

International feasibility trial on the use of an interactive mobile health platform for cardiac rehabilitation: protocol of the Diversity 1 study

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ABSTRACT

Introduction The implementation of home-based cardiac rehabilitation has demonstrated potential to increase patient participation, but the content and the delivering of the programmes varies across countries. The objective of this study is to investigate whether an Australian-validated mobile health (mHealth) platform for cardiac rehabilitation will be accepted and adopted irrespectively from the existing organisational and contextual factors in five different European countries.

Methods and analysis This international multicentre feasibility study will use surveys, preliminary observations and analysis to evaluate the use and the user's perceptions (satisfaction) of a validated mHealth platform in different contextual settings.

Ethics and dissemination This study protocol has been approved by the Australian research organisation CSIRO and the respective ethical committees of the European sites. The dissemination of this trial will serve as a ground for the further implementation of an international large randomised controlled trial which will contribute to an effective global introduction of mHealth into daily clinical practice.

INTRODUCTION

Cardiac rehabilitation (CR) is a comprehensive programme involving exercise training, risk factor modification, education and psychological support (guidelines). Large studies in postmyocardial infarction (MI) or revascularisation patients have shown that CR decreases hospital admissions, improves health-related quality of life and may reduce long-term mortality.¹ However, referral, participation and components of the CR programmes vary widely across countries.² The implementation of home-based CR has demonstrated potential to increase patient participation by offering greater flexibility and options for activities, and by supporting

behavioural change³ although, to date, a relatively small number of CR programmes offer home-based programmes in Europe.⁴ The unstoppable increase of internet and communication technologies (ICT) integrated in modern societies can contribute to extending the delivery of home-based CR programmes. But, despite non-invasive mobile health (mHealth) technologies (including smartphone apps and wearable devices) having shown promising results for the delivery of CR content,⁵ their utilisation has not been effectively integrated in routine clinics.⁶ A limited number of controlled studies have shown the efficacy of using a smartphone app to improve uptake, adherence and completion in CR compared with centre-based programmes.⁷ However, it is not clear whether these results may be directly translated across countries with their respective different health systems, health organisations and CR protocols. As a practical example, cardiologists in Europe are generally active members of the CR team, whereas in Australia (the country in which the referred study was conducted) cardiologists have a limited referral and/or a consulting role. The purpose of this study is to trial a new model of digital health CR using platform in five different European countries. Cardihab is a start-up company based on an Australian-validated research programme.⁷ The main hypothesis is that this platform will be used and accepted as a complement to the traditional programmes in all five different European countries, irrespectively from the existing organisational and contextual factors of each country. A secondary hypothesis is that the use of mHealth will improve the multidisciplinary communication and coordination

into the CR team and, all this in alignment with the European Clinical Guidelines for Cardiac Prevention.⁸ Based on the current experience from this work, potential challenges and opportunities for international collaboration in mHealth studies will be discussed.

Aims

The study will assess the use and user's satisfaction (patients and healthcare professionals) of an Australian-validated mobile-based system for secondary prevention outcomes in European patients with post-MI.

METHODS

Study design, setting and inclusion criteria

This is a multicentre international feasibility study which will use surveys, preliminary observations and analysis. A total of 100 participants (20 patients per site) will be recruited in accordance with local routines from selected Health and Hospital Services of Belgium, Netherlands, Poland, Spain and Sweden. In total, more than 1500 patients are treated for acute MI every year at the five study centres and they will form the basis for the project cohort.

Patients will be sequentially screened for eligibility and offered participation in the study within 4 weeks of their index event (MI), preferably while still being treated in the coronary care unit or during their first visit at outpatient CR services. Specially trained research nurses and physiotherapists will be responsible for the recruitment process.

Inclusion criteria

1. Confirmed ST-elevation myocardial infarction (STEMI), non-ST myocardial infarction (non-STEMI) within the last 4 weeks.
2. Owns a smartphone and/or has access to the internet via a computer or tablet (surf pad) and can handle the software (either Android or Apple phones).
3. Ability (and willingness) to upload data either via Wi-Fi or mobile data.

The *exclusion criteria* include patients who have:

1. Remaining cardiac-related symptoms, clinically unstable or high medical care needs.
2. Three-vessel disease requiring coronary artery bypass grafting.
3. Expected survival <1 year.
4. Dementia, severe psychiatric illness or drug abuse.
5. Severe physical handicap limiting the patient's ability to participate in an exercise-based CR programme.
6. Not able to speak or understand the native spoken language at each respective country.

