que je peux appliquer les traitements médicaux dont j'ai besoin à la maison **8.** Je comprends la nature et les causes de ma condition de santé **9.** Je connais les différentes options de traitements médicaux qui sont disponibles pour ma condition de santé **10.** J'ai été capable de maintenir des changements de style de vie que j'ai adopté pour ma santé **11.** Je sais comment prévenir des problèmes ultérieurs en lien avec ma condition de santé **12.** Je suis confiant que je peux trouver des solutions quand des nouvelles situations ou problèmes apparaissent en lien avec ma condition de santé **13.** Je suis persuadé que je peux maintenant des changements de style de vie comme une diète et de l'exercice même durant des périodes de stress
Mesure des résultats
Notation (pour chaque critère) **:** ▪ Fortement en désaccord (1 point) ▪ En désaccord (2 points) ▪ En accord (3 points) ▪ Fortement en accord (4 points) **Niveaux d'activation** (selon la conversion des résultats sur un score de 100) **:** 1. Ne croit pas que l'activation est important (≤ 47) 2. Manque de savoir ou de confiance pour agir (47.1-55.1) 3. Commence à agir (55.2-67) 4. Agit (≥ 67.1)

[1] Adapté de: Moljord I E O, Lara-Cabrera ML. Perestelo-Pérez L, Rivero-Santana A, Eriksen L, Linaker OM. Psychometric properties of Patient Activation Measure-13 among out-patients waiting for mental health treatment: a validation study in Norway. *Patient education and counseling*. 2015*98*(11):1410-1417.

Traduction libre

2. Impacts de l'utilisation de CONCERTO+
Outil utilisé
Questionnaire utilisé lors de l'évaluation de la phase pilote du Programme de santé Concerto [1]
Critères [2]
Résolution de problèmes/conseils : 1. Vous a-t-on demandé quels étaient les effets de votre maladie sur votre vie ? 2. Vous a-t-on aidé à planifier afin de pouvoir prendre soin de votre état de santé même en des moments difficiles ? 3. Vos fournisseurs de soins tenaient-ils compte de vos valeurs et de vos traditions au moment de vous recommander un traitement ? 4. Vous a-t-on aidé à élaborer un plan de traitement que vous pourriez mettre en pratique dans votre vie quotidienne ? **Prestation de soins/aide à la décision :** 1. Vous a-t-on posé des questions sur vos habitudes de santé ? 2. Vous a-t-on encouragé à faire partie d'un groupe ou d'une classe, comme une session d'information éducative, pour vous aider à vivre avec votre état de santé chronique ? 3. Vous a-t-on remis une copie de votre plan de traitement ? **Établissement des objectifs/personnalisation :** 1. Vous a-t-on demandé de parler de vos objectifs en ce qui concerne la manière de prendre soin de votre condition chronique ? 2. Vous a-t-on aidé à fixer des objectifs spécifiques pour améliorer votre alimentation ou votre activité physique ? 3. Vous a-t-on montré comment ce que vous avez fait pour prendre soins de vous-même a influencé votre condition chronique ? 4. Vous a-t-on remis une liste écrite des choses que vous devriez faire pour améliorer votre santé ? 5. Étiez-vous satisfait de la manière dont vos soins étaient organisés ? **Coordination des soins :** 1. Vous a-t-on dirigé vers un diététiste, un éducateur en matière de santé ou un conseiller ? 2. Vous a-t-on dit comment vos visites chez d'autres genres de médecins (p. ex., spécialiste, chirurgien) contribuaient à votre traitement ? 3. Vous a-t-on demandé comment se passaient vos visites chez les autres médecins ? 4. A-t-on communiqué avec vous après une visite pour savoir comment les choses se passaient ? **Globalité des soins :** Depuis que vous utilisez CONCERTO+, avez-vous… 1. Pu obtenir un rendez-vous avec un professionnel de la clinique ? 2. Été aidé(e) lorsque vous en aviez besoin ? 3. Obtenu un rendez-vous de suivi de votre condition de santé ? 4. Eu besoin d'entrer en contact avec un professionnel de l'équipe ou reçu une réponse de l'un d'entre eux à la suite de votre appel téléphonique ? 5. L'impression que votre infirmière coordonne l'ensemble de vos soins ?

[1] Adapté de : McIntosh, CN. Examen de la validité factorielle de certains modules de l'Enquête canadienne sur l'expérience des soins de santé primaires. Statistique Canada, Division de l'information et de la recherche sur la santé. Juillet 2008.

[2] Ces critères ont été développés initialement et validés par Glasgow et collaborateurs : Glasgow RE, Wagner EW, Schaefer J, MahoneyLD, Reid RJ, Greene SM. 2005. Development and validation of the patient assessment of chronic illness care (PACIC). Medical Care. 43, 5: 436–444.

