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Low-risk cardiac rehabilitation in everyday life environments with the help of web technology and mobile apps: might it be as effective as face-to-face rehabilitation at hospital?

Submission date
03/11/2020

Recruitment status
No longer recruiting

Registration date
07/12/2020

Overall study status
Completed

Last Edited
31/03/2025

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
A cardiac rehabilitation program (CRP) helps you get back to as full a life as possible after a cardiac event such as a heart attack, heart surgery or stent procedure.
In Spain, only 3% of heart disease patients carry out a CRP. Among the reasons, the shortage of healthcare resources and inflexible ways of providing CRPs. In this context, online-based healthcare services (e-services), can act as an effective element of coordination and support new models of healthcare provision.
The study aims to investigate the usefulness of a CRP carried out online, compared to the usual in-person CRP.

Who can participate?
Patients aged 18 - 75 years, requiring phase II cardiac rehabilitation.

What does the study involve?
Participants will be randomly allocated to receive either 8 weeks of online CRP or in -person CRP. Participants will perform some tests and answer some questionnaires before the start of the CRP and at a 16 month follow up.

What are the possible benefits and risks of participating?
There are no additional benefits or risks to participating, although some patients may have symptoms of anxiety and concern about the control of their disease.

Where is the study run from?
University Hospital Ramon y Cajal (Spain)

When is the study starting and how long is it expected to run for?
May 2014 to June 2019

Who is funding the study?
Instituto de Salud Carlos III (Carlos III Health Institute) (Spain)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
Implementation and evaluation of a telemedicine-based service to support "e-supervised" regime in Phase II Cardiac Rehabilitation Programs: a randomised controlled trial

Acronym
HAZLO

Study objectives
1. The implementation of e-services through virtual environments that combine aspects of biomedical and contextual monitoring programs with "e-learning" programs, social, educational and interactively structured, can develop models of provision of cardiac rehabilitation programs (PRC) more flexible, personalized, with ubiquitous nature and security for all parties involved
2. The provision by means of this type of e-services of selected therapeutic components from the PRC in phase II cardiac rehabilitation (physical activity, psychological therapy and control of risk factors) is feasible, reaching at least similar results to those of the traditional provided means "supervised regime" in both clinical indicators and those of satisfaction and quality of life
3. The PRC Phase II provided through these e-services can increase patient involvement in self-management of their health during phase III cardiac rehabilitation, stating medium term at least

similar clinical indicators, satisfaction, quality of life and adhesion, regarding patients who followed supervised traditional regime phase II
4. The provision of PRC through this kind of e-services enables increasing the population of patients who can benefit from this therapeutic care process

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/05/2014, Ethics Committee of Instituto Carlos III (Avda. Monforte de Lemos, 5, Madrid, Spain, 28029; cei@isciii.es; +34 918 222 194), ref: CEI PI 13_2014

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cardiac rehabilitation

Interventions
Both groups follow a phase II cardiac rehabilitation program, they are monitored for 8 weeks
Intervention group supervision is by the telemedicine system
Control group have on-site supervision in the rehabilitation unit

After that, both groups continue unattended rehabilitation for 12 months (first year of phase III of cardiac rehabilitation). At the end of the first eight weeks, an intermediate visit is carried out in order to analyze the effectiveness during phase II (main and secondary outcomes). At the end of the last 12 months all of them have a final visit for data collection (secondary outcomes).

Randomisation process
To support the randomisation process, a table of pseudo-random numbers in variable and permuted blocks was generated by computer for random assignment: intervention and control. Through a private secure web service, the values of the randomisation table are delivered in a strictly sequential way. The access to the randomisation web service is done automatically from the Electronic Case Report Form software. Once the patient has given informed consent, random assignment to the intervention or control group takes place on-line, automatically, as the initial step in creating the patient's electronic case report form. There is no possibility of interfering with the randomisation process.

Telemedicine system and onsite supervision
Phase II programs are the central pillar of cardiac rehabilitation. During phase II, systematic rehabilitation activities are carried out, limited in time (around eight weeks), in multiple areas: physical (resistance and strength); psychological (anxiety control, relaxation); education in cardiovascular risk factor control (medication, life habits); return to work; sexual dysfunction; among others. The activities are programmed in relation to their scope and intensity, according to the patient's conditions and a stratification of cardiovascular risk (usually low, medium and

