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STUDY PROTOCOL

Are behaviour change techniques and intervention features associated with effectiveness of digital cardiac rehabilitation programmes? A systematic review protocol [version 1; peer review: 2 approved]

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Abstract

Background: Cardiovascular disease (CVD) is the leading cause of death worldwide. Cardiac rehabilitation (CR) is a complex intervention that aims to stabilise, slow, or reverse the progression of CVD and improve patients' functional status and quality of life. Digitally delivered CR has been shown to be effective and can overcome many of the access barriers associated with traditional centre-based delivered CR programmes. However, there is a limited understanding of the behaviour change techniques (BCTs) and intervention features that maximise the effectiveness of digital programmes. Therefore, this systematic review will aim to identify the BCTs that have been used in digital CR programmes and to determine which BCTs and intervention features are associated with programme effectiveness.

Methods: PubMed, MEDLINE (Ovid), EMBASE, CINHAL, PsycINFO and Cochrane Central Register of Controlled Trials will be searched from inception to June 2021 for randomised controlled trials of digital CR with CVD patients. Screening, data extraction, intervention coding and risk of bias will be performed by one reviewer with a second reviewer independently verifying a random 20% of the articles. Intervention content will be coded using the behaviour change technique taxonomy v1 and the Template for Intervention Description and Replication (TIDieR) checklist and intervention features will be identified. A meta-analysis will be conducted to calculate the pooled

Open Peer Review

Reviewer Status ✓✓

	Invited Reviewers	
	1	**2**
version 1 11 Aug 2021	✓ report	✓ report

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effect size of each outcome, and meta-regression analyses will investigate whether intervention features and the presence and absence of individual BCTs in interventions are associated with intervention effectiveness.

Discussion: The review will identify BCTs and intervention features that are associated with digital CR programmes and adopt a systematic approach to describe the content of these programmes using the BCT taxonomy (v1) and TIDieR checklist. The results will provide key insights into the content and design of successful digital CR programmes, providing a foundation for further development, testing and refinement.

Keywords

Cardiovascular disease, cardiac rehabilitation, digital, behaviour change, systematic review

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Introduction

Cardiovascular disease (CVD) is the number one cause of death worldwide, accounting for almost a third (31%) of global deaths[1]. Cardiac rehabilitation (CR) is a complex intervention that aims to stabilise, slow, or reverse the progression of CVD and improve participant functional status and quality of life. Systematic reviews of CR have shown it is effective at improving lifestyle behaviours and quality of life and can achieve significant reductions in morbidity, mortality and hospital admissions among people with CVD[2]. Despite these benefits, CR is underutilised with participation rates in Europe as low as 36% and dropout between 12-56%[3]. A range of barriers to uptake have been identified, at both the service and system level (e.g., poor referral system), and patient level (e.g., transport, cost, perceptions of CVD and CR)[4]. Furthermore, service delivery has been severely impacted by unit closures and staff redeployment due to the coronavirus disease 2019 (COVID-19) pandemic[5–7], generating an increased need for alternative methods of delivering CR.

CR is a multifaceted intervention and the 'active ingredients' of the intervention are still unclear[8]. This is possibly due to the variety of components and techniques often included in CR, which make it difficult to tease apart the effectiveness of individual parts of the intervention. Digital health interventions (DHIs) have potential as scalable tools to improve health and healthcare delivery. They also allow easier experimental manipulation of intervention components for the purpose of understanding how exactly interventions work and what components of the intervention work better than others[9]. Previous systematic reviews have indicated that secondary prevention DHIs are effective at improving outcomes such as CVD events, hospitalisations, and all-cause mortality[10], as well as modifiable risk factors including physical activity and medication adherence[11]. Furthermore, a systematic review of eHealth cardiac rehabilitation found a positive impact on physical activity, daily steps, quality of life and rehospitalization[12]. Digitally delivered CR has been shown to be at least equally as effective as traditional centre-based CR[13–15] and can address many of the barriers associated with attending centre-based CR[4]. The potential for digital CR is significant, however, a greater understanding of what constitutes an effective digital CR programme is necessary to maximise efficiency and scalability[16].