6. Le sentiment que l'équipe du Programme a tenu compte de votre problème de santé ? 7. Pu constater que l'on a tenu compte de vos consultations avec d'autres professionnels de la santé que ceux de l'équipe du Programme ? 8. Pu vous faire aider à comprendre vos résultats de tests (par exemple : test de laboratoire, prise de pression, etc.) ? 9. Obtenu une réponse lors d'une situation urgente pour vous ?

3. Acceptation de CONCERTO+
Outils utilisé
Questionnaire basé sur le Modèle d'acceptation de la technologie
Critères
Facilité d'utilisation perçue : 1. Mon interaction avec le système CONCERTO+ est claire et compréhensible 2. Je trouve qu'il est facile de demander au système CONCERTO+ de faire ce que je veux 3. L'utilisation de CONCERTO+ améliorera mon suivi 4. L'utilisation de CONCERTO+ améliorera mon efficacité à me prendre en charge **Utilité perçue :** 1. L'utilisation de CONCERTO+ améliorera mon état de santé 2. Je trouve que CONCERTO + est un outil utile pour le suivi de mon état de santé 3. L'utilisation de CONCERTO + plus intéressant. 4. J'aime travailler avec l'ordinateur. 5. Je cherche des aspects de mon métier qui demande d'utiliser l'ordinateur **Intention comportementale d'utiliser :** 1. Je vais utiliser CONCERTO+ dans le futur. 2. J'établis un plan pour utiliser CONCERTO+
4. Utilisation de CONCERTO+
Outil utilisé
Registres d'utilisation de CONCERTO+
Critères
Registres (*Logs*)

Supplementary File 2: Outcome measures and items (original English version)

1. Patient Activation
Tool used
Patient Activation Measure-PAM-13
Criteria[1]
1. When all is said and done, I am the person who is responsible for managing my health condition. 2. Taking an active role in my own healthcare is the most important factor in determining my health and ability to function. 3. I am confident that I can take actions that will help prevent or minimize some symptoms or problems associated with my health condition. 4. I know what each of my prescribed medications does. 5. I am confident I can tell when I need to go get medical care and when I can handle a health problem. 6. I am confident I can tell my health provider the concerns I have even when he or she does not ask. 7. I am confident I can follow through on the medical treatment I need to do at home. 8. I understand the nature and causes of my health condition. 9. I know the different medical treatment options available for my health condition. 10. I have been able to maintain the lifestyle changes I have made for my health. 11. I know how to prevent further problems with my health condition. 12. I am confident I can find a solution when new situations or problems arise with my health condition. 13. I am confident I can maintain lifestyles changes, like diet and exercise, even during times of stress.
Results measurement
Scoring (for each criteria)**:** ▪ Strongly disagree = 1 ▪ Disagree = 2 ▪ Agree = 3 ▪ Strongly agree = 4 **Activation level** (converted into a score of 100)**:** **1.** Not believing that activation is important (≤ 47) **2.** Lack of knowledge or confidence to take action (47.1-55.1) **3.** Beginning to take action (55.2-67) **4.** Taking action (≥ 67.1)

[1] Adapted from: Moljord I E O, Lara-Cabrera ML. Perestelo-Pérez L, Rivero-Santana A, Eriksen L, Linaker OM. Psychometric properties of Patient Activation Measure-13 among out-patients waiting for mental health treatment: a validation study in Norway. *Patient education and counseling*. 2015*98*(11):1410-1417.

2. Impacts of the use of CONCERTO+
Tool used
Survey used for the assessment of the CHP pilot
Criteria[1]
Problem-solving/Advice 1. Have you been asked how your illness affects your life? 2. Have you been helped in planning ahead to take care of your illness even in hard times? 3. Did your care providers ask about your values and traditions when they recommended treatment? 4. Have you been helped in drawing up a treatment plan that you could follow in your daily life? **Delivery system design/Decision support** 1. Have you been asked about your health habits? 2. Have you been encouraged to go to a specific group or class to help you cope with your chronic illness? 3. Have you been given a copy of your treatment plan? **Goal-setting/Tailoring** 1. Have you been asked to talk about your goals in the context of receiving care for your chronic condition? 2. Have you been helped in setting specific goals to improve your diet or fitness? 3. Have you been given a written list of things you should do to improve your health? 4. Have you been shown how taking proper care of your illness influenced your condition? 5. Are you satisfied that your care was well organized? **Follow-up/Coordination** 1. Have you been referred to a dietitian, health educator, or counselor? 2. Have you been told how your visits with other doctors were going? 3. Have you been told how your visits with other types of doctors, such as a specialist or a surgeon, helped in your treatment? 4. Have you been asked how your visits with other doctors were going? 5. Have you been contacted after a visit to see how things were going? **Overall care[2]** Since you began using CONCERTO+ 1. Have you had an appointment with a professional from the clinic? 2. Have you received help when you were in need? 3. Have you had a follow-up appointment for your health condition? 4. Have you been helped through contact with a professional from the team or by receiving an answer from one of the team members after a phone call? 5. Have you had the feeling that your nurse coordinates all of your care? 6. Have you had the feeling that your health problems are being taken into account by the Program team? 7. Have you noticed that your visits with other health professionals are being taken into account by the Program team? 8. Have you been helped in understanding your test results (e.g. laboratory test, pressure tap, etc.)? 9. Have you received an answer in emergency situations?

