

DEVELOPMENT OF THE MEDFIT APPLICATION: A BEHAVIOUR CHANGE THEORETICALLY INFORMED CARDIAC REHABILITATION INTERVENTION

by

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This thesis is submitted for the award of M.Sc. to the School of Health and Human Performance in Dublin City University, Dublin, Ireland.

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Declaration

I hereby certify that this material, which I now submit for assessment on the programme of study leading to the award of Master of Science is entirely my own work, that I have exercised reasonable care to ensure that the work is original, and does not to the best of my knowledge breach any law of copyright, and has not been taken from the work of others save and to the extent that such work has been cited and acknowledged within the text of my work.

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Author contribution to publications/studies

This thesis includes two original manuscripts; one has been published in a peer review journal and the second has been submitted for publication. The development and writing of all manuscripts were the principle responsibility of the candidate. The inclusion of coauthors reflects the fact that part of the work came from active collaborations between researchers in Dublin City University and the University of Limerick. A summary of the candidate's contribution to each manuscript is outlined below. A more detailed description of the candidate's contribution and the extent of the research collaborations have been accurately described in the authors' contribution sections in Chapters 2 and 3. The content of the introduction and conclusion were developed and completed by the candidate.

Thesis	Article title	Publication	Nature and extent of
chapter		status	candidate's contribution
2	Behavior change techniques in physical activity eHealth interventions for people with Cardiovascular Disease: Systematic Review	Published in the Journal of Medical Internet Research	 First author. Developed and conducted the search strategy. Reviewed all manuscripts for inclusion and exclusion. Extracted data from the final papers for inclusion. Manuscript development, write up and submission to the journal.
3	Development of the MedFit Application: A behaviour change theoretically informed mobile application for patient selfmanagement of cardiovascular disease	Submitted for publication to the Journal of Translational Behavioural Medicine	 First author. Recruited participants to focus groups and acted as moderator. Conducted the content analysis. Manuscript development, write up and submission to the journal.

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Abbreviations

BCT: Behaviour Change Technique

CVD: Cardiovascular Disease

CR: Cardiac Rehabilitation

CHD: Coronary Heart Disease

eHealth: Electronic Health

FAQ: Frequently Asked Questions

ICT: Information and Communication Technologies

MRC: Medical Research Council

mHealth: Mobile Health

PA: Physical Activity

UTAUT 2: Unified Theory of Acceptance and Use of Technology 2

SFI: Science Foundation Ireland

Abstract

Development of the MedFit Application: A behaviour change theoretically informed cardiac rehabilitation intervention

Orlaith Duff

Background: Cardiovascular disease (CVD) is the leading cause of premature death and disability in Europe. Cardiac Rehabilitation (CR) can reduce the impact of CVD by lowering mortality and morbidity rates and promoting healthy active lifestyles. Yet adherence within CR is low. Research suggests that mHealth interventions are useful in supporting the self-management of chronic disease. The overall purpose of this research is to facilitate the development of a specially designed Android App called MedFit, which aims to enhance the likelihood of people with established CVD self-managing their disease through participation in an exercise-based rehabilitation programme.

Methods: For the intervention development, the preliminary stages of the Medical Research Council's (MRC) formative process [i) development and ii) feasibility/piloting were used. This was achieved by conducting a systematic literature review, adhering to PRISMA guidelines, to identify what behaviour change techniques (BCTs) are used in physical activity eHealth interventions for adults with CVD (study 1). Study two involved testing the feasibility and acceptability of the prototype application using five focus groups (N=26 CVD patients; average age 64 ± 8.2 years; 65 % male). The focus group script was developed using a questionnaire (N=119 CVD patients; Appendix B.3) based on the Unified Theory of Acceptance and Use of Technology 2 (UTAUT2) which identified the constructs that were the primary concerns for end users. Focus groups were transcribed verbatim and in-depth content analysis was performed.

Results: Twenty-three studies were included in the systematic literature review. The average number of BCTs employed in the studies was 7.2 (range 1-14). The top three most frequently used BCTs were information about health consequences (78.3%), goal setting (behaviour) (73.9%) and self-monitoring of behaviour (47.8%) (study 1). In study 2 the focus group usability feedback included; add in a retrieve password function, play the exercise video continuously and remove leaderboard function. Four key themes were identified following content analysis, these were; support, app as a mentor/guide, translation of activity from gym to home and technology knowledge gap. This feedback was translated into feasible technical improvements through close collaboration with the technical team.

