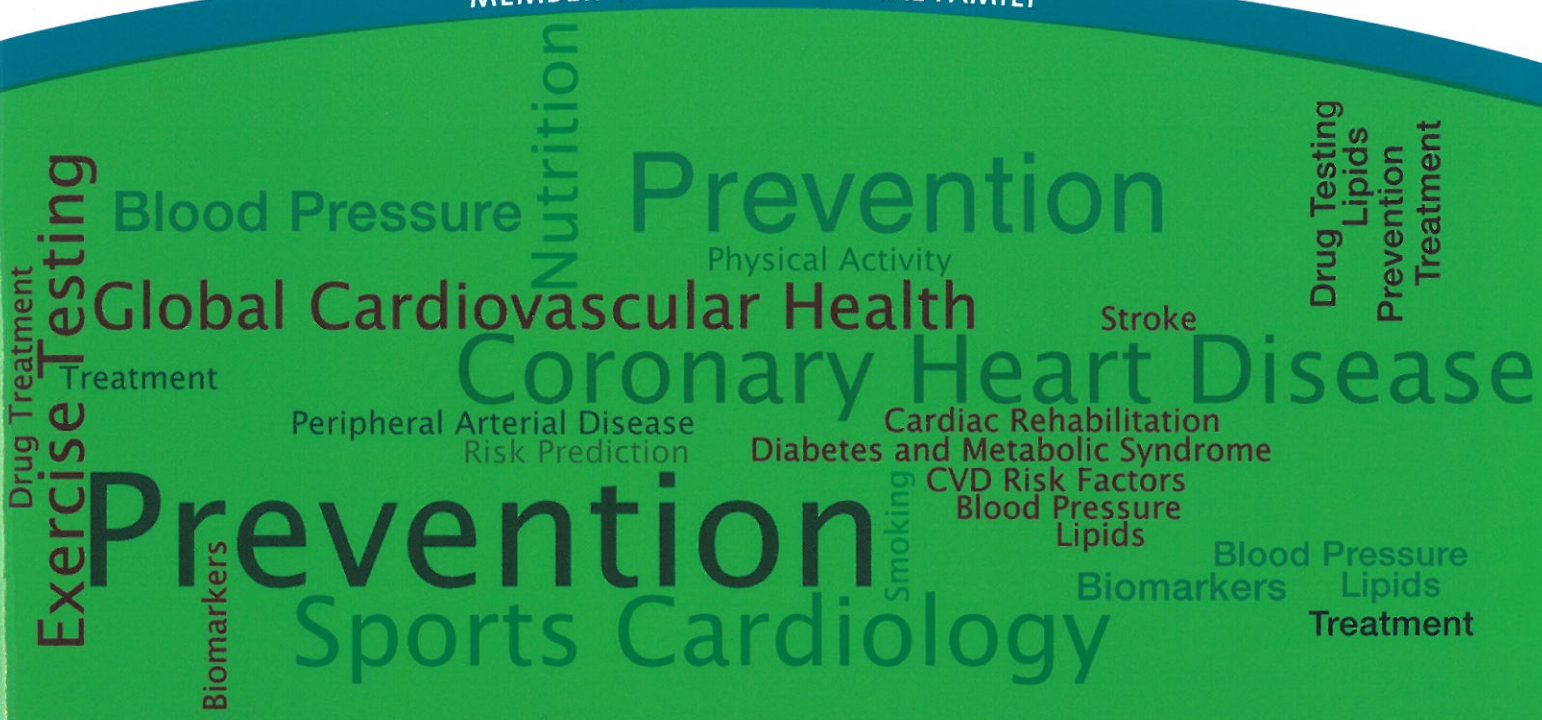


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Contents

Editorial

- eHealth: From unfulfilled promises to large-scale application 3
H Saner

Clinical update

- eHealth in cardiovascular medicine: A clinical update 5
H Saner and E van der Velde

Original scientific papers

- Screening for atrial fibrillation during influenza vaccinations by primary care nurses using a smartphone electrocardiograph (iECG): A feasibility study 13
J Orchard, N Lowres, SB Freedman, L Ladak, W Lee, N Zwar, D Peiris, Y Kamaladasa, J Li and L Neubeck

- Prognostic value of serial six-minute walk tests using tele-accelerometry in patients with chronic heart failure: A pre-specified sub-study of the TIM-HF-Trial 21
S Prescher, C Schoebel, K Koehler, O Deckwart, B Wellge, M Honold, O Hartmann, S Winkler and F Koehler

Best study design paper

- A European study on effectiveness and sustainability of current Cardiac Rehabilitation programmes in the Elderly: Design of the EU-CaRE randomised controlled trial 27
E Prescott, EP Meindersma, AE van der Velde, JR Gonzalez-Juanatey, MC Iliou, D Ardissino, GB Zoccai, U Zeymer, LF Prins, AWJ Van't Hof, M Wilhelm and EP de Kluiver

Abstracts

- European Congress on eCardiology & eHealth October 2016, Selected Abstracts 41

eHealth: From unfulfilled promises to large-scale application

Hugo Saner

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eHealth encompasses the use of information and communication technologies (ICTs) in the support of health and health-related activities.¹ The potential of eHealth to provide innovative solutions to health problems is enormous. This has raised high expectations by the public, by politicians and by healthcare professionals. Many see eHealth solutions as the ‘magic bullet’ to solve the numerous unsolved problems related to healthcare, particularly in times of constrained healthcare funding. Information and communication technology are expected to reduce the burden of diseases, to improve healthcare delivery and the experience of care for those living with chronic diseases, to facilitate more personalised and person-centred care at the right time and in the right place, and all this at reduced, or at least not increased, cost.

In contrast, the European Union eHealth action plan for 2012–2020 states that the promise of ICT to increase efficiency, improve quality of life and unlock innovation in health markets remains largely unfulfilled.² The main barriers to widespread adoption of eHealth have been identified, and the situation has not significantly improved over the last few years. First of all, the evidence base for the value of eHealth and telemedicine in managing a wide range of cardiovascular disease is increasing but is, on the whole, still weak and contradictory. Second, the development of eHealth and telemedicine is still primarily technically driven and not directed by the needs and expectations of clinically active health professionals. Third, common platforms and connectivity between tools and systems are mostly lacking, there are inherent uncertainties in such systems and there are major issues in the area of privacy and data protection. The use of big data and cloud computing have further magnified this problem. Finally, however, the lack of business cases, cost efficacy calculations and regulation of reimbursement of eHealth and telemedicine have turned out to be the major obstacles to the introduction of evidence-based eHealth and telemedicine tools into the healthcare system.

Recent developments in mobile technology, smartphones, widespread and almost permanent

Internet access, together with the speed of data exchange have accelerated the interest of both patients and industry in further exploring opportunities for using mHealth-related technologies to improve prevention, care and cure. Major companies such as Apple, Google, Samsung, etc. are investing heavily in healthcare-related technologies which will further increase the speed of development.

All these developments are overwhelming and need to be brought into perspective. The position of the European Society of Cardiology (ESC) has been recently described in the *European Heart Journal*.³ Cardiovascular medicine is involved with eHealth on many different levels. ESC members deal with the changes in practice that ICT innovation brings, including electronic medical records, e-referrals or e-prescribing, tele-consultation, telemonitoring, mobile health (mHealth) and the use of data mining and machine learning for medical research. Electronic data collection, registries, information networks and semantic inter-operability are further areas of ESC activities. The vision of the ESC is to play a proactive role in all aspects of the eHealth agenda, helping to develop, assess and implement effective ICT innovations in the support of cardiovascular health and health-related activity across Europe.

This supplement is devoted to the third European Congress on eCardiology and eHealth, with the aim of promoting current knowledge in ICT related to cardiovascular disease. The focus is on clinical application, evaluation and integration of eHealth and telemedicine into the healthcare systems of today. However, the integration of eHealth and telemedicine into clinical practice can only be successful if the major stakeholders are communicating better and are working closer together: stakeholders include persons at risk, consumer

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organisations, patients with cardiovascular disease, patient organisations, heart foundations, healthcare professionals, national professional organisations, health administrations, health insurance organisations, the European Commission, ICT researchers, developers of eHealth solutions, the ICT, pharmaceutical, medical diagnostic, therapeutics and device industries, app developers and mobile device manufacturers.

A clinical update article sets the stage for the range of opportunities and challenges in eHealth and telemedicine. The most promising areas, and also major obstacles, for clinical application are outlined. Topics of particular interest are disease prevention by use of mHealth applications to adhere to a healthy lifestyle, telemedicine care in chronic diseases including arterial hypertension, diabetes and heart failure, and telemonitoring of patients with electronic devices including pacemakers, resynchronisation therapy devices and/or internal defibrillators.

People with unknown atrial fibrillation, often asymptomatic, have a substantially increased risk of stroke. Therefore, screening for atrial fibrillation is a major issue for stroke prevention. The article by Jessica Orchard et al. has been selected for publication in this issue because of the innovative approach to integrate ECG screening into daily routine by primary care nurses during flu vaccination. This feasibility study has great potential to promote widespread use of such easily applicable screening procedures and lead to a reduction in the burden of stroke.

Another innovative approach to integrate eHealth and telemedicine into daily clinical practice, is the use of tele-accelerometry as an alternative to the traditional six-minute walking test for diagnostic and prognostic purposes. This has been evaluated in a field study in Germany and is described in a original research paper in this issue. Results are promising and the application of this test should be further evaluated in larger scale studies.

Although cardiac rehabilitation (CR) is an evidence-based intervention to improve quality of life and to increase survival, it is widely underused. In particular, elderly patients are less frequently referred to CR, show less uptake of CR and more drop-out from CR

programmes. Therefore, research efforts are important to improve this situation. The EU-CaRE randomised controlled trial aims at finding solutions to improve CR uptake in elderly patients. In the framework of this European multicentre study, the researchers' plan for finding ways to improve the effectiveness and sustainability of current CR programmes in the elderly is outlined in a study design paper.

This supplement also contains abstracts which have been submitted for this Congress and have been selected by the Congress faculty for publication based on their rating by reviewers. The topics cover a broad spectrum of eHealth and telemedicine and give an insight into the heterogeneity of potential future applications.

We hope that our Congress and this supplement will contribute to close the gap between technically driven progress and clinical application. An important challenge remains to keep the main focus on patient's individual needs and to carefully evaluate the evidence behind the practice.

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eHealth in cardiovascular medicine: A clinical update

Hugo Saner¹ and Enno van der Velde²

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Abstract

Demographic changes, progress in medicine technology and regional problems in providing healthcare to low density populations are posing great challenges to our healthcare systems. Rapid progress in computer sciences and information technologies have a great impact on the way healthcare will be delivered in the near future. This article describes opportunities and challenges of eHealth and telemedicine in the framework of our health systems and, in particular, in the context of today's cardiology services. The most promising applications of eHealth and telemedicine include: (a) prevention and lifestyle interventions; (b) chronic disease management including hypertension, diabetes and heart failure; (c) arrhythmia detection including early detection of atrial fibrillation and telemonitoring of devices such as pacemaker, internal cardioverter defibrillators and implantable rhythm monitoring devices; (d) telerehabilitation. Major obstacles to the integration of eHealth and telemedicine into daily clinical practice include limited large-scale evidence, in particular, for cost-effectiveness, as well as lack of interoperability, inadequate or fragmented legal frameworks and lack of reimbursement. An important challenge for those involved in these new technologies will be to keep the main focus on patient's individual needs and to carefully evaluate the evidence behind the practice.

Keywords

eHealth, telemedicine, digital health, mHealth, prevention, remote monitoring, tele-rehabilitation, cardiovascular disease

Introduction

Our health systems are facing great opportunities and at the same time great challenges. This is due to demographic changes, progress in medicine technology and regional problems in providing healthcare to low density populations. Furthermore, due to the increase of life expectancy and the increasing number of elderly people, there is an increasing need for the care and monitoring of elderly people still living at home and of people with chronic diseases.

eHealth encompasses the use of information and communication technologies (ICTs) in the support of health and health-related activities.¹ eHealth and telemedicine, as they are today, are not only seen as a supplement to the classic health delivery methods but will be integrated into private and public health economy as a main component of modern healthcare. Progress in eHealth and telemedicine is not only driven by health economic factors but in particular by the breathtaking speed of progress in computer sciences and information technology (Table 1).

However, there are major obstacles to the integration of eHealth and telemedicine into daily clinical practice. First of all, the evidence base for the value of eHealth and telemedicine in managing a wide range of cardiovascular disease is, on the whole, still weak and contradictory. Furthermore, the development of eHealth and telemedicine is still primarily technically driven and not by the needs and expectations of health professionals and patients, and thirdly, common platforms and connectivity between tools and systems are mostly lacking. Furthermore there are major issues in

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Table 1. Major opportunities for eHealth and telemedicine.

- Demographic changes:
 - More elderly people
 - More chronic diseases
- Increased need for treatment of chronic diseases
- Reverse negative life-style changes
- Take advantage of progress in medicine today
- Solve regional problems in providing healthcare to low density populations
- Provide easy access to data and documents:
 - Optimisation of treatment
 - Avoidance of redundant interventions

the area of privacy and data security. Last, but not least, there is a lack of business cases, cost efficiency calculations and regulation of reimbursement of eHealth and telemedicine which ultimately may turn out to be one of the biggest obstacles for the introduction of evidence-based eHealth and telemedicine tools into the health delivery system (Table 2).

This article provides an overview of the current status of eHealth and telemedicine in cardiovascular care with a main focus on cardiovascular disease prevention, therapy and rehabilitation and summarises the actual base of evidence for the most promising applications.

Table 2. Major challenges for eHealth and telemedicine.

Expectations public/media/political/industry
Scientific knowledge
Technical potential/opportunities
Political goals (national, European Union, worldwide)
Lack of communication between stakeholders
Lack of outcome research
Lack of business cases

eHealth

The term eHealth encompasses a range of services or systems that are at the edge of medicine/healthcare and information technology, including:²

- clinical information systems (electronic medical records, decision support and monitoring clinical and institutional practice);
- telemedicine and telecare (including disease management services, remote patient monitoring, teleconsultations and homecare);³
- integrated regional and national information networks and associated e-referrals and e-prescribing;
- disease registries and other non-clinical systems used for education, public health, patient/

disease-related behaviour and healthcare management;

- ‘mobile’ health (mHealth) including the use of mobile devices in collecting aggregate and patient level health data providing healthcare information to practitioners, researchers and patients, real-time monitoring of patient’s vital signs and direct provision of care (via mobile telemedicine using smartphones, mobile applications (apps)), social media, analytics and e-Cloud;
- ‘personalised’ health (pHealth): wearable or implantable micro- and nano-technologies with sensors and/or therapy delivery devices to help facilitate health and social care decision-making and delivery (including fall detectors, implantable insulin pumps, defibrillator vests, etc.);
- ‘Big Data’ – large scale integration and analysis of heterogeneous data sources, usually of high volume (amount of data), velocity (speed of data in and out), and variety (range of data types and source), ideally linked at the individual person level to provide a more holistic view of patient/individual and shed light on social and environmental factors that may influence health.⁴

mHealth

mHealth can be defined as the use of mobile computing and communication technologies for health services and information.⁵ It involves the use of mobile phone core functions including voice and short messaging services (SMSs), as well as more complex functions and specialized applications.^{5–12} Smartphones can be linked via Bluetooth technology with health parameter sensors and devices (i.e. glucometers). Use of these devices at the point of care is resulting in a change in the method of healthcare delivery from one that was health-systems generated to one that is remote and patient generated. The culmination of these factors presents unparalleled opportunities to increase patient engagement, to reduce healthcare costs, and to improve outcomes. Interventions may also include a platform where patients can contact their care provider by phone or via a video connection in case they have questions or emergency. The growing mobile phone networks, with increased accessibility providing the opportunity for more personalised and citizen-centred medical care, have been found to lower health system barriers, particularly patient access, as well as reduce healthcare service costs. A recent systematic review shows evidence of improved adherence, as well as health outcomes in disease management using mobile SMS systems and/or voice calls.¹³ Significant improvement has been

found on adherence with taking medicine, following diet and physical activity advice, as well as improvement in clinical parameters like glycohemoglobin (HbA1c), blood glucose, blood cholesterol and control of blood pressure and asthma.

As mHealth devices are becoming increasingly available, three important questions arise. Who should be the first digital health adopter: the patient, the provider or the healthcare system? What factors of mHealth are most effective? And what is the evidence supporting the clinical utilisation of such devices? A review searching for answers to these questions has recently been published in the *European Heart Journal*.⁸

Telemedicine

The term ‘telemedicine’ has a wide definition and is considered to be medicine practice at a distance and corresponds to a wide range of telemedicine applications.³ Telemedicine interactions have been of two types, either taking place in real-time such as for video conferences, or asynchronously such as store and forward transmission of data from home-based measurement of body weight, blood glucose, blood pressure and others. Mobile apps may be either automatic (e.g. passive monitoring of activity using room sensors) or require the patient to do something (e.g. transmitting home-measurement values using conventional telephones or, increasingly and in particular, smartphones).

Educational applications depend on web access from personal computers (PCs) or smartphones and are increasingly applied in medicine for distant learning and information. This application will turn out to be particularly useful for primary and secondary prevention of cardiovascular disease. Another important application includes remote monitoring of devices such as internal cardioverter defibrillators (ICDs) and/or pacemakers. Transmission of data from the device to a central database with the opportunity to survey patients’ data, and in particular heart rhythm, has a great potential to increase patients’ safety and, hopefully, also comfort. However, the evidence-base for the value of eHealth and telemedicine in managing a wide range of chronic diseases is still weak and contradictory. Promising applications of remote patient monitoring include prevention and lifestyle interventions, control of hypertension, diabetes and heart failure, arrhythmia detection and telerehabilitation (Table 3). However, first results from a most recent trial (Remote Management of Heart Failure Using Implantable Electronic Devices – REM-HF) challenges the expectation that remote ICD monitoring add clinical benefit in heart failure patients (oral presentation at ESC meeting 2016).

Table 3. Most promising application of remote patient monitoring.

-
- Prevention and lifestyle interventions
 - Chronic disease management
 - Hypertension
 - Diabetes
 - Heart failure
 - Arrhythmia detection
 - Telerehabilitation
-

Prevention and lifestyle interventions

Cardiovascular prevention is the most important intervention in cardiology economically and carries the greatest potential to reduce the burden of cardiovascular disease. Monitoring of cardiovascular risk factors seems to be particularly appealing for the use of telemedicine and in particular health applications to improve lifestyle and adherence to pharmacotherapy by surveillance, education, psychological support and interactive motivational tools i.e. to improve physical activity, healthy nutrition and smoking cessation and thus reduce metabolic risk factors and improve cardiovascular health.

Activity tracking devices are used widely across a variety of contexts. The expansion of activity tracking and personal data collection offers the potential for patient engagement in prevention and management of chronic diseases. Consumer-wearable devices for activity tracking have shown promise in post-surgery recovery in cardiac patients, pulmonary rehabilitation and activity counselling in diabetic patients, among others. Unfortunately, the data generated by wearable devices is seldom integrated into programmatic self-management chronic disease regimens. In addition, there is a lack of evidence supporting sustained use or effects on health outcomes, as studies are primarily focused on establishing the feasibility of monitoring activity and the association of measured activity with short-term benefits.¹⁴ Although smartphone apps and wearable sensors have the potential to help people make healthier lifestyle choices, scientific evidence of mHealth technologies’ effectiveness for reducing risk factors for heart disease and stroke is limited, according to a scientific statement from the American Heart Association (AHA).⁵

There are several studies in the area of telemonitoring and self-management in the control of hypertension.^{15–17} They show that monitoring blood pressure at a distance is effective and therefore is one of the most promising applications of telemonitoring of cardiovascular risk factors in primary care. However, results in regard to outcome and, in particular, to cost-effectiveness are either controversial or lacking.

Telemonitoring and self-management of diabetes is also an area of great interest. Research is somewhat less advanced in this area compared to blood pressure control. And reliable results in regard to feasibility, effects on blood glucose control, prognosis and cost-effectiveness are not yet available.

Furthermore, there are open questions in regard to liability. What are the responsibilities of the patient, what kind of action does he need to take under specific circumstances such as potentially dangerous measurement results and what is the task and responsibility of the telemedical centre or hospital being in charge of data surveillance? Which algorithms should be best used for big data management and for alerts in case of emergencies? Who is paying for what in such a telemedicine system? And will it improve outcome and save money long-term?

Early detection of arrhythmias

For a long time, remote monitoring of heart rhythm has been of interest for prevention of sudden death due to ventricular fibrillation in patients at risk and in patients with devices such as ICDs, pacemakers, Cardiac Resynchronization Therapies (CRT)s and implanted monitoring systems. Another emerging and very promising application of remote monitoring of heart rhythm is early detection of atrial fibrillation (AF).

AF is the most common clinical arrhythmia, which is responsible for at least 15% of strokes, and is the leading cause of stroke among patients >75 years old.^{18–20} Moreover, strokes due to AF are largely avoidable, as the use of oral anticoagulants along with the diagnosis and treatment of hypertension, can prevent >65% of all strokes. Therefore, early detection of AF, assessment of stroke and bleeding risk, and beginning of appropriate prevention are most important components of healthcare not only to reduce the burden of disease but also to reduce health costs.^{21,22}

Telemedicine in heart failure

Heart failure is a prevalent condition in western societies, affecting 1.5% of the population, and is associated with high hospitalization and readmission rates, high mortality and cost of care.²³ Management of acute and chronic heart failure poses substantial challenges to healthcare systems worldwide. Advances in telecommunication technologies have created opportunities to provide telemedical care as an adjunct to medical management of patients with heart failure.