[1] These criteria were originally developed and validated by Glasgow RE, Wagner EW, Schaefer J, Mahoney LD, Reid RJ, Greene SM. 2005. Development and validation of the patient assessment of chronic illness care (PACIC). Medical Care. 43, 5: 436–444.

[2] Adapted from McIntosh, CN. Examen de la validité factorielle de certains modules de l'Enquête canadienne sur l'expérience des soins de santé primaires. Statistique Canada, Division de l'information et de la recherche sur la santé. July 2008.

3. Acceptance of CONCERTO+
Tool used
Survey based on the *Technology Acceptance Model*
Criteria
Perceived ease of use 1. My interaction with CONCERTO+ is clearer and more comprehensive. 2. I find it is easy to get CONCERTO+ to do what I want it to do. 3. The use of CONCERTO+ will improve my follow-up. 4. The use of CONCERTO+ will improve the effectiveness of my care. **Perceived usefulness** 1. The use of CONCERTO+ will improve my health condition. 2. I find CONCERTO+ to be a useful tool for the follow-up of my health condition. 3. The use of CONCERTO+ is interesting. 4. I like to use a smart phone or a tablet to look for health information. 5. I'm eager to use technology to manage my health condition. **Behavioural intention to use** 1. I'm going to use CONCERTO+ in the future. 2. Using CONCERTO+ is part of my plan.
4. The use of CONCERTO+
Tool used
CONCERTO+ logs use
Criteria
Logs

Supplementary File 3: ExpandNet recommendations for scaling up (WHO, 2013) Original English version

1. Engage in a participatory process involving key stakeholders.
2. Ensure the relevance of the proposed innovation.
3. Reach a consensus on expectations for scale up.
4. Tailor the innovation to the socio-cultural and institutional settings.
5. Keep the innovation as simple as possible.
6. Test the innovation in the variety of socio-cultural and institutional settings where it will be scaled up.
7. Test the innovation under routine operating conditions and existing resource constraints of the health system.
8. Develop plans to assess and document the process of implementation.
9. Advocate with donors and other sources of funding for financial support beyond the pilot stage.
10. Prepare to advocate for necessary changes in policies, regulations, and other health systems components.
11. Develop plans for how to promote learning and disseminate information.
12. Plan on being cautious about initiating scale up before the required evidence is available.

Supplementary File 4: Recommandations d'ExpandNet pour le passage à l'échelle (OMS, 2013) (French translation)

1. Engager un processus participatif impliquant les principales parties prenantes
2. Assurer la pertinence de l'innovation proposée
3. Trouver un consensus sur les attentes à propos du passage à grande échelle
4. Ajuster l'innovation aux cadres socioculturels et institutionnels
5. Garder l'innovation aussi simple que possible
6. Tester l'innovation dans la variété de cadres socioculturels et institutionnels où elle passera à grande échelle
7. Tester l'innovation dans les conditions de fonctionnement de routine et sous les contraintes de ressource actuelles du système de santé
8. Planifier l'évaluation et la documentation du processus de mise en œuvre
9. Plaider auprès des bailleurs de fonds et autres sources de financement pour un soutien financier au-delà de la phase pilote
10. Se préparer à plaider pour des changements nécessaires dans les politiques, règlements et autres composantes des systèmes de santé
11. Planifier la façon de promouvoir l'apprentissage et la diffusion de l'information
12. Se préparer à la prudence quant au lancement du passage à grande échelle avant l'obtention des preuves requises

Supplementary File 5: Ethical and funding approval (English translation)

ETHICS APPROVAL

Research project involving human beings or the consultation of personal information

This research project is reviewed in accordance with the
ethical procedures management of research with human beings of Université Laval
by the sectorial committee of research ethics in health science

Project title	Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare
Researcher's name	Marie-Pierre Gagnon
Approval number	2018-067 / 01-06-2018
Decision date	June 1, 2018
Approval expiration date	July 1, 2019

After reviewing the information and documents it has been provided, the committee notes that the project respects ethical principles of research with human beings. It takes note of the written confirmation of the researcher that she is aware of the follow-up actions[1] associated with ethical approval of this project and that she has agreed to apply them. Therefore, the committee approves this project for one year.