Developments in behavioural science have provided tools to support the clear specification of intervention content. An example of this is the behaviour change technique (BCT) taxonomy (v1)[17], a comprehensive list of 93 BCTs which allows the 'active ingredients' of interventions to be systematically described and replicated. A further example is the Template for Intervention Description and Replication (TIDieR) checklist[18] which details the why, what, who, where, and how of intervention delivery. More recently, the mode of delivery ontology v1[19] has been developed as a tool for describing the mode of delivery of behaviour change interventions in a consistent and coherent manner. These tools have the potential to enable a greater understanding of the content of effective digital CR programmes, while also improving evidence comparison and study replication. To our knowledge, no systematic review has evaluated digital CR programmes using these tools.

Objectives

Therefore, the aim of this systematic review is to answer the following two research questions:

1. What BCTs have been used in digital CR programmes?

2. Which BCTs and intervention features, including mode of delivery, theoretical framework, dose, intensity, and frequency, are associated with digital CR programme effectiveness?

Methods

This protocol has been reported using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) guidelines[20].

Eligibility criteria

Eligible studies will be peer-reviewed publications in English, that include adults (>18 years old) with any form of heart disease (coronary heart disease, acute coronary syndrome, congenital heart disease, heart failure, valvular heart disease). Studies will be included if they use an randomised control trial (RCT) design to assess the effectiveness of a digital CR programme when compared to usual care. The intervention must be delivered at least in part via the internet or a smartphone application; interventions that solely use landline telephone communication will be excluded. Studies will be included if they report any behavioural outcomes (physical activity, diet, smoking, alcohol use, medication adherence) as either the primary or secondary outcome.

Information sources

A comprehensive database search will be conducted using PubMed, MEDLINE (Ovid), EMBASE, CINHAL, Ovid PsycINFO and Cochrane Central Register of Controlled Trials. Databases will be searched from inception to present date. Included publications will be forward and backward reference searched to identify additional relevant studies. Study authors will be contacted where information is missing and/or the full text article is unavailable.

Search strategy

The search strategy will be developed based upon previous systematic reviews[10–12] and in consultation with a specialist librarian. It will include a combination of medical subject headings (or equivalent) and free text terms. Table 1 provides an example of the search strategy for MEDLINE (Ovid); the search will be adapted for each database.

Data management

The results from all database searches will be imported into Endnote X20. Duplicates will be removed by the software and then checked manually by the main reviewer (EK). Articles will then be exported to Rayyan[21] for screening.

Selection process

Articles will be screened by abstract and full text by one reviewer (EK), a second reviewer will independently screen a random

Table 1. Search strategy for MEDLINE (Ovid).

Search no.	Search terms
1.	Exp cardiovascular diseases/
2.	Exp cardiology/
3.	(coronary adj3 (artery OR disease)).ti,ab.
4.	(myocardial adj3 (isch?em* OR infarct*)).ti,ab.
5.	(CHD OR CVD).ti,ab.
6.	(cardiac OR cardiovascular).ti,ab.
7.	OR/1-6
8.	Exp cell phone/
9.	(cellphone OR cell phone OR mobile phone OR cellular phone OR smartphone OR smart phone).ti,ab.
10.	text messag*.ti,ab.
11.	Exp telemedicine/
12.	(telehealth OR tele health OR telemedicine OR tele medicine OR telerehab* OR tele rehab*).ti,ab.
13.	Exp internet/
14.	(web OR internet OR online).ti,ab.
15.	(digital health OR tech OR virtual).ti,ab.
16.	(ehealth OR e health OR mhealth OR m health).ti,ab.
17.	OR/8-16
18.	Exp exercise/
19.	(exercis* OR physical activ* OR diet OR nutrition OR tobacco OR smoking OR adherence).ti,ab.
20.	OR/18-19
21.	Exp rehabilitation/
22.	(interven* OR program* OR treatment OR (cardiac adj3 rehabilitation)).ti,ab.
23.	OR/21-22
24.	7 AND 17 AND 20 AND 23

20% of the articles. Any disagreements will be resolved through discussion and the consultation of a third reviewer. Reasons for inclusion/exclusion will be recorded and a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram will be completed[22].