Conclusion: This research describes in detail the design process, first alpha-version of the App and focus group feedback used to develop a CVD mHealth intervention.

CHAPTER 1

Introduction

Introduction

Cardiovascular disease is the leading cause of premature death and disability in Europe, accounting for four million deaths per year and costing the EU economy almost €196 billion annually (Perk et al., 2012). Exercise-based Cardiac Rehabilitation (CR) has numerous health benefits that include reductions in cardiovascular mortality, hospitalisations and improvements in health-related quality of life (Anderson et al., 2016). Cardiac rehabilitation has been shown to improve physical health and therefore decrease morbidity and mortality (Jolliffe 2001; Taylor 2004). Cardiac rehabilitation is comprised of exercise training, education, behaviour change psychological counseling/support and strategies aimed at targeting other risk factors for cardiovascular disease (Davies et al., 2010).

Although CR improves mortality and morbidity rates, adherence within these programmes is generally low (Dalal et al., 2010). Surveys across a number of countries have found that between 14-43% of potential cardiac patients participate in a CR programme (Bethell 2001; Blackburn 2000; Bunker 1999). Furthermore, less than 50% of people who participate in CR programmes maintain regular exercise for as long as 6 months after programme completion (Daly 2002; Moore 2003). Some of the more common issues identified with adherence to CR programmes relate to accessibility and parking at local hospitals, a dislike of group environments, and work or domestic commitments (Dalal et al., 2010). A review by Jackson and colleagues (2005) found that the strongest predictors of non-adherence to CR were the long distance to CR programmes and lack of insurance cover. In terms of differences between the sexes women were less likely to participate than men. Other factors which have been reported as predicting adherence include health belief variables (Al-Ali 2004; Moore 2003), age (Al-Ali 2004; Daly 2002; Moore 2003), annual income (Al-Ali 2004), level of education (Al-Ali 2004; Daly 2002), cardiac functional status (Moore 2003), mood state (Moore 2003; Ziegelstein 2000) and social support (Moore 2003).

To address these issues with adherence to CR new modes of delivery are beginning to be explored. Mobile health (mHealth) is an emerging area of healthcare and is defined as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants and other wireless devices" (World Health Organisation, 2011, p.6). mHealth technologies are a subset of eHealth

(electronic health). eHealth encompasses all forms of technologies for healthcare, whereas mHealth specifically relates to the application of mobile technologies for health. mHealth technologies have the ability to make healthcare more accessible, affordable and available to the public (Akter et al., 2010). mHealth technologies may overcome barriers related to access to CR and provide a useful tool for increasing participation (Beatty et al., 2013). mHealth technologies also have the advantage of being able to influence health behaviours in real-time (Riley et al., 2011). Through mobile technology, a user can receive and interact with information, record and review data, receive automated, personalised feedback and connect with other users or healthcare providers (Beatty et al., 2013). In comparison to internet interventions delivered via laptops or desktop computers, mobile interventions have the capacity to interact with the individual at much greater frequency and in the context of the behaviour (Riley et al., 2011). mHealth apps are particularly appropriate when treatment/care depends on patient behaviour change, such as smoking, obesity, diabetes and other chronic conditions such as cardiovascular disease (McCurdie et al., 2012).

Even though older adults are less likely to use mobile phones than younger adults, recent trends have shown significant increases in internet use and mobile phone ownership among older adults (Smith, 2014). In 2014, 59% of older adults (aged \geq 65 years) reported that they used the internet and 77% had a mobile phone, up from 69% in April 2012 (Smith, 2014). Furthermore, in 2016 a study by Buys and colleagues found that cardiac rehabilitation patients (N=298; 71% male; age 61.7 ± 14.5 years) had a high interest in technology, with 97% owning a mobile phone and 91% using the internet. Although mHealth technologies are still a developing area of research, literature in the area of internet and mobile-based health interventions suggests that such tools can be useful in supporting the self-management of chronic disease (Fanning et al., 2012; Omboni et al., 2013).

Mobile technologies can provide individual level support to health care consumers and are designed to increase healthy behaviours and/or improve disease management (Free et al., 2013). Mobile technologies have numerous functionalities which can be implemented in behaviour change interventions. These functions include communication via SMS messaging and phone calls, the ability to take and access videos and photos, internet access, multi-media playback and software application support (Free et al., 2013). mHealth has the potential to improve the monitoring and tracking of health behaviours

(e.g. physical activity levels, weight and blood pressure), communication between patient and health care providers and adherence to treatment regimes, ultimately leading to patient empowerment with respect to the self-management of disease (Steinhubl, Muse and Topol, 2013).