June 6, 2018

Mahmoud Rouabhia, Chair of the
Research Ethics Committee in
Health Sciences

[1] Follow-up action reminder on the next page.

Follow-up actions associated with ethics approval

For the project entitled **Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare** (file number: 2018-067)

1. Notify the Committee in writing without undue delay (independent of its statutory meeting agenda) in the following situations:

   - Any changes to the project, as approved this day, that would include changes to the choice of participants, to recruitment, to the obtention of consent, to the collection of data, and/or to the incurred risks or disadvantages before the application of any such changes (the template of the letter requesting an amendment is available on the CÉRUL website).

   - Any changes to the instrument used for recruitment (ads, posters, or other instruments), to the confirmation of consent (consent form, information sheet, or other forms of confirmation), or to the collection of data (survey, interview grid, or other data collection mechanisms) by providing the latest version of the document under consideration, where changes will be highlighted, before its use.

   - Any unexpected and serious event (e.g. psychological distress of a participant, threat against a person, unexpected or side effects of a product, a drug or a test) that may occur in the course of the current project and would involve a participant, by completing the VRR-EI form available on the CÉRUL website.

   - Any early termination of this research for any reason, be it funded or not, including reasons due to suspension or cancellation on the part of the granting agency.

2. Until the project is finished, and not only for recruitment, submit an annual renewal request for approval by providing a report on research progress, the number of recruited participants, and the difficulties encountered along the way, by using the VRR-107 form. The renewal request must be sent to the committee at least 30 days before the end date of the approval, independent of the statutory meeting agenda.

I, the undersigned, Marie-Pierre Gagnon, declare that I **have read and understood the above follow-up actions associated with ethics approval** and agree to apply them during the entire research project for which I am the principal researcher.

Signature of the principal researcher:_____ Date: 2018-06-04

Supplementary File 6: Ethical approval (original French version)

UNIVERSITÉ LAVAL

Vice-rectorat à la recherche et à la création
Comité d'éthique de la recherche

APPROBATION DE L'ÉTHIQUE

Projet de recherche impliquant des êtres humains ou
la consultation de renseignements personnels

Ce projet de recherche a été examiné en conformité avec les
Modalités de gestion de l'éthique de la recherche sur des êtres humains de l'Université Laval,
par le Comité sectoriel d'éthique de la recherche en sciences de la santé

Projet intitulé :	Personnaliser CONCERTO : L'expérience patient optimisée pour des soins intégrés, coordonnés et efficients
Nom du chercheur :	Madame Marie-Pierre Gagnon
Numéro d'approbation :	2018-067 / 01-06-2018
Date de décision :	1er juin 2018
Date d'expiration de l'approbation :	1er juillet 2019

Après examen des informations et des documents qui lui ont été transmis, le Comité a constaté que ce projet respecte les principes d'éthique de la recherche avec des êtres humains. Il prend acte de la confirmation écrite de la chercheure à l'effet qu'elle a pris connaissance des mesures de suivi[1] associées à l'émission de l'approbation éthique de son projet et qu'elle accepte de les appliquer. Par conséquent, le Comité approuve ce projet pour un an.

B. Rouabhia — 6 juin 2018

Mahmoud Rouabhia, président
Comité d'éthique de la recherche en sciences de la santé

Date

[1] Rappel des mesures de suivi au verso

Maison Michael-John-Brophy
2241, chemin Sainte-Foy
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cer@vrr.ulaval.ca
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UNIVERSITÉ LAVAL

Vice-rectorat à la recherche et à la création
Comité d'éthique de la recherche

Mesures de suivi associées à l'approbation éthique

Pour le projet intitulé : **Personnaliser CONCERTO : L'expérience patient optimisée pour des soins intégrés, coordonnés et efficients** (numéro de dossier : 2018-067)