Data extraction
One reviewer (EK) will extract data from the included studies using a pre-piloted data extraction form, with a random 20% checked for accuracy by a second independent reviewer. The following data will be extracted:

- General: author(s), year, and country of origin;

- Study characteristics: aims/objectives of the study, study design, inclusion/exclusion criteria, recruitment methods, sample size, and unit of allocation;

- Participants: age, sex, setting, diagnosis, and baseline characteristics;

- Intervention: mode of delivery using the mode of delivery ontology v1[19], duration, BCTs based on the BCT taxonomy (v1)[17], quality of intervention reporting using the TIDieR checklist[18], CR components based on the core components of home-based CR programmes outlined in Thomas *et al*.[23], and theoretical basis;

- Outcomes: Primary outcomes, and secondary outcomes.

Where a study is described across multiple publications, an attempt will be made to extract and combine all the available data. Study authors will be contacted if data is missing.

Outcomes
The primary outcomes are changes in health-related behaviours (physical activity, diet, smoking, alcohol, sedentary behaviour and medication adherence) as CR is an intervention aimed primarily at improving modifiable CVD risk factors. Additional outcomes will include psychological well-being, quality of life, adherence rates, lipid profile, blood pressure, weight/body mass index (BMI), cardiac events, revascularisation, rehospitalisation and mortality.

Risk of bias in individual studies
Study quality will be assessed using the Cochrane risk of bias yool (version 2)[24]. This tool assesses study quality on the domains of selection bias, performance bias, detection bias, attrition bias, reporting bias and other biases. One reviewer (EK) will complete the assessment and a second reviewer will check a random 20% of the studies.

Data synthesis
A summary of the information extracted from each study, including outcomes reported, BCTs and content from the items on the TIDieR checklist, will be provided in narrative and tabular form. A meta-analysis to calculate the pooled effect size of each outcome will be considered if there is sufficient homogeneity of outcomes across studies, with the Higgins I^2 statistic being used to assess heterogeneity. A random-effect or fixed-effect model will be chosen depending on the level of heterogeneity of intervention effects. The meta-analysis will be conducted using Review Manager (RevMan) version 5.4[25]. For continuous variables, the mean difference will be calculated if the same measurement scale was used, alternatively the standardised mean difference (SMD) will be calculated (with 95% CI [confidence interval]). For dichotomous variables, proportions will be compared using risk ratios (with 95% CIs). If a meta-analysis is not possible, a narrative synthesis will be conducted.

A meta-regression analysis will be performed if there are at least 6-10 studies for a continuous study-level variable[26]. The meta-regression analysis will examine whether intervention features (e.g., mode of delivery, theoretical framework, dose, intensity, and frequency) and the presence and absence of individual BCTs in the interventions are associated with each outcome.

Subgroup analyses will be performed where appropriate and possible, comparing studies based on intervention components, duration of the intervention and type of control used (centre-based versus home-based CR).

Meta-bias(es)

Study protocols will be assessed for evidence of selective reporting within studies. Reporting bias will be analysed using funnel plots.

Confidence in cumulative evidence

The quality of evidence will be assessed using the Grading of Recommendations Assessment, Development and Evaluation guidelines (GRADE)[27].

Discussion

Digitally delivered CR has the potential to improve behavioural outcomes for patients with CVD and to overcome some of the barriers associated with traditional CR service delivery. This review will identify the BCTs and intervention features that are associated with effective digital CR programmes and adopt a systematic approach to describe the content of these programmes using the BCT taxonomy (v1) and TIDieR checklist. This detailed intervention description will provide insight into the content, design and active ingredients of successful digital CR programmes, providing a foundation for further development, testing and refinement. This systematic review is being conducted in the broader context of developing a conceptual model of digital CR as the first step in an optimisation trial.