Feasibility and perception of telemedical care by patients and physicians have been studied in the framework of the Telemedical Interventional

Monitoring in Heart Failure (TIM-HF) trial with the objective of proving the superiority of remote patient monitoring compared to guideline-based usual care in terms of total mortality, heart failure hospitalisation, quality of life and other markers of cardiovascular health.^{24,25} Two telemedical centres – located in two German regions – provided physician-led medical support for 24 h/day, seven days a week, according to defined standard operating procedures. Patients were enrolled from 165 practices in cardiology, internal medicine or general medicine, and were followed for at least 12 months with several outpatient visits. Results have been encouraging, showing the feasibility of telemedical care and good perception by patients and physicians.

Findings from four meta-analyses^{26–29} have shown that telemedical monitoring in chronic heart failure can reduce total mortality at a follow-up of 6–12 month, and can reduce the number and duration of hospital admissions for worsening heart failure. Since these meta-analyses were published, two prospective randomised prospective clinical trials of non-invasive approaches^{24,30} have not corroborated these findings for morbidity-related and mortality-related endpoints. The Sensitivity of the InSync Sentry OptiVol feature for the prediction of Heart Failure (SENSE-HF) trial³¹ used an invasive approach but also did not find benefit. By contrast, the CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in New York Heart Association (NYHA) Class III Heart Failure Patients (CHAMPION) trial^{32,33} reported that wireless implantable haemodynamic monitoring of pulmonary artery pressure used to guide efforts for treatment optimisation significantly reduced the risk, compared with the control group, of hospital admissions due to heart failure in patients with chronic heart failure in the New York Heart Association (NYHA) functional class III. A review searching for reasons for these contrasting results found that they are most probably due to the fact that telemedical approaches vary, and that a meta-analysis that combines different approaches is probably inappropriate.³⁴

Further research is needed to better define the role of telemedicine in the care of acute and chronic heart failure patients. However, there are some emerging and consistent findings indicating that (a) only high-risk patients can profit from telemonitoring after hospitalisation for acute heart failure (they represent approximately one-sixth of the total heart failure population), and (b) remote patient management (RPM) has the potential to reduce mortality in heart failure patients up to 30% (Implant-based multiparameter telemonitoring of patients with heart failure - IN-TIME) and reduction of heart failure related hospitalisations and

to improve quality of life (CHAMPION, TIM-HF).^{24,32,33,35}

The actual European Society of Cardiology (ESC) guidelines for the diagnosis and treatment of acute and chronic heart failure³⁶ recommend for the first time RPM of heart failure patients with a recommendation of grade II b. Further research to improve the burden of heart failure to patients and the community is better directed to define individual needs of heart failure patients and to study the potential benefits of RPM in heart failure patients to overcome regional differences in care (TIMI-HF II).

RPM with devices

The implantation of electronic cardiac devices such as pacemakers and ICDs has increased substantially over the last decade. Subsequent monitoring is an integral part of both device and patient care. Traditional practice consists of an in-clinical follow-up by physicians and/or device specialists to retrieve stored diagnostic data. This generates an enormous clinical workload which increases further when devices approach the moment when they need to be replaced, either electively, or in response to product advisories and recalls. The application of eHealth and telemedicine for RPM with implanted devices may provide mechanism(s) for facilitating these tasks.^{37–53}

Data are promising and it can be expected that remote monitoring systems will develop into dedicated monitoring and therapy platforms. We expect that data retrieved from these systems will form an integral part of the electronic patient record in the future as more and more outpatient clinic care will shift to personalised care provided at a distance, in other words at patients' homes. A provider perspective in five European countries on costs and net financial impact of follow-up with and without remote monitoring indicates that, for all patients as a whole, follow-up related costs for providers are no different for remote versus purely in-office follow-up, despite reorganised care. However, disparity in the impact on provider budget among different countries illustrates the need for proper reimbursement to ensure effective remote follow-up implementation.

Telerehabilitation

Exercise-based cardiac rehabilitation (CR) in hospital or in rehabilitation centres is the supervised intervention with the best scientific evidence: mortality reduction, symptom relief, smoking cessation and improved exercise capacity, risk factor modification and overall psychosocial wellbeing.⁵⁴ Based on the evidence-based benefits, CR is recommended by the AHA, the

American College of Cardiology (ACC), and the ESC guidelines for patients with coronary artery disease (CAD).^{55,56}

Despite evidence from trials and meta-analyses that CR 'works', only 15–30% of eligible patients participate.⁵⁷ This causes many to lament: 'Why don't more patients get referred to and use cardiac rehabilitation programs?'

Using telehealth to deliver cardiac rehabilitation has been proposed as an innovative way of improving patients uptake, choice and access.^{58,59} Systematic reviews have shown the benefits of telehealth programmes when compared to usual care.^{58–60} Telehealth exercise CR appears as effective as centre-based exercise CR for improving modifiable cardiovascular risk factors and functional capacity, and could enhance CR utilisation by providing additional options for patients who cannot attend centre-based exercise CR.⁶¹

A recent cost-effectiveness analysis shows the addition of cardiac telerehabilitation to conventional centre-based CR to be more effective and efficient than centre-based CR alone.⁶² These results are useful for policymakers responsible for deciding how limited health care resources should best be allocated in the era of exploding need. In Australia, a smartphone-based home care model improved post-myocardial infarction CR uptake, adherence and completion and may turn out to be another promising adjunct to centre-based rehabilitation.⁶³ Telerehabilitation may also support the patient in adhering to a healthier lifestyle (smoking cessation, activity tracking) and in adhering to medication use by integrating mobile phone text messages⁶⁴ and mHealth behaviour change interventions.⁶⁵ Furthermore, physical activity telemonitoring might be an effective intervention to increase the medium-term clinical benefits of hospital-based CR.⁶⁶

Conclusions

eHealth and telemedicine are rapidly evolving and will become an important component of today's medical care, but there is an important gap between technically driven progress and application-oriented research. Therefore, a great challenge for those involved in developing and implementing these new technologies will be to keep the main focus on patient's individual needs and not to be overwhelmed by the enormous speed of progress in technology and informatics and to carefully evaluate the evidence behind each new technology.

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Screening for atrial fibrillation during influenza vaccinations by primary care nurses using a smartphone electrocardiograph (iECG): A feasibility study

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Abstract

Background: People with unknown atrial fibrillation (AF), who are often asymptomatic, have a substantially increased risk of stroke. Although recommended in European guidelines, AF screening is not routinely performed. Screening at the time of influenza vaccination presents an ideal opportunity to detect AF in large numbers in a primary care medical setting, with an existing annual recall system for patients aged ≥ 65 years.

Design: Cross-sectional pilot study of handheld smartphone electrocardiogram (iECG) screening to identify unknown AF.

Methods: General practices in Sydney, Australia, were recruited during the influenza-vaccination period of April–June 2015. Practice nurses screened patients aged ≥ 65 years with a 30-second iECG, which has a validated algorithm for detecting AF in real time. In order to confirm the accuracy of the algorithm, two research cardiologists reviewed de-identified iECGs. In order to explore barriers and enablers, semi-structured interviews were conducted with selected nurses, practice managers and general practitioners.

Results: Five general practices were recruited, and 973/2476 (39%) patients attending influenza vaccination were screened. Screening took an average of 5 minutes (range 1.5–10 minutes); however, abnormal iECGs required additional time. Newly identified AF was found in 8/973 patients (0.8%). The sensitivity of the iECG automated algorithm was 95% (95% confidence interval: 83–99%) and the specificity was 99% (95% confidence interval: 98–100%). Screening by practice nurses was well accepted by practice staff. Key enablers were the confidence and competence of nurses and a ‘designated champion’ to lead screening at the practice. Barriers were practice specific, and mainly related to staff time and funding.

Conclusions: Screening with iECG during influenza vaccination by primary care nurses is feasible and well accepted by practice staff. Addressing barriers is likely to increase uptake.

Keywords

Atrial fibrillation, screening, stroke prevention, practice nurses, flu vaccination

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Introduction

Atrial fibrillation (AF) is the most common cardiac arrhythmia, affecting 5% of people aged ≥ 65 years, and its prevalence is predicted to at least double in the next 20 years due to the ageing population.¹ People with AF have greatly increased stroke risk, with such strokes likely to be severe.² At least one in three strokes are AF related,² and the proportion of strokes due to AF is increasing. The direct annual AF health system costs in Australia are at least \$874 million, largely being stroke related.³ Many people, particularly the elderly, are unaware that they have AF as they have no symptoms, with first diagnosis often made when they have a stroke.^{2,4} Stroke is highly preventable in AF with the appropriate use of oral anticoagulants (OACs),⁴ but worldwide, OACs are under-prescribed, with rates of approximately 60% of those eligible.⁵ In addition, only a quarter of people with AF-related stroke are on OACs at the time of their stroke.²

International guidelines recommend opportunistic screening for AF in the clinic by pulse palpation in people aged ≥ 65 years in order to reduce stroke due to AF,⁶ because increasing age is a strong risk factor for incident AF, as well as AF-related stroke. However, in practice, this recommendation is rarely implemented. Practice nurses are ideally placed to screen for AF, as people aged ≥ 65 years account for approximately a third of all general practice encounters.⁷ Practice nurses have been used to deliver a range of interventions and to improve the management of chronic conditions in primary care in Australia.⁸ In the UK, practice nurses have successfully delivered systematic AF screening using 12-lead electrocardiography (ECG); however, this was not deemed to be cost effective compared to general practitioner (GP) opportunistic screening.⁹ Our group has demonstrated that opportunistic screening in pharmacies using a handheld smartphone ECG (iECG) is feasible and cost effective,¹⁰ and that it is also feasible for practice nurses to screen using the iECG.¹¹

Ideally, iECG screening could be tied to a regular annual health appointment with the practice nurse, such as the seasonal influenza (flu) vaccination. A study in The Netherlands found that screening patients aged >65 years for AF during flu vaccination in the general practice setting was promising.¹² In Australia, the annual flu-vaccination programme is well entrenched and has excellent uptake, and is a time when patients are likely to be available and receptive to AF screening in an appropriate setting. Approximately 74% of Australians aged ≥ 65 years receive a flu vaccination each year,¹³ mostly from the practice nurse. Our health economic model, developed and published with SEARCH-AF,¹⁰ indicates that if a

single time point screening for unknown AF was extended to the 74% of Australians aged between 65 and 84 years who have an annual flu shot, >1300 strokes would be prevented due to the first round of screening alone. Therefore, our study aimed to determine the feasibility of practice nurse screening in Australia during the flu-vaccination period.

Methods

Study design

A cross-sectional pilot study of smartphone-based screening in order to identify unknown AF in Sydney, Australia, was conducted between April 2015 and June 2015 (ACTRN12615000622505). The study was approved by the University of Sydney Human Ethics Committee (2014/962). The iECG screening device used was the AliveCor Heart Monitor (Figure 1), which has approval from the Australian Therapeutic Goods Administration as a Medical Device, Class IIa, and has an automated algorithm that we have previously validated.¹⁴

A convenience sample of five general practices was recruited, and practice nurses at each general practice received face-to-face training from a member of the research team (LL) on implementing the screening protocol. This training involved an initial session of approximately 45 minutes and subsequent training/device support as required. All people aged ≥ 65 years attending their general practice for the flu vaccination were eligible to participate, with the exception of those with insufficient cognitive capacity or English proficiency to understand the consent process. Eligible participants from participating general practices were notified of screening in a letter that accompanied the invitation to have the annual flu vaccination. The Participant Information Sheet was also enclosed. Participants provided verbal consent, and this was documented on a consent log.



Figure 1. AliveCor heart monitor.

Screening procedure

Screening was conducted on consecutive participants attending the practice during the flu-vaccination period. Patients were asked to hold a smartphone in order to record an iECG for 30 seconds (Figure 1). The nurse entered the patient's details into the app and the iECG was then sent via Wi-Fi to a secure server and imported into the patient's electronic medical record. The algorithm provided an on-screen message at the end of the recording, which stated the recording was 'Normal', 'AF detected' or 'ECG unable to be classified'. For normal ECGs, no further action was taken. If AF was detected or if the ECG was not able to be classified, a 12-lead ECG was obtained, except where the participant had previously documented ECG abnormalities in their medical record. Subsequent management was at the discretion of the GP, and the study team had no involvement in determination of the management plan.

Individual patient-level data were not available to the study team. In order to confirm the accuracy of the automated algorithm, two research cardiologists (SBF and WL) reviewed de-identified iECGs. In order to ensure confidentiality, the research team could only view the iECGs on a purpose-built study website that removed all patient identifiers from the obtained iECGs. After completion of the screening period, practices were asked to provide additional de-identified data only on those who had AF detected on the iECG. These data included demographic data, together with the patients' CHA₂DS₂-VASc score and information on whether the patients were prescribed OACs or antiplatelets before and after screening.

Process evaluation and qualitative analysis

In order to understand the relevant barriers and enablers to screening for AF in general practice, a detailed process evaluation was carried out. Semi-structured interviews were conducted face-to-face with selected practice nurses, practice managers and GPs. Interviewees provided written informed consent. Interviews were audio-recorded, transcribed and analysed thematically by four members of the research team (LN, NL, LL and JO). The analysis explored participants' views on screening by nurses during the flu-vaccination period, the screening workflow and protocols for an abnormal result. The interviews were complete when thematic saturation was achieved. The research team discussed and refined the analysis in order to reach a final consensus on the main themes in terms of barriers and enablers.

Outcomes

Primary outcome

1. Proportion of people aged 65 years or over attending their general practice for a flu vaccination screened with the iECG by the practice nurse.

Secondary outcomes

1. Proportion of participants with newly identified AF (identified on the iECG AliveCor app and confirmed with a 12-lead ECG).
2. Estimate stroke risk of participants identified with AF (calculated using CHA₂DS₂-VASc score).
3. The accuracy of the automated AF algorithm for identifying AF (calculated using sensitivity and specificity; compared to two cardiologists' interpretations of the iECG).
4. Identify relevant barriers and enablers to screening.

Results

General practices

Five general practices in urban Sydney were recruited to the study. One practice had participated in a previous trial of AF screening with the practice receptionist delivering the intervention.¹¹ The others had responded to an article about the study published in a Primary Health Network (previously Medicare Local) e-newsletter, or were recruited through personal contacts. Each practice had at least two practice nurses employed.

Participants

A total of 2476 patients aged ≥ 65 years attended the general practices for the annual flu vaccination. Of these, 972 (39%) unique patients had an iECG recorded. From these recordings, the on-device algorithm identified 846 iECGs as normal, 44 as possible AF and a further 82 were unable to be classified (Figure 2). Across the different practices, screening was reported to take from 1.5 to 10 minutes.

AF identified from screening

Of the 44 participants with possible AF on iECG, 29 had a known history of AF. Of the 15 participants without a history of AF, 13/15 participants were referred for a 12-lead ECG. In total, newly identified AF was found in 8/972 patients (0.8%). The sensitivity

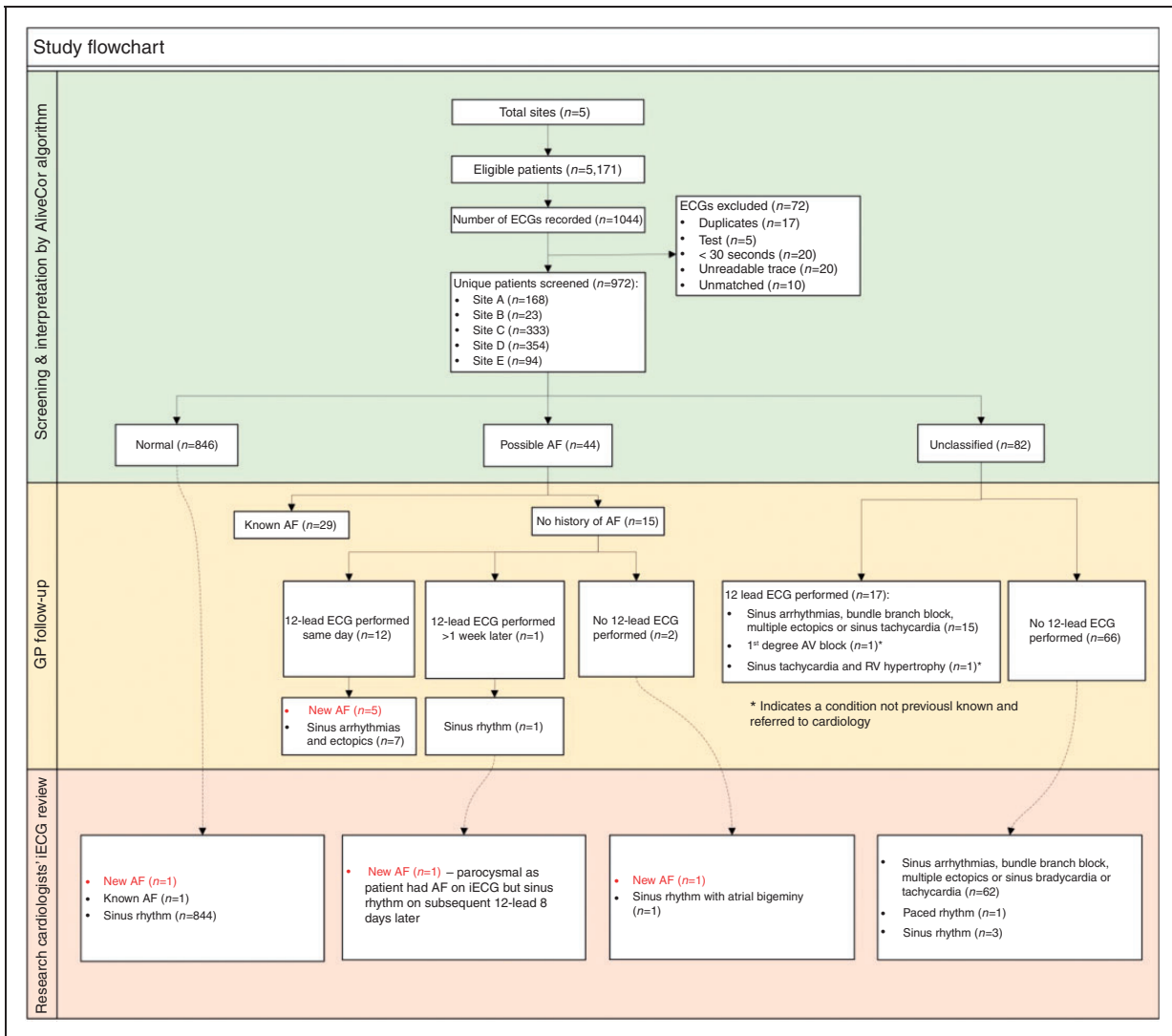


Figure 2. Study flowchart.

AF: atrial fibrillation; AV: atrioventricular; ECG: electrocardiogram; GP: general practitioner.

of the iECG automated algorithm for detecting AF was 95% (95% confidence interval (CI): 83–99%) and the specificity was 99% (95% CI: 98–100%).

As shown in Table 1, of the eight patients with newly identified AF, one could not be re-identified within the practice and, similarly, of the 30 patients with known AF, one could not be re-identified within the practice. The mean age of the remaining seven patients with new AF was 80 ± 3 years, and three were male. Before screening, none were on OACs, and after screening, three were on OACs. In relation to antiplatelet medications, three were on antiplatelets before screening and two were commenced on antiplatelets after screening. All seven had a CHA₂DS₂-VASc score of ≥ 2 .

Qualitative results

In total, 17 semi-structured interviews were conducted across all five practices, comprising seven nurses, five GPs and five practice managers. Interviews ranged from 5 to 14 minutes and the key barriers and enablers for each group are summarised in Figure 3.

GPs. Overall, GPs really liked the device and the fact that it raised awareness of AF. They were positive about screening during flu vaccinations as it captured patients who only came into the practice very occasionally throughout the year, although they noted that it made this period very busy. They also liked nurses performing the screening.