The intervention

All patients will be offered participation in CR programmes according to the usual routine at each centre. In all sites, usual clinical rehabilitation practice delivers in accordance to the 2016 European Guidelines

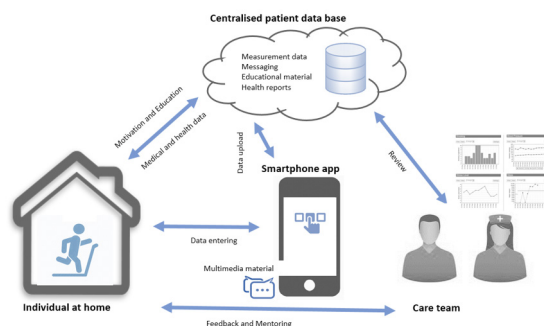


Figure 1 The new model of mobile-based cardiac rehabilitation.

on cardiovascular disease (CVD) prevention.⁸ The participants of the study will additionally receive access to a mobile-based CR service through an Australian company named Cardihab. This service is designed to support post-MI persons included in CR programme in terms of monitoring health measures and symptoms, as well as providing lifestyle and medication advice. Cardihab consists of three main parts: a mobile app for patients, a cloud-based database and a clinician dashboard for healthcare professionals (figure 1).

The patient interface

The patient interface is a mobile app that can be installed on smartphones or tablets (for both Google Android and Apple iOS operating systems), and will operate in the same manner in all countries. The patient can log information about his/her lifestyle (ie, physical exercise and smoking), measurements (ie, weight, pulse and blood pressure on a daily basis), symptoms and medication. Screenshots of the multilingual mobile app can be seen in figure 2. The patients can review their data in different graphs displaying registered values. The patient's customised tasks are presented daily where they are asked to confirm their adherence or what they did relevant to the task details. The software provides multilingual educational content on exercise, daily physical activity and healthy diet. If desired, short text messages are sent on a scheduled time. The text messages are tailored based on the patient's risk factors. The patient programme is customised, turning lifestyle/measurement options and reminders on or off depending on the needs and preferences of each patient.

The clinician interface

The app provides visual (graphical) and textual reports based on entered data, and the entries on the app will be automatically uploaded to the web-based database and displayed on the clinician dashboard (figure 3). This information is reviewed by a member of the CR team (doctors, nurses, physiotherapists, and so on) on a weekly basis, which allows targeted interventions and better resource management. The system also has the capability to deliver electronic reminders to assist medication management. In addition, the system gives the caregiver

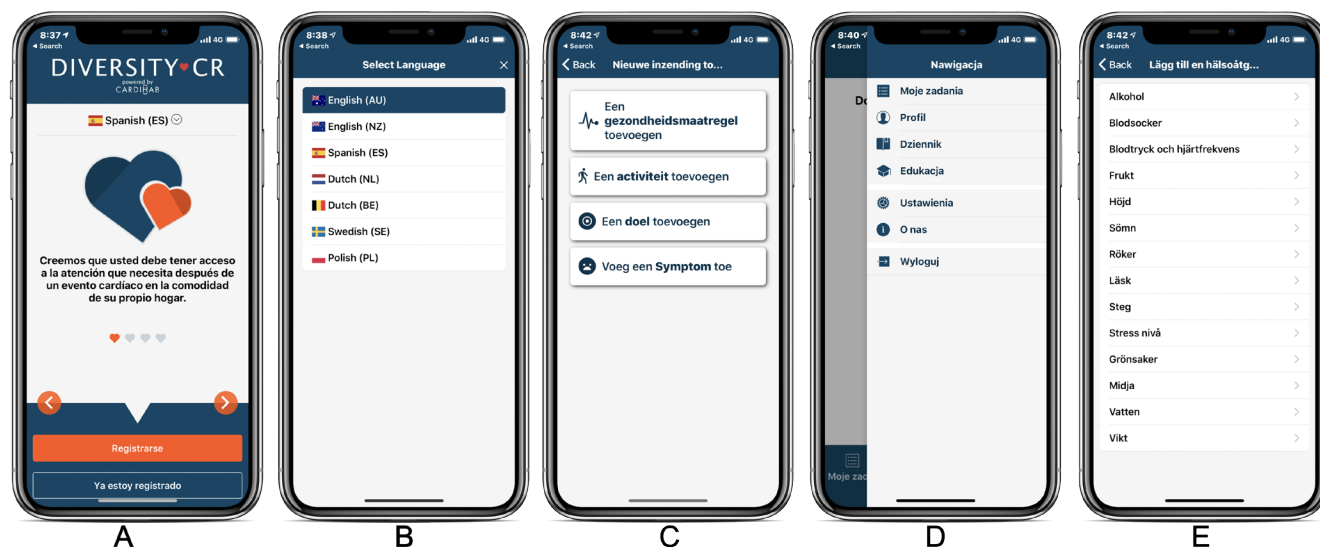


Figure 2 Screenshots of the multilingual Cardihab mobile app showing (A) Registration page in Spanish; (B) Select Language page in English; (C) New Data Entry page in Dutch; (D) Menu page in Polish; and (E) Health Measures in Swedish.