MedFit is designed to utilize the expertise of a community-based exercise rehabilitation programme, called MedEx, and the Insight Centre for Data Analytics, to allow people with CVD to participate in an exercise-based rehabilitation programme remotely, through a specially designed Android App called MedFit. Its aim is to enhance disease self-management and quality of life in people living with CVD. It will be offered to patients who have completed a hospital-based CR programme, with the aim of extending and augmenting their care. Like CR it will use exercise as its main modality, and provide advice on other health behaviours (healthy eating, alcohol moderation, smoking cessation, medication adherence, stress management and sexual functioning). The MedFit App offers the potential to make exercise-based rehabilitation programmes more effective by making them more accessible, more personalised and more interactive, by providing real-time support and feedback for participants.

Aim:

To facilitate the development of a specially designed Android App called MedFit
which aims to enhance the likelihood of people with established CVD selfmanaging their disease through participation in an exercise-based rehabilitation
programme.

Objectives:

- 1) To conduct a systematic literature review of the use of behaviour change techniques in physical activity eHealth interventions for adults with cardiovascular disease.
- 2) To inform the development of the app using the results of the systematic literature review and by working in collaboration with the technical design team.
- 3) To conduct user validation of the alpha version of the MedFit app through questionnaire and focus group work.

In order to develop an evidence-based effective mobile app for CVD embedded within health behaviour change theory, a framework for the development and evaluation of mHealth interventions was followed. This framework is made up of five steps; conceptualisation, formative research, pre-testing, trial and qualitative follow-up (Whittaker et al., 2012) (Figure 1.1). This framework is also in line with best practice guidance from the Medical Research Council (MRC; Craig et al.,2008) (Figure 1.2). This masters project details the development phase of the framework, called the formative research process (Figure 1.1). The formative research process is a critical step in the development of health behaviour change interventions and consists of 4 key stages; development, feasibility/piloting, evaluation and implementation (Craig et al.,2008). This research masters will focus on the first two phases of the formative research process; development and feasibility/piloting. These key steps are outlined below and provide part of a best practice framework for App development within a health behaviour change and public health setting.

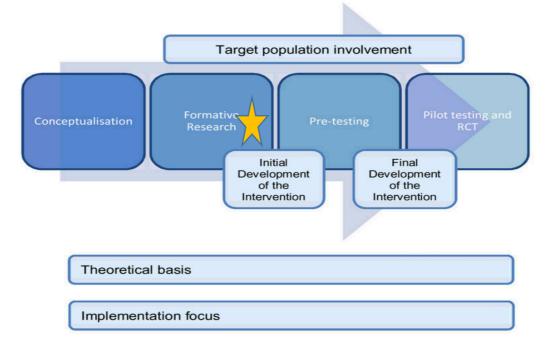


Figure 1.1: mHealth development and evaluation framework (Whittaker et al. 2012). The star highlights the formative research stage undertaken as part of this masters' project.

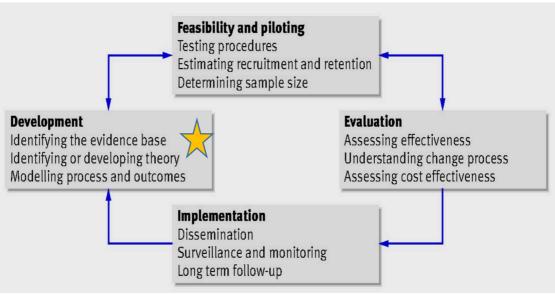


Figure 1.2: Medical Research Council's key elements of the development and evaluation process (Craig et al. 2008). The star highlights the development stage undertaken as part of this masters' project.

The first phase of the research involved conducting a systematic review to identify the relevant, existing evidence base, as well as potential gaps in the literature (Bowen et al., 2009). Within MedFit a crucial step of the development was to systematically examine previous research to assess eHealth (electronic health) interventions to identify what behaviour change techniques are applied in these interventions. The review was entitled a 'Systematic review of the use of Behaviour Change Techniques (BCTs) in physical activity eHealth interventions for adults with cardiovascular disease'. It aimed to identify the BCTs used in physical activity eHealth interventions for CVD patients. Subsequently, the results of this study were translated into technical requirements, informing the development and functionality of the application 'MedFit'. This ensured that both the technical aspects of the application (i.e., push notifications and the user interface) as well as the tailored interactive content were all based within an evidence and theory-based framework of health-behaviour change.