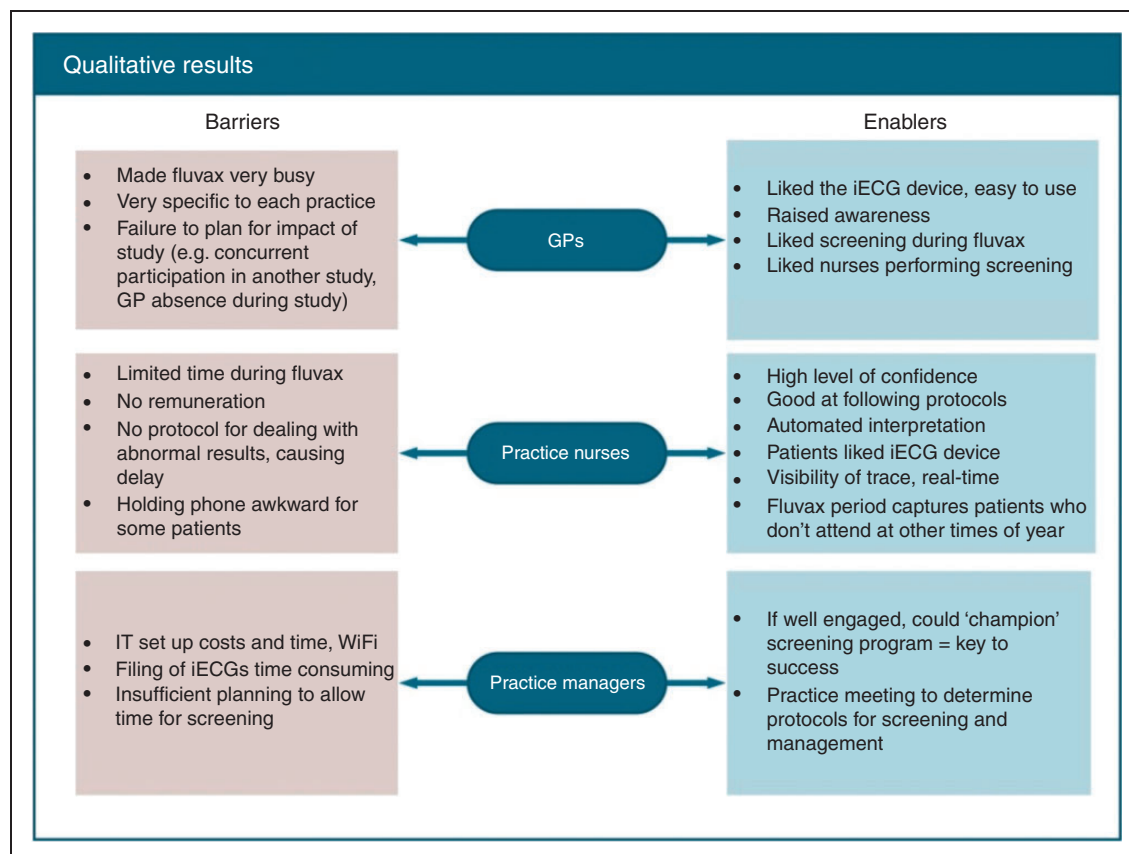
Table 1. Atrial fibrillation identified through screening.

	Newly identified AF (data available for $n = 7$)	Known AF (data available for $n = 29$)	All participants with AF identified through screening (data available for $n = 36$)
Age, mean \pm SD, years	80 \pm 3	77 \pm 1	78 \pm 1
Male gender, n (%)	3	15 (52%)	18 (50%)
On OAC before screening, n (%)	0	26 (84%)	26 (72%)
On OAC after screening, n (%)	3	26 (84%)	29 (81%)
On antiplatelets before screening, n (%)	3	6 (21%)	9 (25%)
On antiplatelets after screening, n (%)	5	6 (21%)	11 (31%)
CHA ₂ DS ₂ -VASc score, mean \pm SD	4 \pm 0.8	4 \pm 0.3	4 \pm 0.3

AF: atrial fibrillation; OAC: oral anticoagulant; CHA₂DS₂-VASc: C, congestive heart failure/left ventricular dysfunction; H, high blood pressure; A₂, age >75 years; D, diabetes; S₂, stroke/transient ischaemic attack/thromboembolism; V, vascular disease (coronary artery disease, myocardial infarction, peripheral artery disease or aortic plaque); A, age 65–74 years; Sc, sex category female.

Barriers were very specific to each practice; for example, one practice was also participating in another study at the same time and had IT issues with setting up the Wi-Fi. The key message was that practices needed to

recognise that the study would take time to set up, and so to appropriately plan for this. In this respect, it was key to have someone (either a GP or practice manager) at the practice to ‘champion’ the screening programme.

**Figure 3.** Qualitative results.

GP: general practitioner; iECG: smartphone electrocardiogram.

Practice nurses. Practice nurses were very confident at providing screening. They noted that screening was very straightforward for the vast majority of patients who received a 'normal' reading. Nurses generally enjoyed the extra interaction with patients, who liked the screening.

The key barriers were how busy it made them during the flu-vaccination period, the need for elderly patients to hold the device very still to take a reading and the additional time required to follow up an abnormal result with the GP. Given that nurses often had many people waiting for flu vaccinations, an unexpected abnormal result put them under substantial time pressure, as additional time was not allocated for screening during the flu-vaccination consultation. Nurses from practices that had established protocols for dealing with abnormal results found this process much easier.

Practice managers. Practice managers were very important to the success of the screening program. A positive practice manager could 'champion' the program and greatly enhance its success. Engaging practice managers in the planning process for screening was helpful. One practice manager commented that their practice had taken the time to review their planning for the flu-vaccination process to include screening, and that this contributed to the success of the programme.

Practice managers highlighted the administrative, IT and filing requirements in addition to the nurses' time requirements in performing the screening. They suggested that funding would be desirable in order to cover the costs of the required IT setup and filing, which would provide an incentive for the time taken for screening.

Discussion

Screening for AF by practice nurses in the general practice setting is feasible and was generally well accepted by the practice staff. Key enablers were the confidence and competence of nurses providing screening and a 'designated champion' (any staff member) to lead screening at the practice. Barriers were mainly practice specific and included concurrent participation in another study, IT issues and failure to establish a protocol/workflow to deal with abnormal iECGs. Other barriers included no funding for the screening (i.e. no incentive to allocate additional practice time for the screening during the flu-vaccination consultation) and the additional time required to action abnormal iECGs (i.e. review and arrange 12-lead ECGs). Staff indicated that patients generally liked the device and the screening process. These enablers and barriers were generally similar to those identified recently by Taggar et al. in a

UK survey of primary healthcare professionals seeking opinions on AF screening.¹⁵

Consistent with findings from our previous pilot study,¹¹ the practice nurse model works well due to nurses' confidence in explaining and providing screening, ease of training and clinical understanding of the reasons for screening. Nurse-led screening during flu vaccination is clearly more feasible than opportunistic receptionist screening, as we were able to recruit more than 10-times as many patients in a similar time frame in this study compared to our previous pilot study.¹¹

Some practices liked the timing of the flu vaccination as a prompt for screening. GPs noted that this was a time of year when many patients in the target group attend the practice, and the flu vaccination provided a useful 'prompt' for screening. However, nurses and practice managers did note that it made the flu-vaccination period very busy, particularly when patients received a 'possible AF' or 'unclassified' reading that required follow-up. Screening could be done at a different time (e.g. during wound dressing or chronic care consultations), but does require some kind of prompt.

This study had several limitations. An important issue was that the version of the AliveCor algorithm used by the app during the study was subsequently discovered to have undergone an intentional change by AliveCor.¹⁶ This algorithm provided 95% sensitivity and 99% specificity in this study, which is substantially better than has been reported by Desteghe et al.,¹⁷ but was less sensitive than the earlier version of the algorithm (98% sensitivity), although with greater specificity (99% vs. 91%).^{10,14} For this study, there was one case of new AF and one case of known AF, both of whom received a 'normal' algorithm interpretation, but were in AF at the time of the screening based on the research cardiologists' review. There is always a trade-off between sensitivity and specificity,¹⁸ and this compromise (95% sensitivity and 99% specificity) may be optimal. The major ECG issue in this study was the 'unclassified' iECGs that were clearly in sinus rhythm, but because of sinus tachycardia or bradycardia or broad QRS complexes could not be classified as normal. This category leads to a lot of unnecessary work in the primary care setting, and could easily be reduced by additional category(ies) of diagnosis in the AliveCor algorithm.

There were several limitations of the study in relation to recruitment. Only five metropolitan practices were recruited, which may not be representative of all practices in the state. There were marked variations in recruitment between the sites, ranging from 23 patients screened at one practice to 354 screened at another. Overall, the fact that only 39% of eligible patients were screened during the period was a limitation, and is likely to relate to the workload of nurses during flu

vaccination and the lack of remuneration for screening. In addition, one site had been involved in a previous pilot study for AF screening, which may have influenced screening practice at that site in regard to the identification of unknown AF.

One interesting finding from this study is that evidence-based OAC prescription was not followed in four of the seven people with new AF, and antiplatelet prescription was increased contrary to guideline recommendations. This suggests that screening for AF alone is not enough, and that there may well be a place for a decision support tool to improve prescription practice. A number of programmes have been previously developed in order to increase evidence-based prescription of OACs, including electronic decision support tools,¹⁹ targeted GP education programme,²⁰ and patient-focused education interventions.²¹ The results of these programmes were generally positive, although they were also varied.²¹ There is a need for future research to test an electronic decision support tool integrated with clinical software in order to improve evidence-based OAC prescription and 'close the gap' between evidence and practice in OAC prescription. Tying this with iECG screening for AF seems a logical use of e-medicine.

In summary, screening with iECG during flu vaccination by primary care nurses is feasible and well accepted by practice staff. Addressing barriers is likely to increase uptake.

Previous presentation

The qualitative results of this study were presented at the World Congress of Cardiology, Mexico, 2016.

Trial registration

Australian New Zealand Clinical Trials Registry (www.anzctr.org.au): ACTRN12615000622505.

Author contribution

All authors contributed to the conception and design of the study. LL, NL, LN, JO, WL and YK contributed to the acquisition, analysis and interpretation of data for the work. JO, NL and LN drafted the manuscript. All authors critically revised the manuscript for important intellectual content. All authors gave final approval and agree to be accountable for all aspects of work ensuring integrity and accuracy.

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Prognostic value of serial six-minute walk tests using tele-accelerometry in patients with chronic heart failure: A pre-specified sub-study of the TIM-HF-Trial

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Abstract

Background: The six-minute walk test (6MWT) is an established functional test assessing exercise capacity and is used to predict clinical prognosis in patients with chronic heart failure (HF). Tele-accelerometry is a novel approach to activity monitoring using telemedical data transfer and allows a Tele-6MWT to be performed in an outpatient setting. It offers patients the option of performing simple serial follow-up tests in their own home.

Aims: The aim of this study was to investigate the prognostic value of serial Tele-6MWTs using tele-accelerometry in patients with HF.

Design/methods: In this proof-of-concept study, 155 patients with HF completed the Tele-6MWT in an outdoor setting once per month over a period of 0.25–21 months. We analysed the differences in the number of steps over time to predict hospitalization as a result of HF or death.

Results: Patients with at least one event ($n = 31$) recorded a lower number of steps and a shorter distance in Tele-6MWT at baseline compared with patients who remained event-free ($n = 124$) (540.1 ± 78.4 steps vs. 601.8 ± 76.7 steps, $P < 0.001$ respectively; 353.2 ± 82.4 m vs. 418.8 ± 95.6 m, $P < 0.001$). Patients ($n = 19$) who performed more than one Tele-6MWT prior to a clinical event showed no significant difference in the number of steps, regardless of whether the baseline test was compared with the last Tele-6MWT before the event or with the last two tests before the event.

Conclusion: Tele-6MWT has a high predictive value with respect to hospitalization as a result of HF or death from any cause and the results were comparable with the prognostic impact of a conventional 6MWT. Therefore Tele-6MWT may be used as alternative test method in the home environment. However, there is no added prognostic value of repeating Tele-6MWTs on a monthly basis.

Keywords

Six-minute walk test, heart failure, activity monitoring, telemedicine, TIM-HF, remote patient management, tele-accelerometry

Introduction

The six-minute walk test (6MWT) is a widely available diagnostic test used to assess exercise capacity in patients with chronic heart failure (HF). According to the recommendations of the American Thoracic Society, the 6MWT should be performed as a walk on a flat corridor of 30 m length accompanied by a member of the medical staff.¹ The distance walked during the 6MWT is a strong predictor for long-term

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mortality and hospitalization as a result of HF. However, there are limited data about the prognostic value of repeated 6MWTs.²

Tele-accelerometry is a new diagnostic approach to activity monitoring with telemedical data transfer. It allows patients to perform the Tele-6MWT in their home environment without the need for an accompanying person.³ In tele-accelerometry, the number of steps walked during a six-minute period is counted instead of the walking distance measured by a hand-wheel in a conventional 6MWT. When the results of the 6MWT were compared using both a conventional hand-wheel and tele-accelerometry, there was a significant correlation between the walking distance and the number of steps. This allowed the conversion of steps into distance.⁴ These results are congruent with other studies evaluating the reliability of different pedometers. A decreased physical state as a result of progressive HF correlates with a decrease in the number of steps, whereas the patients' stride length remains unchanged.⁵

The primary aim of this proof-of-concept study was to assess the prognostic value of repeated Tele-6MWTs to predict death from any cause or hospitalization as a result of HF during a follow-up period of 15 months.

Methods

This proof-of-concept study represents a pre-specified sub-study of the Telemedical Interventional Monitoring in Heart Failure Patients (TIM-HF) trial (clinicaltrials.gov, identifier NCT00543881). A total of 710 patients with chronic systolic HF were included in this multicentre, randomized controlled telemedical trial. The following inclusion criteria had to be fulfilled: chronic HF with New York Heart Association functional class II–III, reduced left ventricular ejection fraction (LVEF) $\leq 35\%$ and at least one hospitalization as a result of HF within 24 months prior to randomization. In patients with an LVEF $\leq 25\%$, proved two times within six months prior to randomization, no hospitalization as a result of HF within 24 months prior to randomization was required.⁶

The TIM-HF study started in January 2008 and was terminated on a fixed date of 30 April 2010. There was an individual follow-up period for every patient lasting from the date of randomization to the fixed termination date. The median (range) follow-up period was 26 (12–28) months. Patients were randomized to a telemonitoring (TM) group ($n = 354$) or a control group ($n = 356$) on an intention-to-treat principle. Home-based TM included daily measurement of body weight, blood pressure, ECG and a self-assessment of well-being. Wireless data transfer was conducted from the patients' homes directly to the Telemedical Centres (TMC) at Charité-Universitätsmedizin Berlin or the Robert

Bosch Krankenhaus in Stuttgart, Germany. A detailed description of the telemedical system and the results of the TIM-HF trial have been reported elsewhere.^{6,7}

A subgroup of telemedicine patients (155/354 patients, 43.8%) performed repeated tests with tele-accelerometry on a monthly basis. The device used (AiperMotion 300 PfH, Aipermon GmbH & Co. KG, Munich, Germany) was a customized accelerometer with a 'start' button and a programmed automatic stop of recording data after six minutes. The reliability and validity of this device and the rationale for selecting patients to participate in activity monitoring has been reported in detail elsewhere.⁴

The study was carried out according to the principles of the Declaration of Helsinki (1996) and the International Conference on Harmonization Good Clinical Practice and was approved by the local ethics committee (EA1/052/07). Written informed consent was obtained from all participating patients.

Tele-6MWT procedure

Tele-6MWT was performed at baseline and then monthly over a period of 12–21 months. Baseline measurements were supervised by nurses from the TMC to train patients in using the device and to find an appropriate test area. To ensure the validity and reliability of tele-accelerometry, the instructing nurse simultaneously measured the 6MWT distance using a conventional hand-wheel at baseline and at 12 months follow-up (364 ± 30.0 days).⁴ After measurement at baseline, the patients were asked to perform the test on their own once a month for the remaining follow-up period.

The data from the accelerometer were automatically transmitted to the TMC via a mobile network after the completion of each 6MWT. However, these data were not used as a part of remote patient management (RPM) in the TIM-HF trial. The data were gathered in a double-blind manner (to the patient and to the medical staff of the TMC) and were analysed retrospectively.

Statistical analyses

Statistical analysis was performed using IBM SPSS Statistics (version 22.0). Patient baseline characteristics were descriptively analysed by reporting mean \pm SD values and frequencies for the quantitative measurements. Differences were compared using a two-tailed *t* test for normally distributed variables. In all data analyses, $P < 0.05$ was considered as statistically significant and these values were reported in an explorative manner. Receiver operating characteristic (ROC) analyses were performed to determine the most reliable cut-off value for the 6MWT steps according to

positive/negative predictive values (PPV/NPV) in terms of classifying the patients correctly for the combined endpoint (all-cause mortality and hospitalization as a result of HF). The area under the ROC curve with 95% confidence intervals (CI) was calculated to assess the overall diagnostic performance of potential explanatory variables (6MWT steps and distance).

Results

Clinical characteristics

A total of 155 patients (mean \pm SD age 67.7 ± 10.8 years) performed the Tele-6MWT once per month; 84% of the study participants were men and the mean \pm SD LVEF was $27.9 \pm 5.2\%$. The mean \pm SD (range) follow-up period for all patients was 15 ± 6 (0.25–21) months.

During follow-up, 31 of 155 patients (20%) had at least one event: death of any cause and/or hospitalization as a result of HF. These 31 patients showed no significant difference in age, LVEF, body mass index or New York Heart Association functional class compared with the patients who remained event-free ($n = 124$) (Table 1). There were significant differences in the baseline levels

of biomarkers (N-terminal pro-B-type natriuretic peptide, midregional pro-adrenomedullin and midregional pro-atrial natriuretic peptide) between patients with and without an event.

In total, 13 patients died during follow-up. Six patients died at home: for four of these patients the cause of death was classified by the endpoint committee as sudden cardiac death; one patient died as a result of end-stage cancer and one patient committed suicide. Seven patients died in hospital: five were admitted to hospital as a result of acute decompensated HF and two died in hospital from other causes (intracranial haemorrhage, incurable gut bleeding).

Death was the first event after starting Tele-6MWT without prior hospitalization as a result of HF in only five patients. Only these five patients were analysed with 'death of any cause' as the first event. In the remaining 26 patients, the first clinical event was hospitalization as a result of HF.

Results of Tele-6MWT

Patients with at least one event ($n = 31$) recorded a lower number of steps at baseline Tele-6MWT than patients who remained event-free ($n = 124$)

Table 1. Baseline characteristics of patients.

	Patients with no event ($n = 124$)	Patients with event ($n = 31$)	P
Age (years)	64.8 ± 10.9	66.7 ± 10	0.153
Male sex	100 (80.6)	30 (96.8)	0.029 ^a
Body mass index (kg m^{-2})	28.9 ± 5.3	30.5 ± 5.4	0.153
New York Heart Association Class	2.4 ± 0.5	2.5 ± 0.5	0.153
Left ventricular ejection fraction (%)	28.4 ± 5.1	26.1 ± 5.6	0.027
6MWT distance (m) at baseline	418.8 ± 95.6	353.2 ± 82.4	$<0.001^a$
6MWT steps at baseline	601.8 ± 76.7	540.1 ± 78.4	$<0.001^a$
N-terminal pro-B-type natriuretic peptide (pg mL^{-1})	1515.4 ± 1734.8	2878.8 ± 3334.9	0.002 ^a
Midregional pro-adrenomedullin (nmol L^{-1})	247.6 ± 146.5	375.4 ± 260.7	$<0.001^a$
Midregional pro-atrial natriuretic peptide (pmol L^{-1})	0.8 ± 0.3	1.1 ± 0.6	$<0.001^a$
Cardiomyopathy	70 (56.5)	18 (58.1)	0.814
Coronary heart disease	85 (68.5)	20 (64.5)	0.458
Cardiac resynchronization treatment	27 (27.8)	5 (16.5)	0.491
Implantable cardioverter defibrillator	74 (59.7)	20 (64.5)	0.625
Concomitant treatment			
Statin	86 (69.4)	22 (71)	0.862
ACE inhibitor	95 (76.6)	23 (74.2)	0.779
Beta blocker	115 (92.7)	30 (96.8)	0.417
Diuretic	99 (79.8)	28 (90.3)	0.177

6MWT: six-minute walk test.

Data are presented as mean \pm SD or No. (%) values. Patients were divided into two groups according to the number of 6MWT steps at baseline; post hoc group differences were analysed by a *t* test.

^aStatistically significant at $P \leq 0.05$.

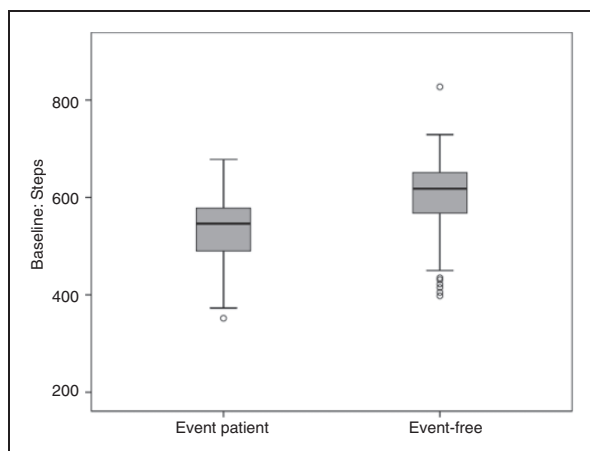


Figure 1. Box plot illustrating baseline steps for patients with and without an event related to heart failure.

(540.1 ± 78.4 steps vs. 601.8 ± 76.7 steps; $P < 0.001$). There was also a significant difference between the two groups in the distances reached at baseline 6MWT (353.2 ± 82.4 m vs. 418.8 ± 95.6 m; $P < 0.001$; Figure 1). Patients with death ($n = 5$) or hospitalization as a result of HF ($n = 26$) as the first event showed no significant difference in the number of steps or distances at baseline (526.8 ± 59 steps vs. 542.7 ± 83.3 steps; $P = 0.686$, 314.3 ± 79 m vs. 360.7 ± 82.4 m; $P = 0.256$).