the opportunity to manage and guide individual patients or a group of patients.

The dashboard is password protected and enables healthcare practitioners to provide comprehensive care through viewing the participant's progress during scheduled case conference discussions and provide early care interventions if required. Data can also be reviewed by the healthcare practitioners during the face-to-face clinic

appointments to aid in discussions with the patients (figure 3).

Data collection and follow-up

After being informed and provided with the participant information sheet, all participants will be asked to sign the participant consent form. Patients who do not wish to be involved in the research will be offered the routine rehab

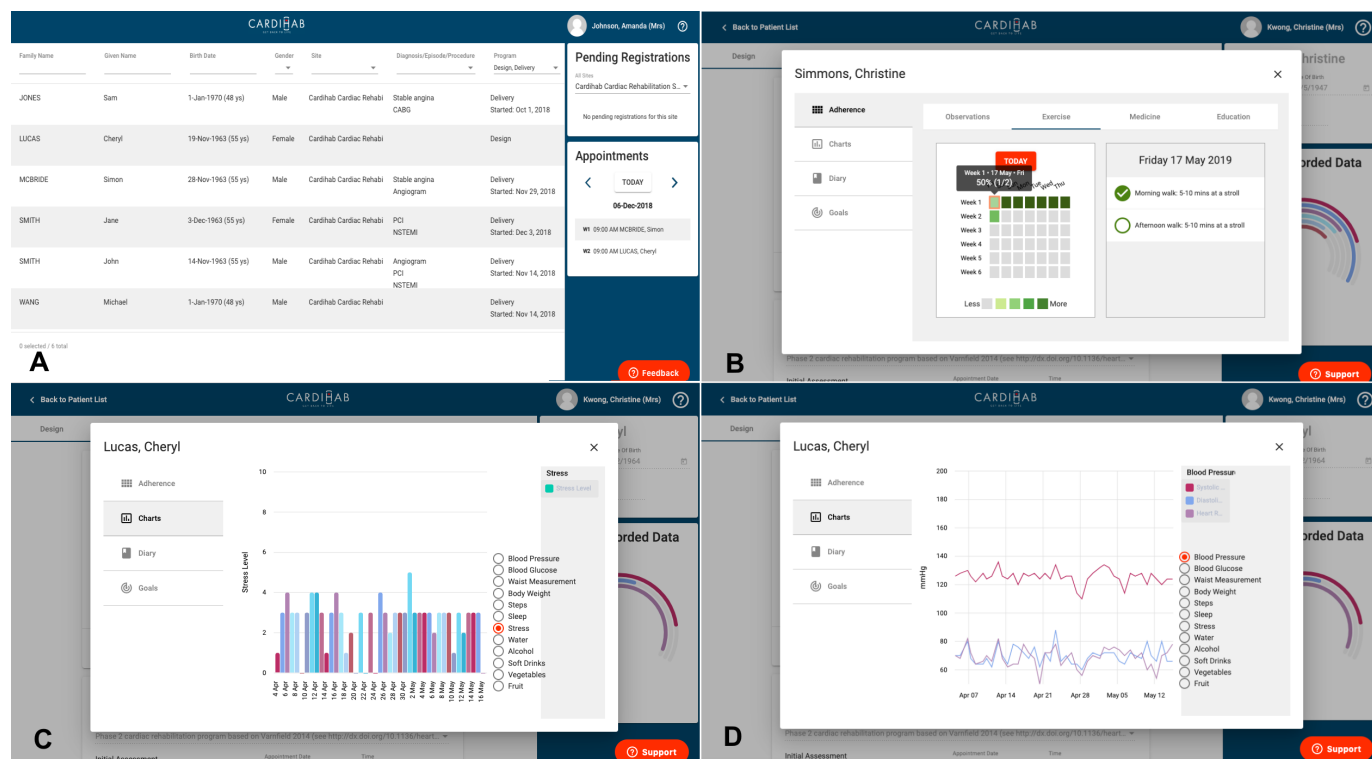


Figure 3 The Cardihab clinician dashboard. (A) List of patients. (B) Adherence page. (C) Stress chart. (D) Blood pressure graph.