In the second stage of the formative research process, the feasibility and acceptability of the prototype application was tested in focus groups. The focus group script was developed and informed using a questionnaire based on the Unified Theory and Acceptance and Use of Technology 2 (UTAUT2) (Venkatesh, Thong and Xu, 2012). This theory has been used to explain technology acceptance and use. The UTAUT2 model was extended to shift towards a more consumer context rather than an organisational context in which the original UTAUT model was predominately used. The original

UTAUT model included the constructs performance expectancy, effort expectancy, social influence and facilitating conditions. The UTAUT2 was extended to incorporate three new constructs: hedonic motivation, price value and habit. Compared to the original UTAUT model, the extensions proposed in the UTAUT 2 produced an improvement in the variance explained in behavioural intention (56% to 74%) and technology use (40% to 52%) (Venkatesh, Thong and Xu, 2012). This implies that the constructs added to the UTAUT model are critical to the predictive validity of UTAUT in a consumer context comparable to what was found in the original model. This model therefore contributes to the understanding of the consumer use of technologies.

Questions relating to the constructs of the UTAUT2 model were developed into a questionnaire entitled the 'Acceptability of mobile phone applications among adults with chronic illness'. The questionnaire was completed by MedEx Wellness participants. MedEx Wellness is a community-based exercise rehabilitation programme for chronic illness located at Dublin City University (DCU). It offers supervised exercise classes to individuals with a range of chronic conditions, including cardiovascular disease, pulmonary disease, diabetes, and cancer. The questionnaire was specifically designed to develop a theoretically informed focus group script by analysing what constructs impacted participants' acceptance and use of apps. As well as that the focus group script also focused on the usability of the MedFit application, by providing participants the opportunity to test the app, inspect its functions and provide feedback on the different app components.

This stage of user validation through focus groups work was a crucial part of the user-led formative research and design process, with the purpose being to gain feedback on the first prototype of the mobile app. The feedback was then translated into feasible technical improvements through close collaboration with the technical design team, who adapted and made modifications and upgrades to the app based on the patient feedback and comments from the focus group. This iterative design process with the end-user allows for the custom design and creation of a truly patient-centric home-based exercise-rehabilitation application for adults with CVD.

Future work (beyond this research masters) will follow in line with the formative research process of implementation and evaluation. This will involve feasibility testing of the app prior to a full-scale intervention and qualitative follow-u

CHAPTER 2

Behavior Change Techniques in Physical Activity eHealth Interventions for People with Cardiovascular Disease: Systematic review

Peer review status

The study in this chapter has been accepted for publication in the Journal of Medical Internet Research. It was accepted for an oral presentation at the 2016 Insight Student Conference and was presented orally at the 2017 PEPAYS Conference.

Citations

- Duff OM, Walsh DMJ, Furlong BA, O'Connor NE, Moran KA, Woods CB. Behavior Change Techniques in Physical Activity eHealth Interventions for People With Cardiovascular Disease: Systematic Review. J Med Internet Res 2017;19(8):e281
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- 3. Duff, O., Walsh, D., Monaghan, D., O'Connor, N., Moran, K. and Woods, C.B. (2016). 'MedFit: The development of a mobile-application to enhance participant self-management of their cardiovascular disease'. *Health Enhancing Physical Activity Europe Conference*, Belfast, 28-30 September 2016.

Keywords: Systematic review, physical activity, behaviour change techniques, eHealth intervention, cardiovascular disease

Chapter 2 Study 1

The overall aim of this study was to conduct a systematic review to assess the application of behaviour change techniques in eHealth interventions designed to increase physical activity in CVD populations.

Purpose of the chapter

The purpose of this study was to assess what behaviour change techniques (BCTs) are used in physical activity eHealth interventions for adults with cardiovascular disease. It is important to identify the BCTs employed in interventions to theoretically understand behaviour change and to improve our understanding of the 'active ingredients' which are essential for evidence-based programmes to produce desired outcomes. To our knowledge this is the first systematic review conducted to identify the key behaviour change techniques applied in eHealth physical activity interventions for adults with cardiovascular disease.