A total of 22 of 31 patients performed Tele-6MWT within a time frame of 4 ± 2 weeks prior to the first event with a mean \pm SD number of steps of 531.9 ± 108.5 . Three of these 22 patients had their first event within the first month after the baseline test (one sudden death, two patients hospitalized as a result of HF). The remaining 19 patients performed at least one additional Tele-6MWT prior their event. There was no difference between the number of steps prior to an event and the results at baseline (-1.4 ± 112.1 , -167 to 383 steps). A total of 18 of these 19 patients completed consecutive Tele-6MWTs within 84 days prior to their event. There was no significant difference in the number of steps between these consecutive tests (543.8 ± 107.5 steps vs. 528.6 ± 112.5 steps; $P = 0.163$).

Almost two-thirds of patients ($n = 13/21$) who were admitted to hospital as a result of HF as their first event resumed their performance of the Tele-6MWT after discharge from their first hospitalization as a result of HF. These patients completed a mean \pm SD (range) of 7.9 ± 5 (1–16) additional tests post-discharge with a mean \pm SD (range) of 506.8 ± 116.2 (337–666) steps. There was no significant difference between the mean number of steps before and after the first hospitalization as a result of HF (528.6 ± 114.7 steps vs. 506.8 ± 116.2 steps; $P = 0.386$). There was also no significant pre- and post-event difference in the number of steps between patients with single or multiple

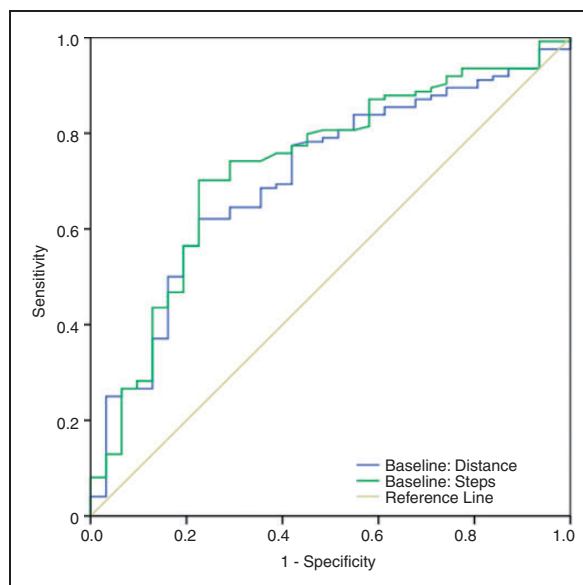


Figure 2. Receiver operating characteristic curve showing value of baseline six-minute walk test steps and distance for predicting first event (all-cause mortality or hospitalization as a result of heart failure).

hospitalizations following a first hospitalization as a result of HF.

Figure 2 shows the ROC curve used to determine the optimum cut-off value of steps in the Tele-6MWT at baseline to differentiate between patients with and without an event. The corresponding area under curve values with 95% CIs for hospitalization as a result of HF were 0.73 ($P < 0.001$; 95% CI 0.630–0.829) for steps and 0.707 ($P < 0.001$; 95% CI 0.608–0.805) for distance in Tele-6MWT. A cut-off value of 495 steps was calculated to determine patients without events (rule-out) with a specificity of 90% (a sensitivity of 26%) (PPV 40%, NPV 83%).

Discussion

We have shown that the initial Tele-6MWT is a predictor for death of any cause or for hospitalization as a result of HF. Statistical analysis showed 495 steps to be the best cut-off value for risk prediction. However, patients did not show a significant difference in the number of steps achieved in monthly repeated Tele-6MWTs compared with the baseline. Thus Tele-6MWTs repeated on a monthly basis do not improve the prognostic impact of the Tele-6MWT at baseline. This finding is in agreement with other studies evaluating the prognostic value of repeated standardized 6MWTs.

In a study by Ingle et al.,⁸ 600 patients with HF with similar clinical baseline characteristics to those in our study performed the standardized 6MWT at baseline

and after 12 months. There was no significant difference in the results between the two tests. The 6MWT distances at baseline were of the same prognostic impact as those performed after 12 months in terms of all-cause mortality during a follow-up period of eight years. Thus Ingle et al.⁸ concluded that the repetition of 6MWTs after one year is only of limited additional value in estimating long-term prognosis.

Taeger et al.⁹ investigated the minimum clinically important difference (MID) between the results of repeated 6MWTs in two cohorts of stable patients with HF. The MID represents a cut-off point to distinguish normal biological variations in the test results from changes resulting from altered functional capacity. The study participants were younger and showed less severe symptoms of HF compared with the baseline characteristics in our study. A total of 461 patients in the first cohort performed a second 6MWT six months after the baseline test, whereas 512 patients in the second cohort repeated the 6MWT after 12 months. In both cohorts, the MID was 36 m between repeated tests.

Anker et al.¹⁰ defined differences in repeated 6MWTs as a secondary endpoint in an interventional study. They investigated the efficacy of intravenous ferric carboxymaltose treatment in patients with HF and iron deficiency compared with usual HF care. The patients completed 6MWTs at baseline, at one month and at six months of follow-up. After six months, the patients who were randomized to the interventional group showed a significant increase of 36 m in the 6MWT. This result supports the finding by Taeger et al.⁹ for the mean MID between repeated 6MWTs.

Thus serial follow-up of 6MWTs might have more diagnostic impact in reflecting the efficacy of a specific treatment rather than having an additional prognostic value. This could be a rationale for the concept of repeated Tele-6MWTs within the RPM of patients with HF. Our study did not show any significant difference between repeated 6MWTs prior to hospitalization as a result of HF by comparing the baseline test with the last test prior to the event or by comparing the last two tests prior to the event. Tele-6MWTs were performed on a monthly basis, resulting in a mean period of three weeks between the last Tele-6MWT and hospitalization as a result of HF. This time frame would be much too long to detect an upcoming acute cardiac decompensation. Therefore our study does not support the concept of a monthly follow-up of Tele-6MWTs. However, the frequency of repetition seems to be a very important issue with respect to diagnostic impact.

The Telemedical CHAMPION-trial investigated the efficacy of RPM based on daily transmitted data on pulmonary pressure to prevent hospitalization as a result of HF. In this trial, all patients underwent

implantation of CardioMEMS, a device that allows the daily transfer of data on pulmonary pressure from an outpatient setting to a telemedical centre. The follow-up data showed an increase in pulmonary pressure as an initial sign of upcoming acute cardiac decompensation and this occurred two to three days before the onset of clinical symptoms.¹¹ As a consequence, it is appropriate to motivate patients to perform Tele-6MWT at least once a week. Such a concept of more frequently repeated Tele-6MWTs could be easily implemented in new clinical trials on RPM. Most patients with HF perform a daily walk of more than six minutes and the majority of patients use modern smartphones with the option of counting steps over six minutes with high reliability.¹² Therefore a specific tele-accelerometer would not be needed by most patients. Only a few patients would need limited initial assistance from an HF nurse, e.g. to find an appropriate test area close to the patient's home. This could be a walk around a playing field.

Limitations

This proof-of-concept study is highly underpowered as a result of the small number of patients, which resulted in only a small amount of Tele-6MWT data and number of clinical events. The average number of patients in observational studies analysing the prognostic value of repeated 6MWTs is about four times that in our study.^{8,9,13} As a consequence, further statistical analyses based on interquartile comparison could not be performed. There is also evidence regarding the influence of age and sex on the 6MWT.¹⁴ However, due to the small number of participants, this analysis could not be performed in our study. In addition, Tele-6MWTs conducted within at least 4 ± 2 weeks prior to the first event were not performed in nine of 31 patients. The reasons for their refusal to perform the Tele-6MWT could not be identified, although a declined physical state may impede patients from performing functional tests and could therefore account for this bias.

Conclusion

The Tele-6MWT is a novel approach to assess functional capacity in patients with HF by counting the number of steps walked in an outdoor setting. It can be self-performed by a patient without additional medical staff. Tele-6MWT was shown to have a high predictive value with respect to hospitalization as a result of HF or death of any cause, which was comparable with the prognostic impact of a conventional 6MWT. Therefore Tele-6MWT may be used as an alternative test in the home environment. However, there is no

added prognostic value to repeated Tele-6MWTs on a monthly basis.

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A European study on effectiveness and sustainability of current Cardiac Rehabilitation programmes in the Elderly: Design of the EU-CaRE randomised controlled trial

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Abstract

Background: Cardiac rehabilitation (CR) is an evidence-based intervention to increase survival and quality of life. Yet studies consistently show that elderly patients are less frequently referred to CR, show less uptake and more often drop out of CR programmes.

Design: The European study on effectiveness and sustainability of current cardiac rehabilitation programmes in the elderly (EU-CaRE) project consists of an observational study and an open prospective, investigator-initiated multicentre randomised controlled trial (RCT) involving mobile telemonitoring guided CR (*mCR*).

Objective: The aim of EU-CaRE is to map the efficiency of current CR of the elderly in Europe, and to investigate whether *mCR* is an effective alternative in terms of efficacy, adherence and sustainability.

Methods and results: The EU-CaRE study includes patients aged 65 years or older with ischaemic heart disease or who have undergone heart valve surgery. A total of 1760 patients participating in existing CR programmes in eight regions of Europe will be included. Of patients declining regular CR, 238 will be included in the RCT and randomised in two study arms. The experimental group (*mCR*) will receive a personalised home-based programme while the control group will receive no advice or coaching throughout the study period. Outcomes will be assessed after the end of CR and at 12 months follow-up. The primary outcome is VO_{2peak} and secondary outcomes include variables describing CR uptake, adherence, efficacy and sustainability.

Conclusion: The study will provide important information to improve CR in the elderly. The EU-CaRE RCT is the first European multicentre study of *mCR* as an alternative for elderly patients not attending usual CR.

Keywords

Cardiac rehabilitation, *mHealth*, coronary heart disease, elderly, Europe, telemonitoring, effectiveness

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Introduction

Cardiovascular disease (CVD) is responsible for over four million deaths in Europe each year.¹ The population of elderly patients with coronary heart disease (CHD) has increased because of increasing age at onset of CVD, the aging of the population and the development of life-saving pharmacological and interventional therapies. A cardiac event in an elderly person is often the beginning point of gradual deterioration and is followed by a high rate of recurrent events. The burden of CVD is not only huge for patients and the healthcare sector, but also encompasses a large economic strain with estimated annual costs of €169b in Europe.² As a result, maintaining autonomous, independent and active elderly patients, after acute coronary syndrome (ACS) or coronary revascularisation, is a huge health and social challenge within Europe and the urgent need for effective (and cost-effective) patient-centred cardiac care is increasing.

Only about one third of CVD patients in Europe receive any form of cardiac rehabilitation (CR), with generally lower uptake in the elderly.^{3,4} The elderly patient is characterised by more co-morbidities, more physical impairment, reduced mobility and a less physically active lifestyle. Additionally, a larger proportion of elderly patients have psychosocial disadvantages such as living alone and transportation difficulties. Although the elderly account for the majority of cardiac admissions and procedures, programmes and studies on CR have traditionally focused on younger patients. The current approach for CR is therefore often less appropriate for the elderly, despite the similar benefits from CR as their younger counterparts.^{5,6} Together with their high risk of recurrent events, the elderly CHD patient is the group most in need of CR, yet studies consistently show that elderly patients are less frequently referred to CR, show less uptake and drop out more often from CR programmes.⁷⁻⁹

Home-based CR programmes have been suggested as an alternative to centre-based CR and may provide a good alternative for the elderly patient unable or unwilling to participate in a centre-based CR.^{10,11} Studies have indicated that home-based programmes are non-inferior to centre-based, supervised programmes.⁷⁻⁹ For many elderly patients, transportation to the standard, centre-based, centralised CR programme is a barrier to participation and leads to lower participation rates and inequality in access to care. This barrier may be overcome by utilising novel technologies developed in tele-rehabilitation. Investigation of mobile telemonitoring guided CR (mCR) as an effective, comprehensive CR programme for the elderly is very promising.

The European study on effectiveness and sustainability of current cardiac rehabilitation programmes in the

elderly (EU-CaRE) project (www.eu-care.org) is a programme conducted in collaboration between eight European healthcare institutions in seven European countries. The main objective of the EU-CaRE project is to obtain the evidence base to improve, tailor and optimise CR programmes regarding sustainable effectiveness, cost-effectiveness and participation level in the elderly, a group defined as patients aged 65 years or above.

Methods

This aim will be pursued in two parallel studies (Figure 1): EU-CaRE, an observational study focusing on predictors of uptake, cost-effectiveness, adherence and sustainability of diverse CR programmes in Europe, and EU-CaRE RCT, a randomised controlled trial (RCT) testing the ability of mCR to improve sustainable effects of CR in elderly patients that would not participate in the regular CR programme offered, to establish its cost-effectiveness, and to investigate the means of increasing CR participation among the elderly by mCR. Both EU-CaRE studies are approved by all relevant medical ethics committees and registered at trialregister.nl (NTR5306 and NTR5308). All patients gave written informed consent before entering a EU-CaRE study. In this article, the EU-CaRE RCT will be explained in context of the total project and in relation to the observational study.

EU-CaRE observational study

Design and objective. The observational study aims at comparing the effectiveness of current CR programmes conducted at the eight participating institutions (Table 1). Based on the data obtained through this observational study, an analysis will be made of the factors which influence participation, drop out (compliance), (cost-)effectiveness and sustainability.

Study population. All patients with recent ACS, coronary revascularisation, surgical or percutaneous treatment for valvular disease, or documented coronary artery disease (CAD) defined by standard non-invasive or invasive methods, in the uptake area of the participating CR are candidates for study inclusion (Table 2). Care will be taken to identify all eligible patients independently of referral to CR. Baseline data on non-participants in centre-based CR will be registered with the aim of identifying characteristics and predictors of non-participation. We aim at including 1760 patients, 220 from each centre.

Participants in the observational study will be monitored at start of the CR programme, T0, end of CR programme, T1, and 12 months after start of the CR

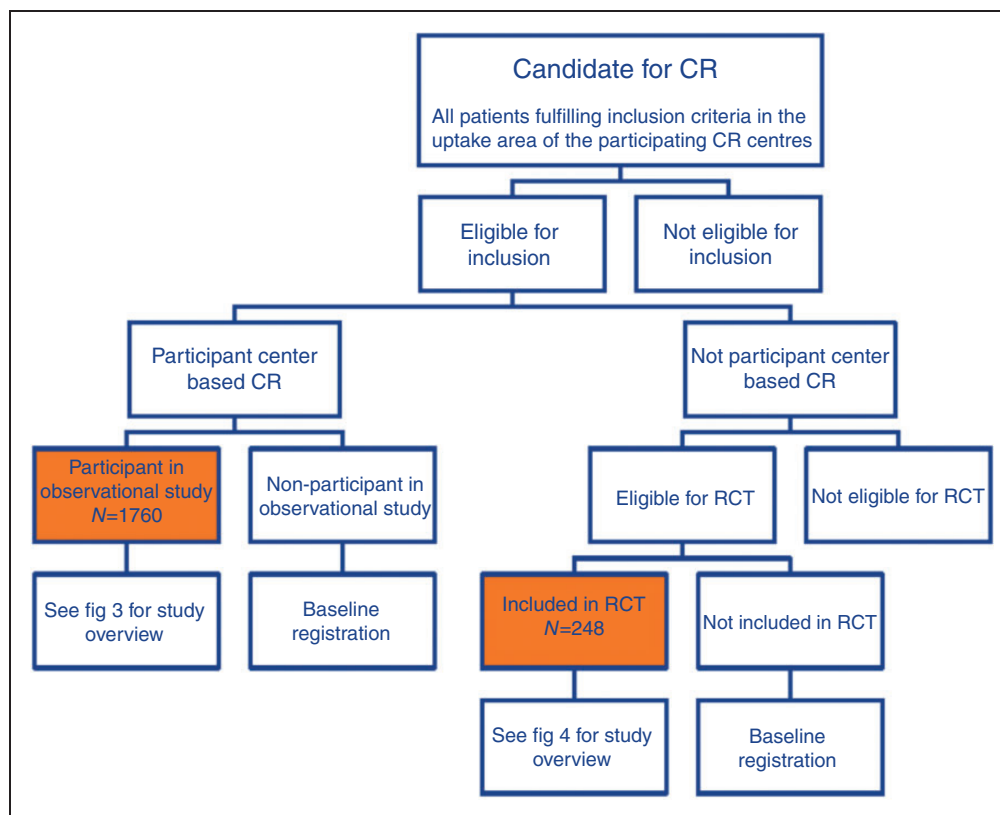


Figure 1. Flowchart of European study on effectiveness and sustainability of current cardiac rehabilitation programmes in the elderly (EU-CaRE) patient inclusion. CR: cardiac rehabilitation; RCT: randomised controlled trial.

programme, T2. Drop-outs from the study will be registered as well as their reason for drop-out.

Outcome measures. The main study endpoints are enrolment, adherence, effectiveness and sustainability of CR and a comparative analysis of health care utilisation. The primary outcome is exercise capacity (VO_{2peak}) at end of CR and at one-year follow-up. Secondary study outcomes are traditional risk factors for CVD, major adverse cardiovascular events (MACEs), general health, care utilisation, costs of care utilisation, adherence and compliance (Table 3). Enrolment is defined as proportion of patients eligible for CR enrolled in a CR programme. This will be compared between participating centres and association with potential predictive factors explored. Adherence is defined as proportion of enrolled patients completing the programme from attendance to exercise training sessions. Sustainability is defined as maintenance of risk factor targets and functional capacity at 12 months.

For measuring care utilisation, costs per patient based on clinical admission days, emergency and outpatient clinic visits, general practitioner (GP) visits for cardiac (related) complaints or issues, cardiac-related radiology/physiology, nuclear or laboratory tests and

other cardiac interventions will be calculated. This endpoint is essential for assessing cost-effectiveness.

The setting in which CR programmes is carried out may be of influence on outcome, especially in the elderly. A number of CR programme-related parameters that might influence outcome will be registered: in/out patient, separate/same institution, with/without multidisciplinary counselling, duration of programme, frequency of exercise session, training volume and training intensity.

For patients enrolled in CR the following data will be registered: demographics, race/ethnicity, educational attainment, employment status, cohabitation, social network, involvement in voluntary work, medical history including co-morbidity including chronic heart failure (CHF), valvular heart disease or atrial fibrillation, indication for CR (index event), exercise capacity, CVD risk factors, medication, symptoms (chronic compartment syndrome (CCS) and New York Heart Association functional classification (NYHA)) and left ventricular ejection fraction. Clinical assessment of patients includes: Cardiopulmonary exercise testing (CPET) or alternatively six-minute walk test (6MWT) in elderly patients not able to perform a CPET, blood pressure, body mass index (BMI), waist-hip ratio, lean

Table 1. Description of centre-based cardiac rehabilitation (CR) programme in participating centres.