1. Informer le Comité par écrit et dans les meilleurs délais (indépendamment du calendrier de ses réunions statutaires) des situations suivantes si elles se présentent :
   - de **toute modification au projet,** comme il a été approuvé en ce jour, qui comporterait des changements dans le choix des participants, dans le recrutement, dans la manière d'obtenir leur consentement, de réaliser la collecte des données ou encore, dans les risques ou inconvénients encourus par la participation, et ce, préalablement à l'application de ce changement (modèle de lettre de demande d'amendement disponible sur le site Internet des CÉRUL) ;
   - de **toute modification** qui serait apportée à un **instrument utilisé pour le recrutement** (annonces, affiches, etc.), pour confirmer le **consentement** (formulaire de consentement, feuillet d'information, etc.) ou pour effectuer la **collecte** des données (questionnaire, grille d'entrevue, etc.) en fournissant la nouvelle version du document concerné, où les modifications auront été mises en évidence, préalablement à son utilisation ;
   - de **tout événement imprévu et sérieux** (ex. : détresse psychologique d'un participant, menace proférée à l'égard d'une personne, effets secondaires ou imprévus ou indésirables d'un produit, d'un médicament ou d'un test, etc.) qui surviendrait dans le déroulement d'une activité du présent projet et qui impliquerait un participant, en complétant le formulaire VRR-EI disponible sur le site Internet des CÉRUL ;
   - de l'**interruption prématurée de ce projet de recherche** pour une raison quelconque qu'il soit financé ou non, y compris en raison de la suspension ou de l'annulation de l'approbation d'un organisme subventionnaire.
2. Tant que le projet ne sera pas terminé, et non seulement le recrutement, présenter annuellement une **demande de renouvellement** de l'approbation, en fournissant un rapport sur le déroulement de la recherche, le nombre de participants recrutés et, le cas échéant, sur les difficultés rencontrées en cours de réalisation, à l'aide du formulaire VRR-107. La demande de renouvellement doit être transmise au Comité dans un délai de 30 jours avant la date de fin de l'approbation, indépendamment du calendrier des réunions statutaires.

Maison Michael-John-Brophy
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Research title: Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare

Supplementary File 7: Consent form for validation cycles

This research entitled "Optimizing patient usability experience with an eHealth platform for embedded, coordinated and efficient healthcare" is conducted by Marie-Pierre Gagnon, from faculty of nursing at Université Laval.

Before you agree to take part in this research project, please take the time to read and understand the following information. This document will explain you the aim of this research project, his process, advantages, risks and disadvantages. We invite you to ask all questions you may deem necessary to the research staff. You can find their contact details at the end of the form.

Type of study

This research project aims to develop, implement and evaluate a user-centered, multifunctional and personalized eHealth platform (CONCERTO+) to promote a more active patient role in chronic disease management and decision-making, satisfaction towards healthcare services and quality of life. Specific objectives are to:

1) develop a module of a multifunctional and personalized eHealth platform integrated to the CHP (Concerto Health Program) for patients and caregivers allowing them to engage in the follow-up and management of their chronic diseases;

2) test the integration of CONCERTO+ in monitoring care pathways of three frequent co-existing chronic diseases (diabetes, hypertension, dyslipidemia) and assess the usefulness and acceptability of the solution for patients with chronic diseases and their caregivers;

3) assess the scalability of the CONCERTO+ solution.

The course of the participation:

Validation of the prototype of the application CONCERTO+

Your participation in this research will consist in validating the prototype of the application CONCERTO+. In practical terms, you should go to the usability laboratory of Université Laval lead by Dr Holly Witteman. The validation of the application will be done either on a smartphone or a digital tablet. The aim is to collect your input in visual presentation, content, usability of the application, the pros and cons and any consideration of the application developed. Iterative testing via three validation sessions will be organized. If you agree to participate to the validation cycles, your participation may have incur parking and travel expenses. In addition, the participation in each validation cycle requires approximately one and a half hour of your time.

Project approved by the sectorial committee of research ethics in health science of Université Laval (Approval number 2018-067), June 1st 2018. MPG

Research title: Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare

Potential benefits and risks or disadvantages related to your participation

There are no direct benefits for the participants. However, this research enables improve the adaptation and value of the CHP in order to provide a multifunctional and personalized eHealth platform, to promote a more active patient and informal care givers role in chronic disease management.

Compensation

If you participate in validation cycles, we can provide you a lump sum amount of 18 $ for the time you have allocated for this activity. This sum will be returned in each validation session.

Voluntary participation and right to withdraw

You are free to participate to this research project. You may voluntarily withdraw at any time without any justification and with no adverse consequences or without prejudice. However If you decide so, It is important to inform the research team whose contact details are included at the end of the document. All your personal information will be destroyed.

Confidentiality and data management

The following measures will be applied to ensure your private information stays private:

•Your name will not be mentioned in any report;

•The various documents will be codified and only the investigator and his team will have access to the list of names and codes;

• Your individual results will never be shared;

• In the interest of scientific rigor, the electronic data will be kept in a folder with a password on the web server of the Canada Research Chair on Technology and Practices in Health at Université Laval. They will be destroyed only five years after the end of the research, in December 2024;

• This research will be publicated in scientific reviews and no one can able to identify you;

• A short summary of the research results will be sent to you if requested by indicating the address where you would like to receive the document, just after the blank space provided for your signature.

Acknowledgment

Your collaboration is useful to achieve this study, thank you for your participation.