Candidates' contribution to the publication

The lead author (OD) undertook the following activities:

- Ran the keyword search in the chosen databases.
- Reviewed all articles for inclusion and exclusion.
- Extracted data from the final papers for inclusion.
- Wrote the paper and made changes based on feedback from the other authors.
- Submitted the paper to the journal, managed communication with the journal, responded to and made alterations based on reviewers' comments, and checked the final 'proof' of the paper.

Contribution of other authors to the publication

All authors read, reviewed and approved the final paper and the resubmitted paper.

- DW was the second reviewer who reviewed the articles for inclusion and exclusion in the review.
- DW and OD independently extracted data from the final papers for inclusion.
- CW was the third reviewer if any discrepancies occurred between OD and DW in the review and data extraction processes.
- CW, DW and BF revised and provided feedback on the drafts on the manuscript.
 KW and NOC also provided feedback on the manuscript.

Abstract

Background

Cardiovascular disease (CVD) is the leading cause of premature death and disability in Europe, accounting for four million deaths per year and costing the EU economy almost €196 billion annually. There is strong evidence to suggest that exercise-based secondary rehabilitation programmes can decrease the mortality risk and increase health among patients with CVD. Theory informed use of behaviour change techniques (BCTs) is important in the design of cardiac rehabilitation programmes aimed at changing cardiovascular risk factors. Electronic health (eHealth), is the use of information and communication technologies (ICT) for health. This emerging area of healthcare has the ability to enhance self-management of chronic disease by making healthcare more accessible, affordable and available to the public. However, evidence-based information on the use of BCTs in eHealth interventions is limited, particularly so for individuals living with CVD.

Aim

The aim of this systematic review was to assess the application of BCTs in eHealth interventions designed to increase physical activity (PA) in CVD populations.

Methods

A total of 7 electronic databases, including EBSCOhost (MEDLINE, PsycINFO, Academic Search Complete, SPORTDiscus with Full Text, CINAHL Complete), Scopus and Web of Science (Core Collection) were searched. Two authors independently reviewed references using the software package Covidence (Veritas Health Innovation). The reviewers met to resolve any discrepancies, with a third independent acting as arbitrator when required. Following this, data were extracted from the papers that met the inclusion criteria. Bias assessment of the studies was carried out using the Cochrane Collaboration's risk of bias tool within Covidence; this was followed by a narrative synthesis.

Results

Out of the 987 studies identified 14 were included in the review. An additional 9 studies were added following a hand search of review paper references. The average number of BCTs used across the 23 studies was 7.2 (range 1 to 19). The top three most frequently used BCTs included information about health consequences (78%, 18/23), goal setting

(behavior; 74%, 17/23), and joint third, self-monitoring of behavior and social support (practical) were included in 11 studies (48%, 11/23) each.

Conclusion

This systematic review is the first to investigate the use of BCTs in PA eHealth interventions specifically designed for people with CVD. This research will have clear implications for healthcare, policy and research by outlining the BCTs used in eHealth interventions for chronic illnesses, in particular CVD. Hence, providing clear foundations for further research and developments in the area.

Introduction

Cardiovascular disease (CVD) is the leading cause of mortality worldwide, accounting for 30% of global death and 48% of deaths in Europe (Allender et al., 2008). Cardiac rehabilitation (CR), which is used to reduce the impact of CVD and to promote healthy behaviours and active lifestyles for those with CVD (Balady et al., 2000), has been shown to improve physical health and decrease subsequent morbidity and mortality rates in CVD populations (Dalal et al., 2010). The main modality of cardiac rehabilitation is exercise. Two systematic reviews of exercise-based CR, which included 48 randomised controlled trials, showed a 20% reduction in all-cause mortality and a 27% reduction in cardiac mortality at 2 to 5 years (Jolliffe et al., 2001) (Taylor et al., 2004).

The efficacy of standard cardiac rehabilitation has been extensively reviewed. In terms of mortality rates a systematic review and meta-analysis of 34 RCTs (n=6111 myocardial infarction patients) showed that those who attended CR had a lower-risk of all-cause mortality than non-attendees (odds ratio=0.74, 95% CI 0.58-0.95) (Lawlor, Filion and Eisenberg 2011). With respect to hospital admissions, a Cochrane review of 33 RCTs (n=4740 patients with heart failure) showed that CR reduced the risk of overall hospitalization (relative risk, RR=0.75, 95% CI 0.62-0.92; absolute risk reduction, ARR=7.1%; number needed to treat, NNT=15) and hospitalization for heart failure (RR=0.61, 95% CI 0.46-0.80; ARR=5.8%; NNT=18) (Sagar et al., 2015). A US observational study (n=635 coronary heart disease patients) reported improvements in depression, anxiety and hospital scores after CR (Lavie and Milani 2006). Cardiac rehabilitation has also been found to improve psychological wellbeing and improvement in quality of life. One of the most significant benefits of cardiac rehabilitation exercise training to participants is the improvement in aerobic capacity and cardio-respiratory fitness (Menezes et al., 2012).