Centre	Recruitment strategy	General information on cardiac rehabilitation centre	CAD programme characteristics
Bern	<ul style="list-style-type: none"> • Active and passive recruitment • All eligible patients full coverage from private health insurance 	<ul style="list-style-type: none"> • Not part of department of Cardiology, placed within hospital • Urban/rural area • Offers multidisciplinary exercise-based rehabilitation programmes for CAD, CHF, GUCH, PAD, diabetes, neurovascular, and oncology • Only out-patient CR 	<ul style="list-style-type: none"> • Multidisciplinary exercise-based programme of 4 months duration • By cardiologist/dietician/physiotherapist/psychologist, if relevant/sports physician • Standard programme for age ≥ 65 years • Three group-based patient education sessions on psychology, dietary issues and risk factors • On an individual basis psychological, dietary or smoking cessation counselling • Follow-up by GP/cardiologist <ul style="list-style-type: none"> • 2 Sessions per week, 36 sessions in total/1.5–2 h per session/mainly high intensity (HIIT) • A session consists of a 10 min warm-up followed by HIIT mainly on treadmill (4 min intervals at 90–95% of peak heart rate, separated by 3 min of active pauses at 50–60% of peak heart rate). 20 min resistance training/week • Intensity based on CPET and monitored by BORG/heart rate monitoring • Continued supervised training in heart groups run by the hospital offered to all patients
Copenhagen	<ul style="list-style-type: none"> • Semi-automated referral through registries • All eligible patients full coverage by national health insurance 	<ul style="list-style-type: none"> • Part of Department of Cardiology within hospital • Urban area • Offers multidisciplinary exercise-based rehabilitation programmes for CAD, CHF, after heart and lung transplantation, heart valve and vascular surgery • Only out-patient CR 	<ul style="list-style-type: none"> • Multidisciplinary exercise-based programme of 12-weeks duration • By cardiologist/specialised nurse/dietician/physiotherapist • Standard programme for age-mixed groups of 8–10 patients • 6 x 1.5 h Group-based patient education sessions on heart disease, medication, psychological issues, risk factors, etc. • If relevant, smoking cessation aid • Follow up by GP or cardiologist <ul style="list-style-type: none"> • 2 Sessions per week, 16 session in total/1.5 h per session/mainly high intensity interval training • Circular training involving warm up, 30 min HIIT training on cycling ergometer, interval intensity 16–17 BORG scale, resistance training with weights and machines, cardio training on stairs and cool-down • Intensity based on CPET and monitored by BORG/heart rate monitoring • Continued supervised training offered on an individual basis
Ludwigshafen	<ul style="list-style-type: none"> • Individual referral and active telephone contact • Length of CR programme dependent on health insurance coverage 	<ul style="list-style-type: none"> • Not part of Department of Cardiology, placed within hospital ground • Urban area • Offers Multidisciplinary exercise-based rehabilitation programmes for CAD patients • Out-patient with full day programme 	<ul style="list-style-type: none"> • Multidisciplinary exercise-based programme of 3–5 weeks duration • By cardiologist/specialised nurse/dietician/physiotherapist/psychologist, if relevant/social worker, if relevant/sports physician • Programme 5 days per week, 6 h per day • Group-based patient education sessions on heart disease, medication, diet, <ul style="list-style-type: none"> • Several training sessions daily, total 2.5 h/day, 11–13 h/week/mainly moderate intensity training • Daily sessions with cycling and Nordic walking, ball-games, respiratory exercise, swimming, 60 min resistance training • Intensity based on CPET and monitored by BORG/heart rate monitoring/blood

(continued)

Table 1. Continued

Centre	Recruitment strategy	General information on cardiac rehabilitation centre	CAD programme characteristics	pressure
Paris	<ul style="list-style-type: none"> • Semi-automated referral through registries • All eligible patients full coverage from insurance companies 	<ul style="list-style-type: none"> • Part of Department of Cardiology within hospital ground • Urban area • Offers multidisciplinary exercise-based rehabilitation programmes for CAD, CHF; after heart and lung transplantation • Both in- and out-patient programme 	<ul style="list-style-type: none"> • exercise, psychological issues, risk factors, etc. • If relevant a course in smoking cessation • Other training sessions and groups depends on medical prescription of cardiologist from the initial interview • Multidisciplinary exercise-based programme of up to 4 weeks duration • By cardiologist/specialised nurse/dietician/physiotherapist/psychologist, if relevant/social worker, if relevant/sports physician • Programme 5 days per week • 3–5 weekly sessions group based patient education on coronary heart disease, nutrition, exercise and sports, anti-coagulants, stress management • If relevant, a course in smoking cessation • Follow-up by GP or cardiologist 	<ul style="list-style-type: none"> • Follow-up programme with 24 training sessions offered to patients with insurance coverage. For all patients: Heart groups sponsored by health insurance with medical prescription from general practitioner, 1–2 x/week • 3–5 Sessions/week, 15–20 sessions in total/15–20 h of training of which 8–10 h of endurance training) • Each session 30 min • Individualised: aerobic training treadmill/cycle ergometer, resistance training, coordination • No HIIT • Intensity based on CPET and monitored by BORG/heart rate monitoring • Limited availability of continued training in patient groups
Parma	<ul style="list-style-type: none"> • Individual referral from cardiology and cardio surgery department • Coverage for all eligible patients • Access is regulated by Local Health System budget assigned to institution 	<ul style="list-style-type: none"> • Not part of Department of Cardiology • Urban area • Offers multidisciplinary exercise-based rehabilitation programmes for CAD, after heart valve and vascular surgery • Both in- and out-patient program 	<ul style="list-style-type: none"> • Multidisciplinary exercise-based programme of up to 12 weeks duration • By cardiologist/specialised nurse/dietician/physiotherapist/psychologist, if relevant/social worker, if relevant/ • Follow-up by GP or cardiologist 	<ul style="list-style-type: none"> • Inpatients programme: • A mean of 12–13 days for 20–26 training session (twice daily=11 h/week) • Outpatients programme: • 8–12 weeks/2–3 session/week/no less than 24 training session/1 h per session/moderate intensity • 15 min of respiratory FKT and calistenic exercise, 30 min of aerobic training (interval or endurance), 15 min cool down • No resistance training, 5% HIIT • Intensity based on CPET data, monitored by BORG scale and/or heart rate monitor
Rome	<ul style="list-style-type: none"> • Individual referral from cardiac surgery department 	<ul style="list-style-type: none"> • 7 Cardiac rehabilitation units cover patients from one cardiac surgery department 	<ul style="list-style-type: none"> • Multidisciplinary exercise-based programme of 3–4 weeks duration • By cardiologist/specialised nurse/ 	<ul style="list-style-type: none"> • 3–4 Session/week/total of 12 training session/1 h per session/mainly moderate intensity

(continued)

Table 1. Continued

Centre	Recruitment strategy	General information on cardiac rehabilitation centre	CAD programme characteristics
Santiago de Compostella	<ul style="list-style-type: none"> All eligible patients full coverage by national health insurance Screening at hospital admission and discharge Full coverage for all eligible patients through national insurance 	<ul style="list-style-type: none"> Urban and rural areas Offer multidisciplinary exercise-based rehabilitation programmes for CAD patients Only out-patient programmes Part of Department of Cardiology within hospital Mainly rural area Offers multidisciplinary exercise-based rehabilitation programmes for CAD Only out-patient CR 	<ul style="list-style-type: none"> dietician/physiotherapist/psychologist, if relevant/social worker, if relevant Standard programme for groups of 8–10 patients 7×2 h Group-based patient education sessions on heart disease, medication, psychological issues If relevant, smoking cessation aid Follow-up by GP or cardiologist Multidisciplinary exercise-based programme of 12 weeks duration By cardiologist/specialised nurse/dietician/physiotherapist/psychologist, if relevant/social worker, if relevant/sports physician and rehabilitation physician 10×1 h Group based sessions in patient education programme If relevant smoking cessation, sleep-apnoea and obesity Follow-up: 6 and 12 months contact
Zwolle	<ul style="list-style-type: none"> Active recruitment during admission and by telephone call Full coverage for all eligible patients through insurance schemes 	<ul style="list-style-type: none"> Part of Department of Cardiology located in separate building Mainly urban Offers multidisciplinary exercise-based rehabilitation programmes Only out-patient CR 	<ul style="list-style-type: none"> Ergometer cycling, treadmill and walking, in a few centres also resistance training and/or HIIT Intensity based on CPET data, monitored by BORG scale and/or heart rate monitor Continued supervised training offered on an individual basis 2–3 Visits per week total 24 sessions/30–40 min per session/moderate training intensity Progressive, up to 30–40 min, first week cycling. Circuit training cycling and treadmill if possible. Progressive heart rate goals(75–85%). Resistance training 10 min per sessions. 10 muscular groups. No HIIT Intensity based on CPET data, monitored by BORG scale and/or heart rate monitor Continued training in heart groups ('Corazonadas') promoted by patients that completed the CR 4 Weeks 2 per week, 2 weeks 1 per week, total 10 sessions, 1 h duration, high intensity 1 h of aerobic training cycling and treadmill, HIIT 4×3 min per session from session 5. No resistance training Intensity based on CPET data, monitored by BORG scale and/or heart rate monitor No possibility of continued training

CAD: coronary artery disease; CHF: chronic heart failure; CPET: cardiopulmonary exercise testing; FK T: function test; GP: general practitioner; GUCH: grown ups with congenital heart diseases; PAD: peripheral artery disease.

Table 2. Inclusion and exclusion criteria for European study on effectiveness and sustainability of current cardiac rehabilitation programmes in the elderly (EU-CaRE).

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Patients of 65 years or older who have accepted CR
- Signed written informed consent
- One of the following criteria:
 - Patients with an ACS, including myocardial infarction and/or revascularisation within 3 months prior to the start of the CR programme
 - Patients that underwent a PCI within 3 months prior to the start of the CR programme
 - Patients that received CABG within 3 months prior to the start of the CR programme
 - Patients that were treated surgically for valvular heart disease (including TAVI) within 3 months prior to the start of the CR programme
 - Patients with a stable angina with documented significant CAD (defined by standard non-invasive or invasive methods)

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Contraindication to CR
- Mental impairment leading to inability to cooperate
- Severe impaired ability to exercise
- Signs of severe cardiac ischaemia and/or a positive exercise testing on severe cardiac ischaemia
- Insufficient knowledge of the native language
- Implanted cardiac device (CRT-P, ICD)

ACS: acute coronary syndrome; CR: cardiac rehabilitation; CRT-P: Cardiac Resynchronization Therapy Pacemaker; TAVI: Transcatheter Aortic Valve Implantation.

body mass, spirometry, heart rate and rhythm. Blood samples will be analysed for the following: renal function, HbA1c and serum lipids. Questionnaires include three distinct validated questionnaires Patient Health Questionnaire-9 (PHQ-9), Generalised Anxiety Disorder-7 (GAD-7) and 36-item Short Form Health Survey version 2 (SF-36v2).

EU-CaRE RCT

Design and objective. The trial is an open, prospective, investigator initiated multicentre RCT. The objective of EU-CaRE RCT is to assess whether *mCR* as an alternative for patients who decline participation in a conventional CR programme, is an effective means of increasing participation and adherence of elderly patients to a CR programme, and whether this results in better sustained effects. Patients will be randomised in two study arms to either: (a) join *mCR* programme for six months, or (b) no *mCR* programme (control).

Both groups have an additional six months of follow-up after the first period without any intervention.

Study population. A total of 238 patients will be included from five European countries. The Departments of Cardiology of five European cardiac institutions participate in the EU-CaRE RCT: Isala (Zwolle, The Netherlands), Region Hovedstaden (Copenhagen, Denmark), Assistance Publique – Hôpitaux de Paris (Paris, France), Universität Bern (Bern, Switzerland), and Servizo Galego de Saúde (Santiago de Compostella, Spain). All patients eligible for inclusion in EU-CaRE observational study (Table 2), but refusing regular CR are candidates for EU-CaRE RCT. No access, availability or insufficient knowledge of a computer with Internet, and implanted cardiac device (ICD, pacemaker) are additional exclusion criteria.

Intervention. Patients randomised to intervention will undergo six months of telemonitored guidance followed by six months without telemonitoring. The *mCR* programme involves a home-based programme in which patients are supplied with a heart rate belt to wear while exercise training and a smartphone/application (app) with a data subscription from MobiHealth BV. The wireless connected heart rate belt measures the heart rate of the patient during the activity and the data are subsequently transferred to the smartphone app by a Bluetooth connection. Through this app, patients are able to measure and register physical activity, heart frequency and intensity (BORG scale) and can monitor progress. The patient has access to a MobiHealth Rehabilitation secured web portal where data are presented and compared to their personal goals for activities. The research team (typically a CR nurse or physiotherapist) also has access to the web portal to monitor progress of participants, advise on rehabilitation approach and stimulate compliance at regular intervals described below.

Patients are instructed to exercise while wearing the heart rate monitor for a minimum of five days per week for at least half an hour at an individually selected level of intensity and self-chosen type of activity. The outcomes of the CPET on the first visit (T0) will guide the individual heart rate zones. A personal guideline regarding the intensity and frequency for the self-chosen activity for the patient is entered once at the start of the study by the researcher/nurse. During training sessions, the patients wear the heart rate monitor and select on their smartphone the type of activity they are going to perform from a predefined list (cycling, running, walking, home trainer, gardening, etc.). After finishing the exercise, patients enter the rate of perceived exertion for the training session (6–20 BORG score). Accordingly, the duration, intensity (based on

Table 3. Overview of data acquisition in the observational study.

Aim	Main outcome measures	CR centre and programme-related parameters	Patient-related parameters
Enrolment	Proportion of eligible patients enrolled in a CR programme	<ul style="list-style-type: none"> • Method of referral • Level of access to CR (health insurance coverage) • Urban/rural <p>Programme characteristics:</p> <ul style="list-style-type: none"> • In/out patient CR • Separate/same institution • W/wo multidisciplinary counselling 	<ul style="list-style-type: none"> • Demographics^a • Comorbidity • Ethnicity • Education • Employment status • Co-habitation • Type of index event • CV risk factors • Substance abuse • Travelling distance to centre • Reason for non-participation
Adherence to centre-based CR	<p>Proportion of patients enrolled in a CR programme who complete the programme</p> <p>Percentage training sessions attended</p>	<p>Programme characteristics:</p> <ul style="list-style-type: none"> • In/out patient CR • Separate/same institution • W/wo multidisciplinary counselling • Duration of programme (in weeks), • frequency of supervised training sessions (number per week), • training volume (h/weeks), • Intensity training session (light to moderate or moderate to intense) • HIIT versus moderate training • Multidisciplinary counselling 	<ul style="list-style-type: none"> • Demographics • Comorbidity • Ethnicity • Education • Employment status • Co-habitation • Type of index event • CV risk factors • Substance abuse • Travelling distance to centre • Social network • Involvement in voluntary work • Medical history • LVEF • Symptoms: CCS and NYHA
Effectiveness of CR	<p>At end of CR program:</p> <ul style="list-style-type: none"> • VO_{2peak} • Lipid profile • HbA1c • BMI • Lean body mass • Blood pressure • Smoking <p>General health</p> <ul style="list-style-type: none"> • Depression/anxiety • QoL • Symptoms 	<p>Programme characteristics:</p> <ul style="list-style-type: none"> • In/out patient CR • Separate/same institution • W/wo multidisciplinary counselling • Duration of programme (in weeks), • frequency of supervised training sessions (number per week), • training volume (h/weeks), • intensity training session (light to moderate or moderate to intense) • HIIT versus moderate training • Multidisciplinary counselling 	<p>Baseline measures:</p> <ul style="list-style-type: none"> • VO_{2peak} • Lipid profile • HbA1c • BMI • Lean body mass • Blood pressure • Smoking • Depression/anxiety • QoL • Symptoms
Sustainable effect of CR	<p>At 1 year follow-up:</p> <p>Physical fitness</p> <ul style="list-style-type: none"> • VO_{2peak} (primary endpoint) <p>Risk factor control</p> <ul style="list-style-type: none"> • Lipid profile • HbA1c 	<p>Programme characteristics:</p> <ul style="list-style-type: none"> • In/out patient CR • Separate/same institution • W/wo multidisciplinary counselling • Duration of programme (in weeks), • frequency of supervised training 	<p>Baseline measures:</p> <ul style="list-style-type: none"> • VO_{2peak} • Lipid profile • HbA1c • BMI • Lean body mass • Blood pressure • Smoking

(continued)

Table 3. Continued

Aim	Main outcome measures	CR centre and programme-related parameters	Patient-related parameters
	<ul style="list-style-type: none"> • BMI • Lean body mass • Blood pressure • Smoking • General health • Depression/anxiety • QoL • Symptoms 	<ul style="list-style-type: none"> • sessions (number per week), • training volume (h/weeks), • intensity training session (light to moderate or moderate to intense) • HIIT versus moderate training • Multidisciplinary counselling • Follow-up 	<ul style="list-style-type: none"> • Depression/anxiety • QoL • Symptoms
Care utilisation and costs	Health care utilisation	<ul style="list-style-type: none"> • Hospital admissions • Emergency care visits • GP visits • Cardiac interventions/tests 	

BMI: body mass index; CR: cardiac rehabilitation; CV: cardiovascular; GP: general practitioner; QoL: quality of life; HbA1c: Hemoglobine A1c; HIIT: High Intensity Interval Training; LVEF: left ventricular ejection fraction.

^aAll data sought registered on participants and non-participants of CR alike.

the heart rate zones) and BORG score of each training/activity are collected by the smartphone and transferred to a secured website where both patient and researchers/nurses involved in the study can view the results.

The aim of *mCR* is to improve the self-management skills, stimulate patients to exercise independently and increase self-confidence. During the first month patients receive weekly individual coaching and feedback on their training results by telephone, in the second month they will be coached every two weeks, and in months 3–6 one monthly call will be held. For the individual coaching the motivational interviewing method is used. The concept of motivational interviewing evolved from experience in the treatment of problem drinkers.¹² Motivational interviewing is a directive, client-centred counselling style for eliciting behaviour change by helping people to explore and resolve ambivalence. Researchers involved in the RCT have received training on motivational interviewing during the initiation visit. Furthermore, a standard operating procedure for the individual coaching is used in order to ensure a similar mode of operation.¹³ At the end of the first six months, the patients are asked to return the heart rate monitor and smartphone. In the subsequent six months until the end of the study patients will receive no further coaching or feedback.

Patients randomised to the control group will not receive any form of CR. During the 12-month study period both groups will receive locally defined standard patient care.

Randomisation. Before randomisation patients will receive oral and written information and sign a consent form. Patients will be randomised 1:1 to active intervention or control by a centralised computerised

allocation system, applying an algorithm that prevents the care providers and/or the investigators from predicting the outcome of the randomisation process. It is not possible for the full research team to be blinded towards the allocation but centres are instructed to have CPET performed by personnel not knowing the randomisation outcome and to inform patients afterwards on the randomisation outcome.

Study endpoints, baseline and follow-up assessments. The patient assessment and measurements will be performed at baseline (T0), six months (T1) and end of follow-up at 12 months (T2) (Figure 2, Table 4).

Physical fitness defined as VO_{2peak} is currently the best predictor for sustained patient health outcomes and change in peak oxygen uptake (VO_{2peak}) derived from CPET at six months compared to VO_{2peak} from baseline, was chosen as primary endpoint.^{14,15}

Secondary endpoints are changes in the following conventional CVD risk factors: lipid profile, hemoglobin A1c (HbA1c), renal function, lean body mass, blood pressure and smoking habits; changes in depression score assessed by: PHQ-9 questionnaire; anxiety score assessed by GAD-7 questionnaire, and Quality of Life assessed by SF-36v2 Physical Component Summary Score and Mental Component Summary Score and MACEs, a composite of all-cause mortality, near sudden cardiac death and hospital admission for cardiovascular disease. MACEs will be registered and/or collected by monthly telephone calls with the participants throughout the study period.

Care utilisation will be expressed as costs per patient based on clinical admission days, emergency and outpatient clinic visits, GP visits for cardiac-related complaints or issues, cardiac-related radiology/physiology, nuclear or laboratory tests and other cardiac

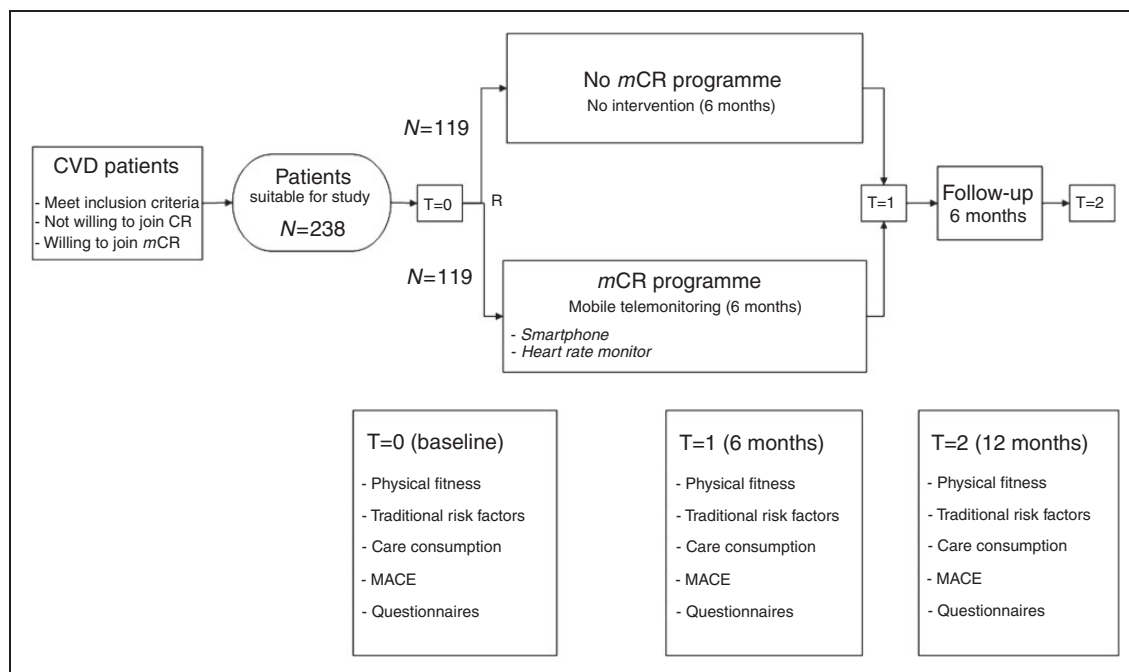


Figure 2. Overview of assessments in European study on effectiveness and sustainability of current cardiac rehabilitation programmes in the elderly (EU-CaRE) randomised controlled trial (RCT). CR: cardiac rehabilitation; CVD: cardiovascular disease; MACE: major adverse cardiovascular event; mCR: mobile telemonitoring guided CR.

Table 4. Overview of data acquisition for European study on effectiveness and sustainability of current cardiac rehabilitation programmes in the elderly (EU-CaRE) randomised controlled trial (RCT).

Procedure/test	Enrolment randomisation (±7 days)	End of mCR programme (T1: 6 months) (±14 days)	End of study (T2: 12 months) (±14 days)
Patient eligibility	✓		
Patient informed consent	✓		
Patient characteristics:			
- Demographic	✓		
- Physical	✓		
- Medical history	✓		
- Risk factors	✓		
- Medication	✓		
- Indication for CR	✓		
Centre characteristics:			
- Mobile telemonitoring guidance	✓		
- Maximal ergometer test	✓ ^a	✓ ^a	✓
- 12-lead ECG	✓ ^a	✓ ^a	✓
Physical examination:			
- Weight, length, BMI, lean body mass, blood pressure	✓ ^a	✓	✓
Clinical laboratory test:			
- Lipid profile, renal function and HbA1C	✓ ^a	✓ ^a	✓
Questionnaires:			
- SF-36v2, PHQ-9, GAD 7, Mediterranean diet score	✓	✓	✓

(continued)

Table 4. Continued

Procedure/test	Enrolment randomisation (± 7 days)	End of <i>mCR</i> programme (T1: 6 months) (± 14 days)	End of study (T2: 12 months) (± 14 days)
Care utilisation monitoring ^b	✓	✓	✓
(Serious) adverse events monitoring ^b	✓	✓	✓

BMI: body mass index; CR: cardiac rehabilitation; ECG: electrocardiogram; *mCR*: mobile telemonitoring guided CR.