high risk) and the units' own capacities and resources.
The objective of this action has been to implement and evaluate a low-risk phase II cardiac rehabilitation program (called “e-supervised”), with high personalization capabilities, aimed at the daily life environment of the patient-citizen, using information and communication technologies. The “e-supervised” program has been evaluated by means of a randomized controlled clinical trial to demonstrate no inferiority in the results of the efficacy of an eight weeks phase II intervention, compared to a traditional “supervised” program carried out in person at the Cardiac Rehabilitation Unit.
Traditional onsite phase II cardiac rehabilitation is carried out “face-to-face” (patient and multidisciplinary teams) and with close supervision of the patient in cardiac rehabilitation units. This “supervised” phase II programs incorporate above mentioned therapeutic activities (physical, psychological, education), very systematic but with an inflexible schedule for the patient and limited capacity-availability.
The "e-supervised" program incorporates the following components (supported by a telemedicine platform): resistance physical rehabilitation components (walking sessions); psychological rehabilitation components (relaxation sessions in 5 modalities); multimedia educational program (12 educational environments and 70 resources); web messaging with guaranteed response in less than 24h (from both, the healthcare and the technical support teams); video call; and discussion forums. The program is personalized through the specification of a 4-dimensional patient profile (diagnostic profile, risk factors, psychological, others) and 26 distributed characteristics from which the program components are automatically selected (from the working heart rates in walking sessions, to the videos that have to do with the educational program and its sequencing). Both patients and professionals have the possibility of carrying out the follow-ups and interactions through a web platform. Walking and relaxation activities are performed through apps with real-time heart rate monitoring (smartphones and heart rate monitoring wearable devices); apps incorporate algorithms that, based on the heart rate, geolocation information and profile data, make it possible to parameterize and control the sessions and automatically guide the patient during the activities (walking and relaxation) through audio messages. Through this virtual assistant service, the therapeutic result of the activity and the objective and subjective security perceived by the patient (and by the health professional) are optimized.
The "e-supervised" program has been designed to be consistent and complementary to traditional "supervised" programs. It is also a highly customizable program in relation to its components, duration and activity scheduling; the timing of activities is adjusted to patient preferences rather than to necessary on-site assistance. The monitoring, computing and interaction capabilities that technology makes possible to objectify not only the result but also the development of the activities, so that it is possible to control and guide the patient through automatic virtual assistants, improving therapeutic effects and perception of security. In relation to the interaction channels, it offers patients and professionals with a flexible messaging system with the capacity to distribute messages among the multidisciplinary healthcare team and with a guarantee of an agreed response in short periods of time, in order to improve the perception of safety and adherence of the patient to the therapeutic and education activities. Additionally, the possibility of offering to low-risk patients to carry out phase II programs outside the cardiac rehabilitation units with no inferior results, makes it possible to decongest the units and redirect them to the treatment of medium and low-risk groups, rationalizing and increasing the benefit of the care resources. In addition, the ubiquity of the program's provision allows citizens who do not have any access to specialized units to benefit from cardiac rehabilitation.

Intervention Type
Behavioural

Primary outcome(s)
Functional capacity in METs (metabolic equivalent), measured using the measured MET exercise test (ramp protocol), at baseline and the end of stage 1 (final phase II cardiac rehabilitation program)

Key secondary outcome(s)
Measured at baseline, week 8 and week 60:
1. Improvement in functional capacity in METs measurement by exercise testing (ramp protocol) at the end of the study (first year of Phase III).
From exercise testing also: clinical (positive / negative) response; electrical response (positive /negative / not assessable); significant arrhythmias (atrial / ventricular); heart rate (basal /submaximal-60%/submaximal-80%/end/first minute of recovery).
2. Left ventricle Ejection fraction (echocardiogram).
Cardiovascular risk factors: smoking (defined by smoking at enrollment); LDL cholesterol levels above 100 mg / dl; hypertension (defined as greater than 140 mm / Hg systolic or 90 mm / Hg in diastolic blood pressure 130 and 80 mm / Hg in diabetics or antihypertensive drugs); glucose, glycated Hb.
3. Psychological information:
3.1. Beck (depression)
3.2. STAI (anxiety)
3.3. Quality of life (EQ-5D-5L)
3.4. Individualized treatment (psychological / psychiatric).
4. Employment information: nature of work (white collar, blue collar, self employed, time of return to work in days) measured using self-report
5. Complications (angina, reinfarction, arrhythmias, heart failure, need for revascularization), mortality (cardiac or due to other causes) measured using patient records
6. Motivation by the program (self-reported Likert scale of 5 points between "high" and "very low").
7. Self-reported satisfaction with the program at the end of the study (Likert scale of 5 points between "high" and "very low")
8. Usability of the system (System Usability Scale)

Completion date
30/06/2019

Eligibility

Key inclusion criteria
1. Patients requiring phase II cardiac rehabilitation at the center due to ischemic heart disease (myocardial infarction, percutaneous or surgical revascularization); operated valvular heart disease or mixed heart surgery
2. Patients able to commit to the demands of the trial: the ability to understand, read and write the Spanish language, cognitive and manual ability to use the technological devices intended for the study
3. Patients who agree to participate in the study (sign oral or written informed consent)
4. Patients who have internet access at home

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Sex
All

Total final enrolment
256

Key exclusion criteria
1. Severe injury of three vessels not appropriate for revascularization
2. Angina/severe ischemia in provocation tests
3, Severe arrhythmia
4. Severe Left ventricle disfunction (EF <30%)
5, Musculoskeletal diseases or limited walking
6. Arterial insufficiency of the lower limbs
7. Age >75 years
8. Any type of physical or mental disability that prevents the use of technological devices in the system and not have family support or otherwise

Date of first enrolment
01/10/2014

Date of final enrolment
30/11/2017

Locations

Countries of recruitment
Spain

Study participating centre
University Hospital Ramon y Cajal
Cardiac Rehabilitation Unit
Carretera De Colmenar Viejo Km 9.1
Madrid
Spain
28034

Sponsor information

Organisation
Hospital Universitario Ramón y Cajal

ROR
https://ror.org/050eq1942

Organisation
Instituto de Salud Carlos III

ROR
https://ror.org/00ca2c886

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Instituto de Salud Carlos III; Research projects PI12/00585 and PI12/00389

Alternative Name(s)
SaludISCIII, InstitutodeSaludCarlosIII, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, La misión del Instituto de Salud Carlos III (ISCIII), ISCIII

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other unpublished results			31/03/2025	No	No

Participant information sheet	Study website	06/11/2020	07/12/2020	No	Yes
Study website		11/11/2025	11/11/2025	No	Yes