care and will be excluded from data analysis. The mobile-based service aims to support the existing CR programme at each site. All components of the CR programmes will accomplish with recommended standards by the European Guidelines on CVD prevention in clinical practice.⁸ The existing CR programmes at each participant country may slightly differ in their follow-up timelines but, in all cases, the patients' first contact after discharge from hospital services (t1) will occur within 4 weeks and will be conducted either by a CR nurse or a physiotherapist visit. In the last case, a symptom-limited bicycle ergometer test will be performed. An end-study visit with a member of the CR team (physiotherapist or nurse) will occur when the patients had completed their CR programme at the CR centre and will occur in any case later than 6 weeks after the index event (t6). During this last visit, a second ergometer test may be offered. Laboratory measures of serum lipids, fasting plasma glucose and HbA1c are performed at the beginning of the programme (t1) and 6 weeks (t6) after the index event, followed by a telephone call in case of abnormal results. Web-based monitoring on lifestyle and risk factors (exercise, daily physical activity, diet and smoking) and self-rated health are weekly monitored by a CR nurse. In week 4 (t4), the nurse calls the patient after reviewing the data on the clinician dashboard to discuss progress on the programme. At baseline (t1) and end study (t6) satisfaction surveys will be collected from the patients (see online supplementary file 1) and from the multidisciplinary CR team involved in the study (see online supplementary files 2 and 3). The timeline and summarised study action plan are represented in a table (see online supplementary file 4).

Outcomes

The *primary outcomes* of this study are:

1. Use of the programme (mobile app and clinician dashboard) collected from server logs.
2. Users' perceptions (satisfaction levels) based on the responses from health workers and patients collected into REDCap surveys.

The *secondary endpoint* is:

- The proportion of enrolled patients completing the 6 weeks' Cardihab CR programme.

Timeline of research

As recruitment is projected to start progressively through 2019, and in each site, all participants are followed for 6 weeks, and the whole study will last 6 months, the final study results will first be available in the beginning/middle of 2020.

Integrity, security, interoperability and management of the data

Data provided by the patients are transferred to Cardihab's platform, which is deployed to a secured server hosted by Amazon Web Services (AWS) EU-central-1 region. All data will always remain within the EU-central-1 region. AWS cloud deployments have a shared responsibility model for

cloud security (<https://aws.amazon.com/compliance/shared-responsibility-model/>). AWS manages security 'of the cloud' while Cardihab is responsible for security 'within the cloud'. Cardihab has implemented comprehensive security management regulations which are based on AWS recommendations and industry best practice. Cardihab uses Health Level Seven International Fast Healthcare Interoperability Resources extensively, as an appropriate standard for data exchange, interoperability and processing by certified users.

Primary responsibility for data monitoring will be assumed by the local study coordinators at each site. The principal investigator (PI) at CSIRO will oversee all data sharing, data integrity and data security. The PI takes primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting. The trial will be run in accordance with Good Clinical Practice and all data will be handled according to European Data Protection Regulations.

Ethical considerations

All patients sign an informed consent before entering the study. The study complies with the Declaration of Helsinki. The study has been approved by the regional ethical review boards at each country and the CSIRO Ethical Committee.

DISCUSSION

The interest in mHealth for the management of chronic diseases has grown exponentially during the last years, equally so from the industry, from patients, as well as from healthcare services. As the adoption of ICT and mHealth is very limited in real clinical settings, further studies in the field are highly needed. In addition, the international research collaboration confers clear benefits to scientific progress in general (WHO). This study combines these two postulates evaluating the acceptance and adoption of a particular mHealth solution independently of the particular sociocultural and organisation's backgrounds. Based on our current transnational working experience, we anticipate some potential benefits of attempting the establishment of common protocols and research ground. Our international approach may present some methodological opportunities as, for example, enriching the study protocol with inputs from researchers with different experiences and backgrounds, increasing the number of potential study participants, increasing the visibility of the results and the potential of generating new research ideas, not necessarily related to the original trial and, last, but not least, by increasing funding opportunities for future studies. We expect that the outcomes of this feasibility study will support the implementation of further controlled trials and contribute to filling evidence gaps towards effective integration of mHealth technology in promoting participation and supporting the implementation of the current CR programmes.

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