^aRoutine practice.

^bBetween T1 (6 months) and T2 (12 months) monitoring of care utilisation and registration of events is by monthly telephone calls with the participant.

interventions. For each country cost prices per activity will be assessed and for each patient the cardiac problem-related costs can be calculated.

The patient-related data that will be collected are the same as in the observational. Additional to that, the following data will be registered: number of training sessions, logged volume and intensity of training sessions and patient compliance to the programme. Full compliance will be defined as fulfilling the planned exercise session with *mCR* for at least 30 min, five days per week.

Patients can leave the study at any time for any reason if they wish to do so without any consequences. Patients will not be replaced after withdrawal from the study. Drop-outs from the study will be registered as well as their reason for drop-out. They will be encouraged to participate in follow-up visits and will be included in intention to treat analyses. Patients who experience a new event will receive normal follow-up.

Sample size calculation and projected statistical analyses. For the randomised tele-monitoring trial, the sample size calculation is based on the expected difference in increase in level of 3.0 ml/kg/min between the control and intervention group with an estimated standard deviation of 5 ml/kg/min in the intervention group and 6 ml/kg/min in the control group. Assuming 80% power and a 5% two-sided significance level ($\alpha = 0.05$), the sample size (n) required to achieve a probability of 80% of detecting a difference in an increase level between two independent groups is $n = 55$ per randomisation group. Since this is a multi-centre study in different countries, we will use an adjustment based on the estimated intraclass correlation coefficient (ICC) for the study centres to calculate the sample size. An ICC of 0.05 is used in the sample size calculations. After adjustment for the ICC, the sample size in $n = 83$ per randomisation group. Based on 30% withdrawal we aim for a group size of $n = 119$ per randomisation group ($n = 238$ in total). Five centres will participate in the RCT so we will aim at including 48 patients per centre. As this is a cooperative trial, centres may recruit more patients than this recruitment goal. When

one centre starts to dominate enrolment, however, recruitment might need to be capped. The total sample size ($n = 238$) would be sufficient to detect a clinically and physiologically relevant change in peak oxygen consumption, despite a 30% dropout.

The primary endpoint of the RCT is the change in $VO_{2\text{peak}}$ level between baseline and six months and the null hypothesis that there is no difference in mean change in $VO_{2\text{peak}}$ level between the two groups. Group comparison will be by linear mixed models with the intervention as a fixed effect, the effect of centre on the outcome modelled with a random effect and adjustment for baseline value of $VO_{2\text{peak}}$. A two-sided p -value of less than 0.05 will be considered to be statistically significant. Similar analyses will be performed for effects at 12 months and for the secondary outcomes. This analysis allows for missing values. Missing values will be analysed in order to determine whether they systematically differ between groups or are related to baseline value. In this case multiple imputation methods will be used to calculate parameter estimates as a sensitivity analysis.

Group comparison will be by linear mixed models with the intervention as a fixed effect, the effect of centre on the outcome modelled with a random effect and adjustment for baseline value of $VO_{2\text{peak}}$. A two-sided p -value of less than 0.05 will be considered to be statistically significant. Similar analyses will be performed for effects at 12 months and for the secondary outcomes.

The cumulative incidences of the composite endpoint MACEs and the elements from which it is constituted will be presented by intervention group and plotted in Kaplan-Meier survival curves for one year of follow-up. We will test for differences in hazard rates between the *mCR* and control group using Cox regression analysis allowing the baseline hazard functions to differ between centres.

Cost-effectiveness analyses

The economic method of evaluation is a cost-benefit analysis. The two main benefits are survival and quality of life. Survival will be measured by the

surrogate endpoint VO_{2peak} , a reliable predictor for mortality, and quality of life will be represented by the difference in two composed scores between T2 (the end of follow-up) and T0 (enrolment): Physical Component Summary Score and Mental Component Summary Score.

All costs with regard to the cardiological diagnostic and therapeutic process from the moment of inclusion in the study until the end of follow-up will be included. The cost categories that are examined are all direct costs within and outside the health care system. Direct costs in healthcare comprise GP consultations, admission days, outpatient visits, and diagnostic and therapeutic activities. The direct non-medical costs include travel and time costs of the patient and in relation to visits to the doctor and health care institutions. Medication is not included in the analysis, because all patients receive normal cardiology care. For the assessment of volume all observations registered in the e-CRF will be used. All activities performed during one outpatient visit or admission period are considered to be one patient visit to the hospital. Confounders may have a large impact on the results and uncertainty in measurement. For this reason, a sensitivity analysis will be performed.

Data management

The gathered data are entered into an electronic case record form and managed by a Contract Research Organisation (CRO) (diagram) responsible for the data management, monitoring of participating centres and quality of data; this includes full source data verification for at least the first five included patients per centre and 10% of the other included patients. At the end of the project all data will be integrated in a data warehouse, and made query free and available for statistical analysis.

Discussion

Even as the global incidence and mortality from CHD is declining, the burden of elderly patients suffering from chronic CHD is increasing in Europe.¹ In this light, CR is of particular importance. The quality of life of CVD patients is significantly impaired, especially in the elderly, due to several factors including high risk of recurrence of events, hospital admission, physical disability, co-morbidity and general frailty. With physical limitations, social limitations, and unstable health, many CHD patients become anxious or depressed. These factors render elderly CHD patients, more than half of whom are women, more vulnerable not only in terms of recurrent events but also in terms of maintaining ability to lead an independent life. Yet

paradoxically, uptake of CR remains poor, particularly in the elderly. Practical barriers, like distance, insufficient transportation infrastructure, mobility problems and lack of social support are proven to be factors for low participation. With the objective of contributing significantly to a solution, the EU-CaRE consortium hopes that by adding novel components to existing CR there will be increased success.

The current project aims to address these issues by targeting the challenges related to CVD and ageing. EU-CaRE compares existing CR programmes in the elderly as well as an innovative mobile tele-monitoring guided CR focusing on sustainability, (cost-) effectiveness and participation grade. The study will map the current practice and effectiveness of CR and through this identify characteristics of successful CR. This will contribute to the understanding of the predictors for effectiveness of individual CR components, provide the evidence base to redesign and improve CR and allow tailoring of CR delivery towards the elderly.

mCR technology

Smartphone apps are becoming increasingly popular among physicians, patients and general public. The majority of these apps are general health and fitness apps that both facilitate the tracking of health parameters by private users, and provide users with basic health and fitness-related information as well as guidance. There is, however, very little evidence for the effectiveness of mobile health apps and as a consequence very little experience on how to best evaluate these apps: especially when the use of an app is combined with individual coaching as in the EU-CaRE RCT. The mCR technology that will be used in this project, has recently been tested in addition to conventional CR in a pilot study at Isala Zwolle in the Netherlands. The outcomes are being evaluated. Recently, Frederix et al. showed that the addition of cardiac tele-rehabilitation to conventional centre-based CR proved to be more effective and efficient than centre-based CR alone.¹⁶ Cardiac tele-rehabilitation reduced the number of readmissions during the follow up period from 22.9% to 10.1%, an average cost reduction of €564 per patient and an increased quality of life. In the EU-CaRE RCT patients will receive mCR who would otherwise not have received CR at all. Little is known about the effects of mCR in comparison to no CR instead of being added to conventional centre-based CR. mHealth solutions could develop more cost-effective CR, avoid unnecessary hospital visits and develop truly patient-centred CR programmes. The technology could facilitate patient long-term compliance by the capacity to personalise programmes, facilitate communications and monitor patient status,

drug adherence and physical activity during long periods. Also, *mHealth* may overcome barriers related caused by lack of mobility by providing home-based programmes. Small studies have investigated the effectiveness of home-based CR (not based on *mHealth* technology), with guidance in the residential environment, compared with centre-based CR. These findings have generally been non-inferior and have indicated increased participation rates.^{8,9} The implementation of the *mHealth* in a multinational, multicentre trial will overcome the weaknesses of single-centre trials and is a major strength of the study. Use of *mCR* represents an opportunity to increase participation and adherence in elderly patients.

Strengths and weaknesses

The strengths of the project include the prospective nature, the detailed assessment of patients, the focus not only on the effect of the intervention but also on causes of non-referral and non-adherence. A weakness is that due to the organisation of CR, e.g. referral to different CR centres due to health insurance coverage and lack of registries of CHD patients eligible for CR, the actual number of patients eligible for CR may not be accurately recorded in all centres. Thus the true uptake may be overestimated. Further, for ethical and practical reasons the information gathered on patients not referred to CR or who decline is limited and important predictors of CR uptake may not be registered (e.g. related to socioeconomic factors, co-morbidity or social network). The additional strength of the RCT is the randomised setting and the focus on the compliance and adherence to *mCR*.

The aim of the RCT was to test an intervention in patients who currently receive no CR and thus includes only patients who have declined regular centre-based CR. This design was chosen to ensure that patients were not deprived of an evidence-based multidisciplinary intervention. However, this also introduces a bias in the study since the results will only be applicable to a sub-group of the patients eligible for CR. A further weakness may be that *mCR* is focused on exercise training and patients do not achieve the benefit of multidisciplinary programme as provided in the standard CR.

Conclusion

The EU-CaRE project is aimed to provide the evidence base for the development of more effective CR interventions, and for enhanced uptake, adherence and compliance in the elderly population. EU-CaRE RCT in its turn hopes to provide proof that *mCR* is a valuable alternative for elderly population who opt out of current CR offers.

With this study, we hope to identify barriers in the entire chain of events that leads to successful CR, whether these barriers are structural barriers, relate to referral and the organisation of the CR programme, relate to the implementation of the programmes or to patient characteristics. By comparing the elements implemented in experienced CR centres in different parts of Europe and the effects these have on the success of CR we may learn from each other. We further hope to identify patient groups that may need particular attention in terms of improved referral, adherence and effect of intervention.

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Declaration of conflicting interests

The authors declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: EP De Kluiver is shareholder of a company that participates in MobiHealth BV. He is not involved in the implementation of the study and has no contact with the study participants. Other authors state that they have no conflicting interests to declare.

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Category: 01. Basic research, Technologies, Informatics, Platforms, Big data

Contact: Li Jia

Deep neural networks improve atrial fibrillation detection in Holter: first results

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Background: Atrial fibrillation (AF) is the most common human arrhythmia. High prevalence in the aged population (0.5% for 50–59 to 9% for 80–89), and increased risks of hospitalisation, strokes and death call for early detection using long-term ambulatory electrocardiogram (Holter ECG). Previous works concluded that algorithms using RR interval durations as input yield a good sensitivity while being robust to noise. However, such algorithms are characterised by poor specificity and positive predictive value (PPV); no previous algorithm which uses shape information, such as atrial fibrillatory pattern, achieved better overall results. We used deep convolutional neural networks (DNNs) to overcome this difficulty, since such models are known to be well suited for solving pattern recognition problems.

Methods: We trained a DNN (20 M parameters, 1.6 M neurons, 16 layers) on a set of 200,000 annotated 20 seconds ECG in order to classify AF and other arrhythmias. We then processed Holter data by splitting it into 20 second periods, and classified AF episodes (AF vs not AF). The reference standard for performance evaluation was the independent MIT BIH arrhythmia database (not used for training). The MIT BIH arrhythmia database is a reference dataset annotated by cardiologists for automatic arrhythmia detection benchmarking; it consists of 48 30-minute ECG recordings extracted from long-term 24-hour ambulatory ECG recordings, half of which manifest clinically significant arrhythmias. Specificity (Sp),

sensitivity (Se), accuracy (Acc) and PPV were calculated for AF episode detection and compared to that of RR-interval method results as reported in the literature.

Results: Performance of the previously published RR dynamic method compared to the tested DNN method was Sp = 82.8 (81.6–84.0) vs Sp = 98.5 (98.1–98.9), Se = 96.3 (94.5–98.1) vs Se = 96.9 (95.2–98.6) Acc = 85.53 (84.43–86.63) vs Acc = 98.3 (97.9–98.7) and PPV = 58.7 (54.0–63.4) vs PPV = 89.6 (86.7–92.5) (confidence intervals 95%). The DNN was therefore much more specific without any loss of sensitivity. Evaluation for episodes containing either AF or atrial flutter episodes yielded Sp = 99.2 (98.9–99.5), Se = 96.8 (95.1–98.5), Acc = 99.0 (98.7–99.3) and PPV = 92.3 (89.7–94.9), hence improving detection again.

Conclusions: This deep neural network performed significantly better in the detection of AF than previously published RR interval-based methods. This method may be more reliable and accurate than previous methods in the diagnosis of AF on long duration ambulatory ECG and other monitoring devices.

Category: 07. Mobile Health

Contact: Orchard Jessica

Screening for atrial fibrillation during flu vaccinations by primary care nurses using a smartphone electrocardiograph (iECG): a feasibility study

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Background: People with unknown atrial fibrillation (AF), often asymptomatic, have a substantially increased risk of stroke. Screening identifies unknown AF in 1.4% of people aged ≥65 years. Although recommended in some international guidelines, AF screening is not routine. Screening at the time of flu vaccination presents an ideal

opportunity to detect AF in large numbers in a primary care medical setting, with an existing annual recall system for patients aged ≥ 65 years. The objective was to investigate primary care screening for unknown AF by practice nurses using a handheld smartphone electrocardiogram (iECG) during annual flu vaccination; in addition, to identify relevant barriers and enablers to this screening strategy.

Methods: Five general practices in Sydney, Australia were recruited during the flu vaccination period, April–June 2015. Practice nurses screened patients, aged ≥ 65 years, with a 30-second iECG, which has a validated algorithm for detecting AF in real time. Each iECG was imported into the patient's electronic medical record. Management of patients identified with new AF was at the discretion of the general practitioner. To confirm accuracy of the automated algorithm, two research cardiologists reviewed de-identified iECGs on a purpose-built website. To explore barriers and enablers, semi-structured interviews were conducted with seven practice nurses, five practice managers and five general practitioners.

Results: Five general practices were recruited, and 973/2476 (39%) patients attending flu vaccination were screened. Screening took an average of 5 minutes (range 1.5–10); however, abnormal iECGs required additional time. Newly identified AF was found in 8 out of 973 patients (0.8%). The sensitivity of the iECG automated algorithm for detecting AF was 94.9% (95% confidence interval 82.7–99.4%) and the specificity was 99.1% (98.3–99.6%). Screening by practice nurses was well accepted by the practice staff. Key enablers were the confidence and competence of nurses providing screening; and a 'designated champion' (any staff member) to lead screening at the practice. Barriers were practice specific, and included: no funding for the screening, i.e. no incentive to allocate additional practice time for the screening during the flu vaccination consultation; additional time was required to action abnormal iECGs (i.e. review and arrange 12-lead ECG); and three out of five practices did not establish a protocol/workflow to deal with abnormal iECGs.

Conclusion: Screening with iECG during flu vaccination by primary care nurses is feasible and well accepted by practice staff. Addressing identified barriers is likely to increase uptake.

Category: 07. Mobile Health

Contact: Rawstorn Jonathan Charles

Real-time remotely monitored exercise is comparable to traditionally supervised centre-based programmes for coronary heart disease patients: results from the REMOTE-CR non-inferiority randomised controlled trial

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Background: Accessibility barriers constrain utilisation of traditional supervised exercise-based cardiac rehabilitation (exCR). Home-based interventions improve access but relinquish supervision and coaching from clinical exercise specialists during exercise training. Mobile health technologies can bridge these gaps by distributing clinical expertise to remotely located individuals during exercise; however, such an approach has yet to be evaluated.

Methods: A total of 162 adults with coronary heart disease were randomised (1:1) to 12 weeks of remote (INT) or centre-based (CON) exCR. INT included real-time remote physiological monitoring and coaching, theory-based behaviour change, and social support delivered via a novel mobile technology platform comprising smartphones, wearable sensors and custom software (Figure 1). CON comprised traditionally supervised exCR. Exercise programmes aligned with evidence-based exCR guidelines, and both groups could access additional usual care services. Outcomes included aerobic exercise capacity (VO_{2max} , primary), modifiable cardiovascular risk factors and psychological outcomes. We hypothesised remote exCR would be non-inferior to centre-based exCR (inferiority margin -1.25 ml/kg per minute).

Results: Results of a nested pilot trial ($n = 76$) indicate both groups improved VO_{2max} (INT $\Delta = 2.92$ ml/kg/min (1.52–4.32); CON $\Delta = 2.76$ ml/kg/min (1.39–4.12), both $P < 0.001$), with no between-group difference (0.16 ml/kg/min (-1.79 –2.12), $P = 0.87$). Both groups improved physical activity (PA; INT $\Delta = 2786$ METmin/week (1264–4308), $P = 0.001$; CON $\Delta = 3149$ METmin/week (1666–4631), $P < 0.001$) and task self-efficacy (INT $\Delta = 12.87\%$

(8.54–17.19); $CON\Delta = 12.86\%$ (8.66–17.08), both $P < 0.001$). INT acceptability and usability were highly rated; 28/31 INT participants who attended follow-up would choose remote exCR if available via usual care. Full trial results will be available at the 2016 Congress.

Conclusion: Pilot effects of remote and centre-based exCR on VO_{2max} , PA and task self-efficacy were comparable. Remote exCR delivered via novel mobile technology platforms could increase service utilisation by providing additional options with enhanced flexibility for patients whose needs are not being met by existing services. Findings from the full trial may confirm these encouraging preliminary results.

Category: 02. ECG techniques and applications

Contact: Kropf Martin

How far in the future can we predict paroxysmal atrial fibrillation?

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Background: This article describes the evaluation of an algorithm for predicting paroxysmal atrial fibrillation (PAF) from Holter monitor ECG signals in sinus rhythm and compares its efficacy in different follow-up periods. Ectopic beats (i.e. with altered P-wave morphology) act as potential triggers of PAF and thus may have clinical predictive value. Previous evaluations have shown the effectiveness of this algorithm in a 12-month follow-up setting. For a clinical application though it would be very useful to diagnose a risk for AF even earlier. For the scope of this article we have determined the accuracy of different time windows with an extended follow-up period of >24 months.

Methods: The ECGs used for clinical validation had been recorded during a clinical trial. During the trial, a 24 hours ECG was recorded with a Holter machine at baseline for all patients. For calculating PAF risk the baseline ECG was used. We compared the efficacy of the algorithm with different observation periods: 3, 6, 12, 24 and >24 months. PAF was diagnosed by implantable loop recorder or by regular 12-channel ECG at monthly follow-up visits. The algorithm was based on analysing p-wave morphologies of supraventricular premature heart beats and comprises four steps:

1. QRS complexes were detected using our QRS detector.
2. Classification of detected QRS complexes in multiple classes according to morphology.

3. Supraventricular premature beat detection by identifying beats of the most recent morphology class with at least 20% prematurity based on the first derivative of the sequence of the RR intervals.
4. P-wave correlation and statistical comparisons: The two groups of correlation coefficients corresponding to the regular and the premature heart beats were assumed to represent two sets of samples. We assessed the probability P that both samples stem from the same distribution, i.e. that premature and normal beats exhibit the same morphologies. Therefore, we applied the non-parametric U-test to the groups of correlation coefficients.

Results: Sixty-one patients were included for validation. Table I shows the area under curve (AUC), P value and calculated risk factors for both groups (PAF vs non-PAF).

Table I. Results for both groups: PAF vs non-PAF.

	Cumulated N (PAF)	Area under the curve	P value	Risk (PAF)	Risk (non-PAF)
3 Months	2	0.88	0.068	2.55 ± 1.52	0.81 ± 1.26
6 Months	3	0.90	0.019	1.82 ± 1.65	0.82 ± 1.27
12 Months	7	0.80	0.010	1.47 ± 1.38	0.79 ± 1.28
24 Months	11	0.75	0.010	1.40 ± 1.41	0.76 ± 1.25
> 24 Months	12	0.68	0.052	0.58 ± 0.51	0.08 ± 0.28

PAF: paroxysmal atrial fibrillation.

Conclusion: Our analysis has shown that predicting PAF is feasible for up to 24 months with statistical significance. The accuracy of the algorithm was highest for the 6-month time window, which also exhibited statistical significance ($P = 0.019$). Although the AUC was modest (0.68) for >24 months, there was a trend towards a statistical significant ($P = 0.052$) difference between the two groups. Our next step will be to validate these results in a prospective setting to see if earlier diagnosis could finally also lead to a better outcome.

Category: 08. Risk Factors, Rehabilitation and Prevention

Contact: Kraal Jos

Clinical and cost-effectiveness of home-based cardiac rehabilitation compared to conventional, centre-based cardiac rehabilitation: results of the FIT@Home study

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Background: Although cardiac rehabilitation (CR) improves physical fitness after a cardiac event, many eligible patients do not participate in CR. In addition, the beneficial effects of CR are often not maintained over time. Home-based training with telemonitoring guidance could improve participation rates and enhance long-term effectiveness. However, the long-term effects of home-based CR are scarce and cost-effectiveness compared to centre-based CR is unknown.