Additional information

If you have any question on the research, the involvement of your participation or if you want to withdraw from this research, please contact: Mame Awa Ndiaye, research coordinator, Amélie Lampron, research coordinator or Marie-Pierre Gagnon, principal investigator at the following coordinates:

• Mame Awa Ndiaye: mame-awa.ndiaye.ciussscn@ssss.gouv.qc.ca

• Amélie Lampron: amelie.lampron2.ciussscn@ssss.gouv.qc.ca

• Marie-Pierre Gagnon: marie-pierre.gagnon@fsi.ulaval.ca

Complaints and criticism

Any complaint and criticism related to this research project will be addressed to the Ombudsman office at Université Laval:

Pavillon Alphonse-Desjardins, bureau 3320

2325, rue de l'Université

Université Laval

Québec (Québec) G1V 0A6

Information - Secretariat : (418) 656-3081

Project approved by the sectorial committee of research ethics in health science of Université Laval (Approval number 2018-067), June 1st 2018. MPG

Research title: Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare

Toll-free line: 1-866-323-2271
Email: info@ombudsman.ulaval.ca

Signatures

I, the undersigned _____freely consent to participate to the research entitled: «Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare». I have read and understood the aim, type, advantages, risks and disadvantages of the research project. I' m satisfied with the explanations, further details and responses received from the investigator, where appropriate, about my participation to this project.

_____ _____
Participant signature Date

A short summary of the search results will be sent to you if requested by indicating the address where you would like to receive the document. The results will not be available before December 20th. If your address changes by that date, you are invited to inform the research team, the new address you wish to receive the document.

I wish receive a short summary ☐ No, I would prefer not to receive summary ☐

I would like to receive the summary at the following email address or mailing address:

_____

_____

I explained the aim, type of the study, advantages, risks and disadvantages of the research project I have answered to the best of my knowledge the questions asked and have verified the understanding of the participant.

_____ _____
Investigator or research coordinator signature Date

Copy of the participant.

Project approved by the sectorial committee of research ethics in health science of Université Laval (Approval number 2018-067), June 1st 2018. MPG

Research title: Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare

List of the team members/ Names of project partners	Role in the project
Marie-Pierre Gagnon	Specialist of patient engagement and eHealth technology assessment
Christian Chabot	Patient partner, co-designer of the project
Guylaine Chabot, Alain Larouche	Technological partners
France Légaré, Anik Giguère, Annie LeBlanc	Experts in shared decision making
Samira Rahimi Abbasgholizadeh	Expert in decision aids tools
Jean-Paul Fortin, Aude Motulsky, Claude Sicotte	Experts in evaluation of health information systems
Holly Witteman	Expert in adaptation of user-centered technologies
Ronald Buyl	Expert in medical informatics and biostatistics
Carole Délétroz	Expert in health literacy
Erik Kavanagh, Frédéric Lépinay, Jacynthe Roberge	Specialists in application development and design
Amélie Lampron, Mame Awa Ndiaye	Research coordinators

Project approved by the sectorial committee of research ethics in health science of Université Laval (Approval number 2018-067), June 1st 2018. MPG

Research title: Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare

Supplementary File 8: Consent form (patients and informal caregivers) 2a

This research entitled "Optimizing patient usability experience with an eHealth platform for embedded, coordinated and efficient healthcare" is conducted by Marie-Pierre Gagnon, from faculty of nursing at Université Laval.

Before you agree to take part in this research project, please take the time to read and understand the following information. This document will explain you the aim of this research project, his process, advantages, risks and disadvantages. We invite you to ask all questions you may deem necessary to the research staff. You can find their contact details at the end of the form.

Type of study

This research project aims to develop, implement and evaluate a user-centered, multifunctional and personalized eHealth platform (CONCERTO+) to promote a more active patient role in chronic disease management and decision-making, satisfaction towards healthcare services and quality of life. Specific objectives are to:

1) develop a module of a multifunctional and personalized eHealth platform integrated to the CHP (Concerto Health Program) for patients and caregivers allowing them to engage in the follow-up and management of their chronic diseases;

2) test the integration of CONCERTO+ in monitoring care pathways of three frequent co-existing chronic diseases (diabetes, hypertension, dyslipidemia) and assess the usefulness and acceptability of the solution for patients with chronic diseases and their caregivers;

3) assess the scalability of the CONCERTO+ solution.

The course of the participation:

1) Validation of the prototype of the application CONCERTO+

Your participation in this research will consist in using the application CONCERTO+ (intervention group) or to continue your usual health follow-up (control group). For the participants of the intervention group, the use of the application will be explained to you by the members of the research team. You will complete a short questionnaire at the beginning and at the end of a six months period use, which will focus on the following points:

- Health management
- Feelings in competency and self confidence in health management
- Impacts of CONCERTO+ use
- The use of CONCERTO+

2) Focus group

Your participation in this research consists in participating in a focus group composed of 8 -12 people. The discussion will last approximately two hours and will focus on conditions and factors related to the wide-scale dissemination of the solution CONCERTO+.