Data availability

No data are associated with this article.

Acknowledgments

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Open Peer Review

Current Peer Review Status: ✓ ✓

✓   **Garyfallia Pepera** (iD)

Physiotherapy Department, Faculty of Health Sciences, University of Thessaly, Thessaly, Greece
Varsamo Antoniou
Physiotherapy Department, Faculty of Health Sciences, University of Thessaly, Thessaly, Greece
Ladislav Batalik (iD)
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We read with interest the resent systematic protocol by Kenny *et al.* aiming to the identification of the behaviour change techniques (BCTs) that are used in digital cardiac rehabilitation (CR) programs and the determination of the ones that are mostly correlated to the enhancement of the CR program effectiveness (Sandercock *et al.* (2013[1])).

We strongly agree to the authors' assertion that the several barriers related to the underutilization of the traditional center-based CR programs can be addressed by the implementation of digital health interventions (DHIs) (Winnige et al. (2021[2])) Indeed, a recent critical review of ours has proclaimed the potential effective role of telehealth interventions as alternative sufficient methods of delivering CR during over demanding socioeconomic conditions, such is the ongoing COVID-19 pandemic (Stefanakis *et al.* (2021[3]), Pepera *et al.* (2022[5]))

Though, tele-delivered CR is indeed a complex multi-disciplinary intervention, that intergrades several different components and techniques in its design that are aiming to the improvement of varied aspects of the cardiac patients'(CVD) health status. Thus, we also consent to the need to specify and qualify the content of the CR program components and their contribution, separately or combined, in the maximization of the DHIs efficacy and efficiency.

We feel that this ongoing systematic review could provide the necessary background to a more compete design of the CR telehealth interventions and a more profound understanding of the theoretical framework and the practical features (dose, intensity, frequency) of the BCTs used in digital CR programs (Batalik *et al.* (2021[4]))

The use of reliable methods for specifying, interpreting and implementing the active ingredients

of interventions to change behaviors by this systematic review, such are the behavior change technique (BCT) taxonomy (v1) and the Template for Intervention Description and Replication (TIDieR) checklist could lead to a reliable identification and categorization of the most effective digital CR features; thus offering CR researchers and specialists a useful tool for a more sufficient, aim-specific orientated digital CR program implementation.

Baring in mind that DHIs aim to act as secondary preventive interventions that could modify and improve several cardiac risk factors, it is important to gain knowledge over the different characteristics and features of the multiple tools that are being intergraded in their design and better comprehend the way these tools can lead to behavioral changes within the targeted cardiac population.

Nowadays, more than ever, there is an urgent need to adopt a more well-orientated approach to CR design and implementation, based on the choice of the most appropriate CR components that could lead to an effective CR implementation.

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Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Yes

Are the datasets clearly presented in a useable and accessible format?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Cardiac Rehabilitation

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 15 November 2021

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✔ **Jonathan C Rawstorn** (iD)

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Thank you for the opportunity to review this protocol for a systematic review that will aim to synthesise current evidence about digital cardiac rehabilitation including the integration of behaviour change techniques, intervention features, effects on health behaviours and modifiable CVD risk factors, and potential impact of behaviour change techniques and intervention features on outcome effects.

The rationale for this review is solid and the results will likely be impactful for many researchers and clinicians working in the field of digital cardiac rehabilitation. This protocol clearly and succinctly describes relevant aspects of the study design and methods. Terminology suggests the search strategy may not yet have been finalised; however, the provided example looks appropriate for the study aims and, and given the final search strategy will likely be published together with the results in due course, I don't see this as a major problem.

I only have two minor comments:
1. It is unclear whether the authors have registered the review in the PROSPERO database. If so, the registration number could be included in this submission.

2. Articulating the status or current progress of the review would help to determine whether the manuscript presents a prospective or retrospective account of the design and methods.

I look forward to reading the results of this review in due course.

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Yes

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: cardiac rehabilitation, digital health, systematic reviews

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.