Methods: We randomised 90 low to moderate risk patients entering CR to 3 months of either home-based training with telemonitoring guidance or regular centre-based training. Outcome measures were physical fitness, physical activity levels, training adherence, health-related quality of life and costs. Outcomes were assessed at baseline, at discharge from CR, and at one year after inclusion.

Results: Training adherence was similar between the groups. For both groups physical fitness was improved at discharge ($P < 0.01$) and at one year ($P < 0.01$), without differences between groups ($P = 0.31$ and $P = 0.87$, respectively, Table 1). Physical activity levels in both groups did not change during the one-year study period (centre-based group: $P = 0.10$, home-based group: $P = 0.08$). Physical and social subscales of health-related quality of life improved at follow-up in both groups, without differences between groups. Home-based training resulted in non-significantly lower healthcare costs (€110 per patient, 95% confidence interval (CI) –669 to 888, $P = 0.78$). From a societal perspective, a non-significant difference of €2894 per patient in

favour of home-based CR was found (95% CI –1220 to 7007, $P = 0.17$) and the probability that it was more cost-effective varied between 97% (willingness to pay of €0 per quality-adjusted life year (QALY)) and 75% (willingness to pay of €100,000 per QALY).

Conclusion: We found no differences between home-based training with telemonitoring guidance and centre-based training on physical fitness, physical activity levels and health-related quality of life. However, home-based training appears to have lower costs and to be more cost-effective than centre-based training. We conclude that home-based training with telemonitoring guidance can be used as an alternative to centre-based training for low to moderate risk patients entering CR.

Category: 02. ECG techniques and applications

Contact: Sparenberg Adolfo

Fifteen years of a telecardiology network in south Brazil: from dial-up to mHealth technology

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Background: The implementation of a tele-ECG network in the state of Rio Grande do Sul (RS), Brazil started in the year 2000 as a regional project covering four remote institutions. Since 2008, through a public telecardiology initiative, the network was gradually expanded to 30 and to 38 cities (2013) across the state. Currently, the method includes a mobile tele-ECG network, allowing medical doctors to receive and to analyse the exams via mobile phones. This study aims to report major aspects related to the implementation and operational phases in 15 years of a telecardiology project in south Brazil.

Methods: The initial period – the regional network started in 2000 – covered four institutions (three hospitals and one outpatient care unit) connected to a local cardiologist. The teletransmission of 12-lead ECG was held via dial-up and radio-based communication, using remote access software. In 2008, a public tele-ECG network (phase I) was implemented in 10 remote cities across the state, an initiative taken by both the state secretariats of health and of science and technology, also supported by a federal research agency. In 2010, the state-level project was expanded to 30 villages and to 38 in the year 2013 (phase II). At that stage some new facilities were incorporated to the telecardiology project, to know: a new telecardiology central unit and a team of on-duty cardiologists working 24/7, a data processing centre and a multiseat interactive webconferencing training programme. Since July 2013, an Android-based mobile tele-ECG platform was installed in six public healthcare institutions.

Results: In a period of 15 years, around 37,000 digital ECGs were analysed from the regional network. Since 2008, 131,596 digital tele-ECGs were recorded and transmitted to the public telecardiology unit. Their analysis found: 11,014 (8.38%) cardiology urgencies, 41,102 (31.25%) normal ECGs, 77,574 (58.95%) classified as chronic cases and 1906 (1.42%) cases of technical interference or inversion of ECG leads. From the cardiac urgencies, a total of 975 cases of ST elevation myocardial infarction were diagnosed (8.85% of acute cases). Since 2010, a total of 326 healthcare professionals from 38 villages – medical doctors, nurses, IT experts and administrative staff – attended training sessions of the public ECG network.

Conclusion: In less than two decades, conventional analogue ECG machines were replaced by digital equipment, allowing the implementation of ecardiology networks in far remote areas. In south Brazil, since 2000, around 168,000 tele-ECGs were analysed from remote institutions, providing timely diagnosis and advice to on-duty medical doctors. Overcoming major obstacles represented by a shortage of telecommunication infrastructure, taking care of the financial sustainability and paying special attention to the education of the remote staff are all key components of this scenario.

Category: 08. Risk Factors, Rehabilitation and Prevention

Contact: de Kluiver Ed

Rationale and design of a randomised clinical trial for an extended cardiac rehabilitation programme using telemonitoring: the TeleCaRe Study

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Background: Mortality and morbidity of cardiovascular diseases are still high and are a major cause of disability and lost productivity in adults worldwide. Despite the known positive effects of cardiac rehabilitation (CR) and an active lifestyle, the long-term benefits are often disappointing due to lack of adherence to the changes in lifestyle. An explanation for the low compliance to an active lifestyle after CR could be the transition of a supervised and structured training programme to a continuation without this supervision. Prolonging of CR is effective, but unattractive because of the repeated visits to a CR facility. Mobile health (mHealth) in combination with home-based CR seems to be equally effective as centre-based CR and has

the potential to increase participation, compliance, self-management and sustainable effectiveness. Supportive evidence for long-term positive effects is, however, limited. The aim of TeleCaRe is to determine if prolongation of a traditional cardiac rehabilitation programme with additional mHealth guided CR (mCR) for a period of 6 months results in better long-term effects on physical and mental outcomes, care consumption and quality of life.

Methods: TeleCaRe is a prospective single centre randomised controlled trial; a targeted 120 patients with an absolute indication for CR are randomly assigned in a 1:1 ratio to an intervention group with 6 months mCR or a control group with traditional follow-up. Patients in the intervention group are equipped with a smartphone and connected heart rate monitor dedicated for the use of telemonitoring. They receive personal exercise instructions based on VO_{2peak} outcome. The recorded data of physical activity are transferred to a secured website through a secured wireless connection. Patients have access to their individual webpage and their training history on the smartphone. Specialised nurses advise on how to improve patients' LTPA level by using motivational interviewing. The primary outcome is VO_{2peak} after 12 months. Secondary outcomes are VO_{2peak} after 6 months, quality of life (Short Form 36), physical, emotional and social functioning, cardiac structure, traditional risk profile, compliance to the use of the smartphone, major adverse cardiac events and care utilisation.

Intermediate results: TeleCare started in September 2014 and inclusion is completed. September 2016 follow-up will be completed. Preliminary results (see Table 1) show that 40.8% of the screened suitable patients were willing to participate. They are predominantly men (82.5%). The main reasons for refraining from participation were time investment and doubts concerning the added value.

Conclusion: The TeleCaRe study will provide insight into the added value of prolongation of traditional cardiac rehabilitation with 6 months of mHealth guided cardiac rehabilitation. Preliminary results will be presented in Berlin.

Category: 08. Risk Factors, Rehabilitation and Prevention

Contact: Goessler Karla

Isometric handgrip training: a new non-pharmacological tool to control blood pressure? Preliminary results of the TRiHYP (TeleRehabilitation in Hypertension) Study

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Background: Aerobic exercise training is a cornerstone therapy in the prevention, treatment and control of hypertension; however, uptake and adherence are poor. Growing evidence suggests a potential role for isometric handgrip exercise as an easy applicable non-pharmacological highly effective blood pressure (BP) lowering tool. This is based on meta-analytic research demonstrating superior effects on office BP following isometric handgrip training compared to aerobic training. However, a direct comparison between both exercise modes is absent and the effect on ambulatory BP is unknown. The aim of this study was to compare the effects of 8 weeks of aerobic exercise training and isometric handgrip training on office and ambulatory BP in healthy individuals.

Methods: Forty-two individuals ($n = 18$ men; 32 ± 10.9 years, mean BP 114.1 ± 11.9 mmHg/ 77.8 ± 8.3 mmHg) were randomised on a 2:2:1 basis to an isometric handgrip group (IHG, $n = 16$), an aerobic exercise group (AE, $n = 16$) or a control group (CO, $n = 10$). Both exercise interventions (IHG and AE) were performed in the home environment using remote monitoring and telemonitoring guidance. Patients in the IHG performed daily four 2-minute sustained grips at 30% of maximal volitional contraction with one minute rest between sets using a handgrip device and software. Patients randomised to AE were advised to perform at least 150 minutes extra of moderate intensity aerobic exercise (60–70% reserve heart rate) using a heart rate monitor. Patients received individual coaching by telephone or e-mail once a week, based on measured heart rate data or handgrip data that were shared through the internet. Outcome measures were assessed at baseline and after 8 weeks. The primary outcome was ambulatory BP; secondary outcomes included peak exercise capacity, peak isometric handgrip strength, anthropometric characteristics and office BP.

Results: AE resulted in an increase in exercise capacity (284.4 (142.6–426.5) ml/min), which was significantly larger compared to the control group ($P < 0.01$). Both AE (-3.5 (-6.9 – 0.62) mmHg) and IHG (-2.8 (-6.4 – 0.71)) resulted in a significant reduction of office diastolic BP, which was significantly different from CO ($P = 0.01$ for both). Both daytime systolic BP and diastolic BP were significantly reduced following AE ($P < 0.01$ for both) and IHG ($P = 0.01$ and $P = 0.03$, respectively) compared to the control group. No difference could be established between AE and IHG.

Conclusion: Eight weeks of home-based AE and IHG using telemonitoring guidance reduce BP during daily life activities to a similar extent.

Category: 07. Mobile Health

Contact: van der Velde Astrid

A European randomised controlled trial for an eHealth application in cardiac rehabilitation in the elderly: study design and intermediate results of the EU-CaRE randomised controlled trial

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Background: Improving the quality of life and independence of elderly cardiac patients is a major challenge in Europe. Mortality and the disease burden of cardiovascular diseases (CVD) are high, especially in the growing elderly population, causing an increasing pressure on the health-care system. Cardiac rehabilitation (CR) improves quality of life and reduces healthcare costs. There is a substantial variation in CR programmes, which has led to a fragmented approach to CR in Europe. In addition, the knowledge about the effectiveness of the individual components of CR and its suitability especially in the elderly is limited. Mobile health in combination with home-based CR seems to be equally effective as centre-based CR and has the potential to increase participation, compliance, self-management and sustainable effectiveness. However, supportive evidence for long-term positive effects in the elderly is lacking. The EU has approved a major cardiac rehabilitation project: EU-CaRE. A network of leading heart centres and top research institutes from seven European countries compare, improve and tailor CR programmes for the elderly. Part of the project is EU-CaRE RCT, a randomised controlled trial (RCT) investigating the sustainable effectiveness and cost-effectiveness of mobile telemonitoring guided CR (mCR) as an alternative for regular CR. The objectives of this study are to assess – effectiveness of mCR in the elderly – long-term effects on physical, mental and social outcomes of mCR versus no CR – whether mCR as an alternative to regular CR is an effective means to increase participation/adherence of the elderly in CR, and – costs and revenues of mCR and its cost-effectiveness.

Methods: The EU-CaRE RCT is conducted in five European countries (Denmark, France, The Netherlands,

Spain and Switzerland). Patients ≥ 65 years with an indication for CR who refused to follow regular CR are eligible for inclusion. The targeted number of included patients is 240 (120 in each arm). Patients are randomised between regular care (control) and a 6-month mCR programme: specifically programmed smartphone, heart rate monitoring and coaching by motivational interviewing (intervention). Patients and professionals are able to follow progress by personalised web portals. Patients in both arms are followed one year after inclusion. The primary endpoint of the RCT is the difference in VO_{2peak} between the end of CR (T1) and baseline (T0). Secondary endpoints are difference in VO_{2peak} between one year (T2) and T0, difference in VO_{2peak} between T2 and T1, traditional CVD risk factors, major adverse cardiac events, general health (Short Form 36), (costs of) care utilisation, and adherence/compliance.

Results: The EU-CaRE RCT started in September 2015 in The Netherlands. In May 2016 all participating centres received ethical approvals. Nineteen patients were included until mid-June 2016. Intermediate results will be presented.

Conclusion: The use of eHealth in CR might provide novel ways for effective cardiac rehabilitation in the elderly.

Category: 05. E-Learning, Clinical Decision Support

Contact: Frederix Ines

eEduHeart I: a multi-centre randomised, controlled trial investigating the usage of a post-discharge eLearning platform for cardiac patients

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Background: Cardiac telerehabilitation includes, in its most comprehensive format, both telemonitoring, tele-coaching, social interaction and eLearning. In eLearning, patients can be provided with medically and scientifically founded multimedia interactive educational material (i.e. videos) upon discharge from the clinic (when patients are the most motivated for new information). The usage, feasibility and effectiveness of an eLearning platform, however, are not yet known. One of the aims of eEduHeart I is to investigate the usage of a cardiac post-discharge eLearning platform by coronary artery disease patients.

In this interim analysis we provide platform usage results of the first 135 intervention patients included in the study.

Methods: eEduHeart I is a prospective, multi-centre randomised, controlled trial in which 1000 patients with coronary artery disease will be randomised 1:1 to an eLearning intervention group or to conventional cardiac care. Intervention patients receive both conventional cardiac care and one month unrestricted access to the cardiac eLearning platform. Upon discharge from the clinic, they are given a voucher with an anonymous personal code, which provides them with access to the commercially available eLearning platform. The platform is composed of 20 main units. Each unit focuses on a different topic, relevant in secondary prevention for ischaemic heart disease. Each unit contains three videos, one or two with (a) (para-)medical caregiver(s) and one or two with (a) patient(s); and three short texts. For the intervention group patients, data on the eLearning platform usage are gathered through web logging during the study period. The number of log-ins per code (i.e. patient), the total time logged in, the number and type of units watched and the time viewing each specific unit is registered. Descriptive analytics are used to assess platform usage.

Results: A total of 135 out of 166 eligible patients (88% men; aged 62 ± 9 years) agreed to participate in eEduHeart I, 84 of which entered the platform during the study period. Platform users entered the platform 2.3 ± 1.8 times; and spent 44 ± 40 minutes watching 11.5 ± 10.3 video units. Video units 'Physical activity' and 'Cardiac drugs and side effects' were the two most frequently viewed (95 and 82 times, respectively). Platform usage was not different for patients aged >60 years, compared to those aged <60 years ($P = 0.636$, $U = 2303$).

Conclusion: This analysis indicates that the majority of coronary artery disease patients will use eLearning as a means to access disease-related information during the post-discharge period, if provided. Physical activity and cardiac drugs are areas of special interest. Contrary to conventional one-size-fits-all educational sessions in rehabilitation centres, an eLearning platform enables the tailoring of content according to specific patient needs. Future work will indicate whether platform usage also translates into improved patient knowledge.

Category: 01. Basic research, Technologies, Informatics, Platforms, Big data

Contact: Anwer Shehab

Multi-centre experience in electronic data management: another step towards an efficient data collection

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Background: Continual advances in information technology (IT) nourish research by providing a variety of methods for electronic data management (EDM). However, the selection of an efficient method is not an easy task. The purpose of this study is to compare the efficacy of three EDM solutions: local spreadsheets (LSSs), local databases (LDBs), and online research electronic data capture (REDCap) according to the data obtained from the three research centres in Egypt in the terms of time consumption, ease of use, accessibility, data quality and cost effectiveness.

Methods: The data management teams (DMTs) were asked to enter 60 standardised sheets to the different EDM solutions, and record the time required to complete the task by each solution. The questionnaires were designed to understand the DMT's opinion about these EDM methods. Then, statistical analysis was performed using both quantitative and qualitative methods.

Results: Questionnaires were answered by 30 members of the DMTs. Twenty-seven (90%) agreed that online data access is an important option in EDM; 25 (83.3%) were highly satisfied by the ease of use of REDCap; 21 (70%) found the online sheets were more versatile to modify and update without profound IT skills; 28 (93.3%) did not need other software to obtain the basic statistics of their data using LSSs or REDCap. However, 17 (56.7%) preferred the REDCap data analysis interface to that of LSSs, and none was satisfied about LDBs. Regarding data quality, 28 (93.3%) found that REDCap was highly effective to test the data accuracy. Sixteen (53.3%) found REDCap's data transfer across different data analysis software is the most efficient. Nevertheless, 18 (60%) had concerns over online data security in case of hack attacks. Internet connection availability and technical issue concerns were matters raised by 22 (73.3%) and 24 (80%) members, respectively. The mean time required to record a single sheet using REDCap was 7.9 (± 2.9) minutes, significantly less than that of LDBs in 11.7 (± 3.5) minutes ($t(51) = -6.9$,

$P < 0.0001$) (less by 32.5%), and LSSs in 11.9 (± 3.5) minutes ($t(51) = -4.9$, $P < 0.0001$) (less by 33.6%). The incidence of improper data format was 3% in REDCap, 9% in LDBs and 13% in LSSs, while that of missing field detection was 2% in REDCap, 7% in LDBs and 9% in LSSs. LSS or LDB management software, which supports complex functionalities, usually costs around US\$100–200 per license, whereas, REDCap is a free web application that can run on a local host, or online that costs around US\$50 per year. REDCap runs efficiently across different platforms.

Conclusions: REDCap demonstrated superiority in terms of time saving, ease of use, flexibility, data quality assurance and cost effectiveness in comparison to the LSSs and LDBs. However, data privacy, security and availability of internet connection to operate online EDM are still the main drawbacks.

Category: 09. Remote Patient Management: Heart Failure and Devices

Contact: Snir Yehuda

Novel mobile application for assessment of extravascular lung water by acoustic analysis of vocal recording

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Background: Congestive Heart Failure (CHF) is a chronic, progressive condition in which the heart pumps inefficiently. The condition, if not well controlled, leads to pulmonary congestion, which, if left untreated, leads to increasing shortness of breath and may result in pulmonary oedema, often requiring hospitalisation. Approximately 25% of patients hospitalised will be readmitted within one year; early detection of imminent deterioration is essential to reduce these costly readmissions. Non-invasive remote monitoring systems can be of great benefit, but these systems need to be efficient and compliance oriented. The aim of the study was to test the efficacy of a dedicated mobile app (DMA) for assessing extravascular lung water (EVLW) in patients with CHF undergoing dialysis. We developed a DMA by which a patient's voice is recorded by the DMA and is sent to an off-line server for

analysis using acoustics and voice analysis algorithms. This analysis is performed in close to real time.

Methods: Patients with CHF undergoing dialysis were assessed for EVLW by the DMA immediately before and after routine dialysis. Twenty-three renal failure patients with CHF were screened; of these, 10 patients met the criteria of recording quality. A total of 373 recordings from pre and post-dialysis were analysed at the mean of 37.3 ± 10 recordings per patient. Of these, we identified 82 valid matched sets (164 recordings) of pre and post-dialysis.

Results: Using our algorithms, we were able to show significant differences between pre and post-dialysis vocal analyses, with a sensitivity of 71%, specificity of 94% and predictive accuracy of 83.5%. When analysing the 82 matched sets, we correctly identified in 74/82 (90%) whether the patients were before or after dialysis. Our unique digital application, which utilises algorithmic analysis of voice recordings in CHF patients demonstrated high sensitivity of detecting patient status as to pre or post-dialysis.

Conclusion: We assume that regular use of this app could detect early accumulation of fluids in the lungs before the appearance of physical symptoms in CHF patients, by comparing analysis of recordings with a baseline stable recording in each individual patient.

Category: 10. Acute Cardiac Care, Interventional Cardiology, Imaging

Contact: Marino Barbara

Implementation of myocardial system of care in a rural area in Brazil using telecardiology

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Background: In Brazil, there are considerable disparities in access to healthcare. In-hospital mortality in acute myocardial infarction (AMI) patients treated via the public health system is much higher than in those with private health insurance due to limited access to intensive care, reperfusion methods and other therapeutic treatments. Telecardiology may be a tool to improve cardiac care and reduce inequalities of cardiac access to specialised care. The aim of this study was to assess how implementation of a coordinated regional management protocol for

patients with ST-elevation myocardial infarction (STEMI) affected quality of care and outcomes in a rural and deprived Brazilian region with considerable social inequalities.

Methods: The quality of care and outcomes of STEMI was evaluated in two cohorts, before ($n=214$) and after ($n=143$) implementation of a coordinated regional management protocol. Central to this protocol was a tablet-based digital electrocardiogram (ECG) recording in the emergency ambulance that was transmitted for analysis by trained professionals and a flowchart developed to guide the choice of reperfusion therapy for STEMI, according to the transportation time. If the pre-hospital ECG was diagnostic, it triggered a management cascade considering anticipated journey times of (1) less than 2 hours: a direct transfer to the regional intervention centre with reperfusion by primary percutaneous coronary intervention; or (2) more than 2 hours: pre-hospital fibrinolysis.

Results: Following implementation of the protocol, the adjusted medical delay (system delay minus transport time) decreased by 40%, 221 minutes (95% confidence intervals -66% , -13%). The proportion of patients who received reperfusion therapy increased from 70.6% to 80.8% ($P=0.045$), with increases in treatment with aspirin (94.2% to 100%; $P=0.003$) and P2Y12 inhibitors (87.5% to 100%; $P<0.001$). The in-hospital mortality showed a non-significant decrease from 17.2% to 11.6% (odds ratio 0.73; 95% confidence intervals 0.34 to 1.60).

Conclusion: The implementation of a coordinated regional management protocol for patients with STEMI led to marked improvements in the quality of care in a remote Brazilian region with limited resources.