Project approved by the sectorial committee of research ethics in health science of Université Laval (Approval number 2018-067), June 1st 2018. MPG

Research title: Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare

Potential benefits and risks or disadvantages related to your participation

There are no direct benefits for the participants. However, participating in this research enables improve the adaptation and value of the CHP in order to provide a multifunctional and personalized eHealth platform, to promote a more active patient and informal care givers role in chronic disease management.

Compensation

If you accept to participate, a lump sum of 50 $ will be offered to you for the time you have allocated for this activity. This sum will be returned to you during the focus group discussion.

Voluntary participation and right to withdraw

You are free to participate to this research project. You may voluntarily withdraw at any time without any justification and with no adverse consequences or without prejudice. However If you decide so, It is important to inform the research team whose contact details are included at the end of the document. All your personal information will be destroyed.

Confidentiality and data management

The following measures will be applied to ensure your private information stays private:

•Your name will not be mentioned in any report;

•The various documents will be codified and only the investigator and his team will have access to the list of names and codes;

• Your individual results will never be shared;

• In the interest of scientific rigor, the electronic data will be kept in a folder with a password on the web server of the Canada Research Chair on Technology and Practices in Health at Université Laval. They will be destroyed only five years after the end of the research, in December 2024;

• This research will be publicated in scientific reviews and no one can able to identify you;

• A short summary of the research results will be sent to you if requested by indicating the address where you would like to receive the document, just after the blank space provided for your signature.

Acknowledgment

Your collaboration is useful to achieve this study, thank you for your participation.

Additional information

If you have any question on the research, the involvement of your participation or if you want to withdraw from this research, please contact: Mame Awa Ndiaye, research coordinator, Amélie Lampron, research coordinator or Marie-Pierre Gagnon, principal investigator at the following coordinates:

• Mame Awa Ndiaye: mame-awa.ndiaye.ciussscn@ssss.gouv.qc.ca

• Amélie Lampron: amelie.lampron2.ciussscn@ssss.gouv.qc.ca

• Marie-Pierre Gagnon: marie-pierre.gagnon@fsi.ulaval.ca

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Information - Secretariat : (418) 656-3081

Project approved by the sectorial committee of research ethics in health science of Université Laval (Approval number 2018-067), June 1st 2018. MPG

Research title: Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare

Toll-free line: 1-866-323-2271
Email: info@ombudsman.ulaval.ca

Signatures

I, the undersigned _____freely consent to participate to the research entitled: «Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare». I have read and understood the aim, type, advantages, risks and disadvantages of the research project. I' m satisfied with the explanations, further details and responses received from the investigator, where appropriate, about my participation to this project.

_____ _____
Participant signature Date

Do you wish to participate in the first step of this research involving the use of application CONCERTO+ and the completion of two questionnaires on the active involvement?

Yes, i accept to participate ☐ No, i would prefer not to participate ☐

Do you wish to participate in the second step of the project involving the participation in a focus group on factors and conditions related to the wide-scale dissemination of the solution CONCERTO+?

Yes, i accept to participate ☐ No, i would prefer not to participate ☐

A short summary of the search results will be sent to you if requested by indicating the address where you would like to receive the document. The results will not be available before December 20th. If your address changes by that date, you are invited to inform the research team, the new address you wish to receive the document.

I wish receive a short summary ☐ No, I would prefer not to receive summary ☐

I would like to receive the summary at the following email address or mailing address:

_____

_____

I explained the aim, type of the study, advantages, risks and disadvantages of the research project I have answered to the best of my knowledge the questions asked and have verified the understanding of the participant.

_____ _____
Investigator or research coordinator signature Date

Copy of the participant.

Project approved by the sectorial committee of research ethics in health science of Université Laval (Approval number 2018-067), June 1st 2018. MPG

Research title: Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare

Supplementary File 9: Consent form (interviews)

This research entitled "Optimizing patient usability experience with an eHealth platform for embedded, coordinated and efficient healthcare" is conducted by Marie-Pierre Gagnon, from faculty of nursing at Université Laval.

Before you agree to take part in this research project, please take the time to read and understand the following information. This document will explain you the aim of this research project, his process, advantages, risks and disadvantages. We invite you to ask all questions you may deem necessary to the research staff. You can find their contact details at the end of the form.

Type of study

This research project aims to develop, implement and evaluate a user-centered, multifunctional and personalized eHealth platform (CONCERTO+) to promote a more active patient role in chronic disease management and decision-making, satisfaction towards healthcare services and quality of life. Specific objectives are to:

1) develop a module of a multifunctional and personalized eHealth platform integrated to the CHP (Concerto Health Program) for patients and caregivers allowing them to engage in the follow-up and management of their chronic diseases;

2) test the integration of CONCERTO+ in monitoring care pathways of three frequent co-existing chronic diseases (diabetes, hypertension, dyslipidemia) and assess the usefulness and acceptability of the solution for patients with chronic diseases and their caregivers;

3) assess the scalability of the CONCERTO+ solution.

The course of the participation:

Your participation to this research consists in participating in one-on-one semi-structured interview with a member of the team. This interview will last approximately 30 minutes and will focus on the following points:

- Factors facilitating the use of CONCERTO+
- Factors limiting the use of CONCERTO+
- Support to the use of CONCERTO+ by health professionals
- Expansion of CONCERTO+

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Research title: Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare

Potential benefits and risks or disadvantages related to your participation

There are no direct benefits for the participants. However, participating in this research enables improve the adaptation and value of the CHP in order to provide a multifunctional and personalized eHealth platform, to promote a more active patient and informal care givers role in chronic disease management.

Compensation

If you accept to participate, a lump sum of 50 $ will be offered to you for the time you have allocated for this activity. This sum will be returned to you during the focus group discussion.

Voluntary participation and right to withdraw

You are free to participate to this research project. You may voluntarily withdraw at any time without any justification and with no adverse consequences or without prejudice. However If you decide so, It is important to inform the research team whose contact details are included at the end of the document. All your personal information will be destroyed.

Confidentiality and data management

The following measures will be applied to ensure your private information stays private:

•Your name will not be mentioned in any report;

•The various documents will be codified and only the investigator and his team will have access to the list of names and codes;

• Your individual results will never be shared;

• In the interest of scientific rigor, the electronic data will be kept in a folder with a password on the web server of the Canada Research Chair on Technology and Practices in Health at Université Laval. They will be destroyed only five years after the end of the research, in December 2024;

• This research will be publicated in scientific reviews and no one can able to identify you;

• A short summary of the research results will be sent to you if requested by indicating the address where you would like to receive the document, just after the blank space provided for your signature.

Acknowledgment

Your collaboration is useful to achieve this study, thank you for your participation.

Additional information

If you have any question on the research, the involvement of your participation or if you want to withdraw from this research, please contact: Mame Awa Ndiaye, research coordinator, Amélie Lampron, research coordinator or Marie-Pierre Gagnon, principal investigator at the following coordinates:

• Mame Awa Ndiaye: mame-awa.ndiaye.ciussscn@ssss.gouv.qc.ca

• Amélie Lampron: amelie.lampron2.ciussscn@ssss.gouv.qc.ca

• Marie-Pierre Gagnon: marie-pierre.gagnon@fsi.ulaval.ca

Complaints and criticism

Any complaint and criticism related to this research project will be addressed to the Ombudsman office at Université Laval:

Pavillon Alphonse-Desjardins, bureau 3320

2325, rue de l'Université

Université Laval

Québec (Québec) G1V 0A6

Information - Secretariat : (418) 656-3081

Project approved by the sectorial committee of research ethics in health science of Université Laval (Approval number 2018-067), June 1st 2018. MPG

Research title: Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare

Toll-free line: 1-866-323-2271
Email: info@ombudsman.ulaval.ca

Signatures

I, the undersigned _____freely consent to participate to the research entitled: «Personalize concerto: Patient usability experience optimized for embedded, coordinated, and efficient healthcare». I have read and understood the aim, type, advantages, risks and disadvantages of the research project. I' m satisfied with the explanations, further details and responses received from the investigator, where appropriate, about my participation to this project.

_____ _____

Participant signature Date

A short summary of the search results will be sent to you if requested by indicating the address where you would like to receive the document. The results will not be available before December 20th. If your address changes by that date, you are invited to inform the research team, the new address you wish to receive the document.

I wish receive a short summary ☐ No, I would prefer not to receive summary ☐

I would like to receive the summary at the following email address or mailing address:

_____

_____

I explained the aim, type of the study, advantages, risks and disadvantages of the research project I have answered to the best of my knowledge the questions asked and have verified the understanding of the participant.

_____ _____

Investigator or research coordinator signature Date

Copy of the participant.

Project approved by the sectorial committee of research ethics in health science of Université Laval (Approval number 2018-067), June 1st 2018. MPG

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

			Pages
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	6
	6b	Explanation for choice of comparators	
Objectives	7	Specific objectives or hypotheses	9
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	13
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	13
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	13
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	13-15

1Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	15
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	17
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	17
Methods: Assignment of interventions (for controlled trials)			
Allocation:			19
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	19
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	20
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	21
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	

	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	40
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	21-22
	31b	Authorship eligibility guidelines and any intended use of professional writers	
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary Files 6-8
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.