Category: 07. Mobile Health

Contact: Schmidt-Weitmann Sabine

Telemedicine: web-based teleconsultation service in patients with hypertension

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Background: Telemedicine uses telecommunication to deliver healthcare at a distance. It has the potential to improve access to healthcare and patient health outcomes.

The University Hospital Zurich offers an email-based online consultation service (www.onlineberatung.usz.ch) for medical laymen since 1999. Questions in all fields of medicine are asked anonymously to a teledoctor. This study focuses on the evaluation of hypertension-related requests, the characterisation of users, the answers provided and the quality of advice given.

Methods: The retrospective study includes in total 53,570 requests in the period from August 1999 to October 2013. Of these, 197 requests (0.4%) were identified because they contained hypertension-related health issues, as coded by ICD-10. A qualitative approach, described by Mayring, was supported by a professional text analysis program MAXQDA (VERBI Software, Berlin, Germany). The content analysis of the requests with inductive category development was followed by a quantitative analysis.

Results: Of the enquirers 57% were men, 26% were over 60 years old and 37% reported being overweight. In 79% arterial hypertension was previously diagnosed and 31% of the enquirers had suffered more than 6 months from symptoms: complaints such as fatigue, exhaustion, stress or anxiety were most frequently (28%) reported, followed by dizziness, malaise (15%) and headache (12%). Seventy-two per cent took one or more drugs and 60% reported more than one pre-existing condition in the medical history, for example other cardiovascular diseases than arterial hypertension (19%) or musculoskeletal diseases (17%). The intention for the contact with the service included most often the provision of general information (26%), followed by questions about medication, treatment or side effects (17%), as well as information on specific blood pressure values (13%) and lifestyle modification (9%). In 18% questions were asked about gestational hypertension. All users were provided with individualised health information. Sixty-three per cent were also advised to consult a physician. The quality of advice in terms of clarity, support and fulfilled expectations was rated from good to very good in more than 82% of all enquiries.

Conclusions: Teleconsultation in hypertension requires a broad expertise from teledoctors, in particular on issues of multiple medications, cardiovascular risk factors as well as on specific issues such as pregnancy-induced hypertension. An email-based teleconsultation is a non-verbal form of communication with high demands in often complex medical contexts.

Category: 03. Regulation and Health Policy

Contact: Silva Gabriel Fetter

Tele-ECG as a routine public health policy in developing countries: an economic analysis

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Background: Tele-cardiology is now a reality all over the world, even in developing countries. Most of them have public and private health systems using this technology. There are some studies showing the cost effectiveness of using Tele-ECG methods, but none have considered building a cardiological eHealth centre in order to attend to a whole state. Most of the countries are not convinced it is worthwhile so far. This conclusion leads to a lack of investment in this technology, and to a failure in providing immediate expert digital assistance to the population. The objective of this study is to analyse the feasibility of building a cardiological eHealth centre in order to attend to the entire population of a state with high demand in a developing country. How much it will save monthly and how long would it take to recover the initial investment?

Methods: A cardiological eHealth centre was created 5 years ago and it is currently linked to 38 towns in the state. It was built with public budget focusing to attend to all the 497 cities in the state in the near future. The first step was collecting data from the remote towns and obtaining information about the ECG costs, meaning the local ECG price, before implementing a tele-ECG system. Then, getting the monthly number of exams the centre had at the beginning and using the values above to estimate the cost. As a second step the study calculated the real cost to maintain the service running 24/7, attending to 30 towns – at the beginning – and 38 now, foreseeing the total savings. Finally, the total money invested in the construction of this centre's structure was calculated in order to estimate the time interval needed to recover the initial investment.

Results: Before implementing the digital tele-ECG method the average price found using local ECGs was €33.97 for emergency ECG and €17.05 for routine ECG. The estimated cost considering the price above and number of exams the centre performed in 2011 and 2012 (divided into emergencies and routines) was updated. The total cost spent to build the eCardiological centre (infrastructure and equipment) was €65,624.38. It has shown that recovering the initial investment required 16 months (March 2011 to June 2012). The predicted savings now are estimated at €49,657.97 monthly. Therefore, this

initiative has a return on investment rate of 75% per month. Besides, the study discovered a significant reduction of waiting times for a report from 14.7 days to around one hour.

Conclusion: Building an eCardiological centre in order to provide on time tele-ECG diagnosis to a whole state is an extremely worthwhile strategy to be implemented in developing countries. This practice must be included in public health policies due to the important savings it brings to the public treasury. Furthermore, due to a huge reduction in the waiting time for a report through tele-ECG technology, the method allows the speeding up of the adoption of appropriate therapy.

Category: 08. Risk Factors, Rehabilitation and Prevention

Contact: Wallner Kurt

Telerehabilitation in coronary artery disease (TRIC-study): 12 months data

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Background/Objective: The aim of the study was to evaluate the safety and feasibility of home-based telerehabilitation for patients with uncomplicated coronary artery disease (CAD).

Methods: This non-randomised parallel group study assigned 45 male patients for shortened 2 weeks inpatient rehabilitation followed by a 10-week telerehabilitation programme (TRG) versus 47 patients who completed a conventional 4 weeks inpatient rehabilitation programme (CG). After one year we evaluated 41 patient in the TRG und 45 patients in the CG. Outcome measures were assessed at baseline and after 12 months using cardiopulmonary function (W_{peak} (W_{peak}), $W_{\text{peak}}/\text{kgBW}$ (bodyweight), $WVATI$ (ventilatory aerobic threshold₁), $VO_{2\text{peak}}/\text{kg}$, VO_2 $VATI/\text{kg}$, $W@L(\text{lactate})$ 2 mmol/l, $W@L(\text{lactate})$ 4 mmol/l), laboratory parameters (total cholesterol (TC), high density lipoprotein (HDL)-cholesterol; low density lipoprotein (LDL)-cholesterol; TC/HDL-cholesterol quotient), physical parameter (BW; body mass index (BMI), waste circumference (WC), body fat (BF)), and quality of life (HADS; Short Form 36).

Results: No statistical difference was observed between the two groups at baseline. After 12 months in the TRG, W_{peak} (+23, 1%; $P < 0.001$), $W_{\text{peak}}/\text{kg BW}$ (+24.7%; $P < 0.001$), $WVATI$ (+11.2%; $P = 0.014$), $VO_{2\text{peak}}/\text{kg}$ (+7.4%; $P = 0.008$), and VO_2 $VATI/\text{kg}$ (+4.7%; $P = \text{ns}$) were increased. In the CG only W_{peak} and $W_{\text{peak}}/\text{kg BW}$ increased by +3.5% ($P = \text{ns}$) and +3.2% ($P = \text{ns}$),

respectively. In contrast $WVATI$, VO_2 $VATI/\text{kg}$ and $VO_{2\text{peak}}/\text{kg}$ decreased by -15.1% ($P = 0.002$), -11.1% ($P = 0.006$) and -1.3% ($P = \text{ns}$), respectively. The difference between TRG and CG was highly significant for VO_2 $VATI/\text{kg}$ ($P = 0.016$), W_{peak} ($P = 0.019$), $W_{\text{peak}}/\text{kg}$ ($P = 0.005$) and $WVATI$ ($P = 0.002$). In TRG concentrations of LDL-cholesterol (-22.7%; $P < 0.001$), TC (-14.5%; $P < 0.001$), TG (-17.2%; $P = \text{ns}$) and TC/HDL-cholesterol (-16.9%; $P = 0.001$) decreased significantly during the 12 months. HDL-cholesterol (+1.2%; $P = 0.087$) did not increase statistically significantly. In CG none of the laboratory parameters changed statistically significantly. After 12 months except HDL-cholesterol all parameters showed a statistically significant difference between the groups in favour of the TRG. Physical parameters showed no statistically significant difference within and between the two groups after 12 months. Anxiety, depression and quality of life were not different between the groups at baseline and after 12 months, but both groups showed a statistically significant improvement due to physical quality of life after 12 months. **Conclusion:** Accordingly, home-based telerehabilitation can be regarded as safe and feasible for patients with uncomplicated CAD. In addition, we could show significant improvements due to physical fitness and change in risk factors in the TRG compared to regular 4-week inpatient rehabilitation.

Category: 09. Remote Patient Management: Heart Failure and Devices

Contact: Desteghe Lien

Telemonitoring-based feedback improves adherence to non-vitamin K antagonist oral anticoagulant intake in patients with atrial fibrillation

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Background: Effective thromboembolic prevention with non-vitamin K antagonist oral anticoagulants (NOACs) requires a strict therapy adherence given the half-lives of these drugs of about 12 hours. Systematic monitoring of anticoagulation or medication intake is not performed in NOAC patients. Initiatives are needed to monitor and/or improve adherence to NOAC therapy. The purpose of this study is to investigate the effect of personalised feedback, based on telemonitoring of medication intake, on adherence to NOACs in patients with atrial fibrillation (AF).

Methods: In total, 48 AF patients (mean age 72 ± 9 years; 24 on a once daily (OD) NOAC (rivaroxaban) and 24 patients on a twice daily (BID) NOAC (apixaban)) were enrolled in a randomised, single-blind, crossover, controlled trial. The medication event monitoring system (MEMS; WestRock, Switzerland) was used to measure NOAC adherence. Patients were assigned to an observation phase and a feedback phase of 3 months each, in random order. Adherence data were checked on weekdays through telemonitoring. During the feedback phase, patients received a phone call in the case of an 'unprotected day' (i.e. three or more consecutive missed doses for a BID NOAC, one or more missed doses for a OD NOAC or excess doses during the prior 24 hours). Taking adherence (i.e. proportion of prescribed doses taken), regimen adherence (i.e. proportion of days with the correct number of doses taken) and the number of unprotected days were calculated, based on the MEMS data. After 6 months, a questionnaire was used to evaluate the study experience.

Results: A 98% persistence was obtained as no patient stopped NOAC treatment. One patient was switched to VKA after 3 months due to a venous thrombus. Active telemonitoring observation already led to a very high adherence, with a taking adherence of 97.4% and a regimen adherence of 93.8%. Nevertheless, direct telephone feedback further improved the adherence: taking adherence increased with 1.6% to 99% ($P < 0.001$) and regimen adherence with 3% to 96.8% ($P = 0.001$). The number of unprotected days during 3 months decreased from 2.6 to 1.5 ($P = 0.125$). Both during the observation and the feedback phase, taking adherence was higher with the OD NOAC ($P < 0.001$ and $P = 0.018$, respectively) although unprotected days were similar ($P = 0.272$ and $P = 0.251$, respectively). Study experience was positive as 87.2% of the patients found the MEMS monitor practical to use, 63.8% indicated that the study increased their awareness to take their medication at the correct time, and 97.6% of the patients who received a phone call indicated telephone feedback as useful.

Conclusion: Telemonitoring showed an unexpectedly high adherence to NOACs in an elderly unselected population. This may be related to highly motivated patients but certainly also to the sense of being watched. However, telemonitoring-based feedback further optimised the adherence, which may be a valuable approach in selected patients deemed poorly adherent in clinical practice.

Category: 07. Mobile Health

Contact: Brouard Benoît

SOPHOC: Feasibility study to transform high blood pressure management using activity trackers and wireless blood pressure monitors

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Background: Effective high blood pressure (BP) management requires lifestyle changes that may be difficult to sustain in day-to-day life. However, the growing adoption of mobile health technology and connected health devices by the general population may make such behaviours easier to adopt and maintain. Such technology could improve patient compliance for proper high BP management as well as decreasing the societal costs associated with unmanaged high BP. The aim of the SOPHOC study (Suivi Observationnel des Patients Hypertendus grâce aux Objets Connectés) is to investigate the feasibility and acceptability of connected health devices to help ambulatory patients manage high BP over a one-year period.

Methods: The study group included 50 patients with poor high BP control, or poor lifestyle habits, or excess weight, or sedentary lifestyles. The patients were included from December 2015 to May 2016 in various doctors' offices. The patients were each equipped with an activity tracker and a wireless blood pressure monitor (BPM) from Withings. These two devices were connected to the Withings mobile application, Health Mate. The participants were briefed by cardiologists on the purpose of the devices, and were shown how to use them. Once a week for 28 weeks, the patients were automatically sent a message with advice on how to reduce high BP through the mobile application. Anonymous data were then collected on the number of steps taken per day as well as systolic and diastolic BP values. Patients were followed at distance without any intervention from cardiologists. Follow-up consultations will be scheduled at 6 and 12 months. This preliminary study is focused on the 14 first patients achieving 5 months of follow-up.

Results: The mean age of the overall population is 56.2 years, and the study includes 15 women and 35 men. Mean body mass index is 28.33 kg/m^2 . All of the 14 patients with 5 months of follow-up used their tracker for the first 3 months, but only 10 continued usage through the fifth month. Similarly, all 14 patients used the BPM the first month, but only nine continued usage through the fifth month. Patients wore their tracker an average

of 26 days the first month and as many days the fifth month. Patients used their BPM an average of 24 days the first month and 19 the fifth month. The average number of daily steps per month remained fairly constant over time, varying from 5058 to 5489.

Conclusion: Connected devices could transform chronic disease management by allowing doctors to recommend such devices to help patients effectively self-manage their BP. Results from the first 5 months indicate that patient compliance is high with both the activity trackers and the BPMs. At the end of the study, we must examine both the acceptability of the devices over a one-year period and the improvement of the physiological parameters of the patients.

Category: 09. Remote Patient Management: Heart Failure and Devices

Contact: Smeets Christophe

Remote disease monitoring of cardiac resynchronisation therapy patients

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Background: The increased incidence of heart failure (HF) patients results in an increase in cardiac resynchronisation therapy (CRT) device implantations. Many of these devices are currently provided with remote monitoring functions. Remote follow-up of patients undergoing CRT may enhance the detection of device problems and facilitate disease management.

Methods: Consecutive CRT patients ($n = 192$) participating in remote follow-up in a single tertiary care centre were followed prospectively. Incoming device and disease-related alerts were analysed together with subsequently triggered interventions.

Results: During 34 ± 13 months of follow-up, 1372 alarm notifications were received (2.53 per patient-year of follow-up), compromising 1696 unique alerts (3.12 per patient-year of follow-up). In 60% of cases, this resulted in an intervention. Technical device alerts constituted only 8% of all incoming alerts, with a frequency of 0.24 per patient-year of follow-up. A total of 165 patients (86%) were contacted at least once, with 820 (60%) triggered phone contacts (1.51 contacts per patient-year of follow-up) to which 837 interventions were coupled. Rhythm ($n = 775$, 1.43 per patient-year of follow-up) and bioimpedance alerts ($n = 532$, 0.98 per patient-year of follow-up)

were the most frequent disease-related alerts. Clinical outcome was excellent, with 97% survival, 92% freedom from death or heart failure admission, and 88% freedom from death or any hospitalisation after one year.

Conclusion: On average, remote follow-up of CRT patients resulted in one technical device alert per four patient-years of follow-up versus three disease-related alerts per one year. Disease-related alerts constituted the majority of incoming alarm notifications.

Category: 08. Risk Factors, Rehabilitation and Prevention

Contact: Tongpeth Jintana

Collaborative development of an avatar-based application for improving knowledge on symptom recognition and management in patients with acute coronary syndrome

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Background: Lack of knowledge in what are the symptoms of a heart attack is recognised as a major obstacle to timely medical treatment and is associated with potentially preventable death and long-term complications. Current research has demonstrated that integrating patient education with information technology now plays a significant role in improving patients' knowledge and self-management ability. The objective of this study is to develop an avatar-based education application (app) by working collaboratively with patients and carers, cardiac and information technology (IT gaming) experts.

Methods: The development of the app consisted of two action research cycles. Each cycle included four stages (plan–act–observe–reflect) of testing and critical reflection from three groups comprising patients, cardiac and the IT gaming experts. The app was tested on patients with acute coronary syndromes (ACSs) to access its feasibility and acceptability. Knowledge, attitude, symptom recognition and satisfaction were measured with validated questionnaires.

Results: The cardiac experts ensured that the app integrated heart attack messages according to evidence-based guidelines, appropriated interactivities, images, language and voice. Patient feedback focused on usability, ease of navigation, which encouraged both learning and enjoyment. Ten ACS patients (52.2 ± 10.4 years) participated in the feasibility testing. Participants reported a high level of satisfaction with the app (87.3%) and expressed that the app had taught them how to recognise and respond to

symptoms of heart attack. The knowledge score of the ACS index increased 15.7% from $62.4 \pm 13.4\%$ to $78.1 \pm 9.3\%$, \times , belief scores increased by 25.7% ($73.2 \pm 6.1\%$ to $98.9 \pm 1.7\%$) and symptom recognition scores increased by 24.3% ($72.5 \pm 5.6\%$ to $96.8 \pm 8.0\%$).

Conclusion: This study presents a positive outcome for a collaborative and patient centred approach for developing education tools using new technologies. The positive outcomes will lead to a randomised trial to test the effectiveness of an avatar-based application for improving knowledge on symptom recognition and management in patients with ACS.

Category: 07. Mobile Health

Contact: Komkov Denis

Remote blood pressure monitoring in long-term follow-up of patients with arterial hypertension

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Background: As has been shown on our previous investigations, remote blood pressure (BP) monitoring may be useful in patients with arterial hypertension (AH). We recognise that it could provide some benefits in the achievement of target BP levels and could improve the compliance in some cohorts of patients. But our studies also suggested that the positive effect of remote monitoring is rather short and decreasing after the first 1.5–2 months of monitoring. So we aimed to reveal whether long-term (up to 6 months) BP remote monitoring is non-inferior to usual care in target BP level achievement and in patients' compliance to drug intake. The purpose of this study is to evaluate if remote BP monitoring could provide non-inferior to usual care effectiveness in patients with AH.

Methods: There was single-centre randomised controlled parallel group trial in 225 patients aged 25–75 years with AH. The patients were randomly assigned in three remote monitoring groups ($n = 150$). The first group received electronic sphygmomanometers with a transmitting module. The results of BP measurements transferred directly to the monitoring centre and physicians evaluated this information round the clock. The second group received the same sphygmomanometers, but the data from these patients were evaluated only in medical office working hours. The third group received sphygmomanometers without a transmitting module, but they could send the results of measurements via mobile app. The data from these patients were also evaluated in medical office working hours. The fourth group was the usual care group.

The patients from this group received sphygmomanometers without a transmitting module, no remote monitoring was provided. The follow-up duration was 6 months.

Results: After the randomisation there was no significant difference among the groups in the age of patients, mean systolic and diastolic BP, mean Morisky–Green score index (see Table 1, part 1). After the 6-month follow-up in each group the following changes were revealed in comparison with initial data: (a) a significant decrease of mean systolic and diastolic BP; (b) no significant improvement in compliance, measured by the Morisky–Green score. There was no significant difference between the effectiveness of 6-month follow-up among the groups (see Table 1, part 2).

Conclusion: Our results indicate that BP remote monitoring effectiveness is non-inferior to usual care in target BP level achievement and in patients' compliance with drug intake.

Category: 05. E-Learning, Clinical Decision Support

Contact: Tonacci Alessandro

Development of a web-based platform for e-training in echocardiography

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Background: Echocardiography is widely used for the diagnosis and management of heart conditions, as it is non-invasive, low-cost and transportable. However, its images interpretation requires an expert, skilled operator in this field. Thus, health practitioners should meet a consensus to avoid misinterpretation, but the opportunities to train and update their skills are often lacking. The aid of technological advances in such cases is warmly welcome, especially concerning internet and Web 2.0 technologies, representing a useful add-on to current training methods for practitioners. This work aimed to develop an 'e-training' platform for health practitioners, to improve effectiveness in the clinical interpretation of medical, mainly echocardiographic, images. The setting up of a worldwide community of expert practitioners on this topic is also foreseen.

Methods: The platform is composed of a web-based version, while a mobile app is foreseen, allowing the practitioners to log in through their credentials used for social networks (Google+, Facebook, LinkedIn, etc.). The architecture was chosen to get the platform ready to be included in a federation for digital identities, supporting the single sign on (SSO with SAML), allowing all users to

use a single username and password for all services within a federation. The e-training method is based on the Web 2.0 principles, as it relies on the involvement of as many practitioners as possible, in order to share clinical cases with the professional community and to put their knowledge at disposal for peer-comparison with other healthcare specialists. In particular, participants perform measures and interpretations of anonymised echocardiographic images, by on-line periodic exercises on transthoracic echocardiography, stress echocardiography and congenital heart disease. Their answers are next compared, in on-line reports, with those obtained by the other participants.

Results: To date, 107 skilled professionals are registered, and five clinical cases have been developed for each platform programme. Preliminary evidence already displayed a

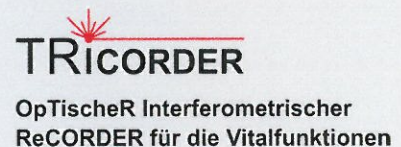
heterogeneity in image interpretation, proving the usefulness of such an approach for health professionals' training. Remote training programmes could reduce the misinterpretation of medical images and improve skills of participants, allowed to enter a healthcare professionals' network for peer-discussion and comparison on medical imaging.

Conclusion: Despite the small audience reached to date, although mainly composed of skilled medical professionals, we expect to receive a larger amount of subscriptions in the near future through our wide dissemination schedule. We think that this approach, given the good success of remote training applications in medicine, could form the basis for future add-ons in healthcare personnel formation.

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