Even though CR has been shown to be effective, adherence to these programmes is generally suboptimal. Participation rates in CR are documented at less than 50% worldwide (Bjarnason-Wehrens et al., 2010). Results from a Cochrane systematic review revealed that common barriers to adherence to CR programmes included accessibility and parking at local hospitals, a dislike of group environments and work or domestic commitments (Dalal et al., 2010). In 2012, a *Heart* journal editorial concluded that CR

should not only focus on content, such as coronary heart disease (CHD) risk factor modification and medication adherence but should also focus on the delivery mechanisms, thereby offering a range of different delivery methods for people according to their preferences and needs, potentially addressing the issue of low levels of participation (Jones et al., 2012). The delivery of CR to date has largely been centre-based, either in hospitals or community centres. However, in more recent times there has been a shift toward a more home-based model of care. A systematic review by Dalal and colleagues (2010) found that both home and center based forms of CR are equally effective in improving clinical and health related quality of life outcomes in patients with CVD, suggesting the further provision of additional evidence-based home CR programmes. A Cochrane review found that home-based interventions may be superior in terms of adherence to exercise, especially in the long term (Ashworth et al., 2005). This would ensure that patients are given the choice of participating in a more traditional supervised center-based programme or a home-based programme, based on their personal preference.

The emerging area of electronic health (eHealth), defined as the use of information and communication technologies (ICT) for health (World Health Organisation, 2012) may provide this alternative home-based delivery method. Interventions that encompass ICT (e.g. internet- and mobile based communications, wearable monitors) enable the efficient delivery of educational resources, individually tailored health and wellness programs as well as time-unlimited feedback, coaching and support (Krebs, Prochaska and Rossi, 2010). Technology solutions for physical activity uptake and monitoring are being undertaken as a new mode of facilitating behaviour change and may impact the current delivery of cardiac rehabilitation (Buys et al., 2016). Tele-rehabilitation solutions refer to the use of Information and Communication Technologies (ICT) to provide rehabilitation services to people. Literature in this area for cardiac patients indicates that such interventions are feasible and effective when compared to conventional centre-based CR (Frederix et al., 2015).

Furthermore, eHealth interventions have been showing promising results in cardiac rehabilitation, supporting behaviour change, clinical improvement and improved social functioning. In 2013, Beatty and Colleagues conducted a review of mobile interventions for CR, identifying only 3 studies for inclusion. More recently the interest in eHealth and mobile health (mHealth) has risen dramatically, indicating the increased focus in this field over recent years. Buys and colleagues (2016) investigated the interest among

cardiac patients in technology enabled cardiovascular rehabilitation. Of the 298 patient (77% male; mean age 61.7 [SD 14.5]) questionnaires included in the analysis, 97% had a mobile phone and 91% used the internet. Physical activity monitoring was reported by 12% of the respondents. Overall cardiac patients showed high interest in CR support through the internet (77%) and mobile phones (68%). These findings suggest that patients with CVD show an interest in technology enabled home-based CR, potentially allowing exercise based rehabilitation programmes to be more effective by making them more accessible, personalised, and more interactive with patients.

Behavior change techniques (BCTs) are integral in the design of complex health service interventions, such as CR. A BCT is defined as "an observable, replicable and irreducible component of an intervention designed to alter or redirect causal processes that regulate behaviour; that is, a technique is proposed to be an 'active ingredient'" (Michie et al., 2013). The Medical Research Council (MRC) guidelines recommend the application of behaviour change theory within complex health service interventions to allow for a theoretical understanding of behaviour change (Davis et al., 2015). The National Institute of Health and Care Excellence (NICE) guidelines on individual-level behaviour change interventions aimed at changing health-damaging behaviours such as unhealthy diet, physical inactivity, excessive alcohol consumption, unsafe sex and smoking, recommend the use of evidence-based BCTs, which have been proven to be effective at changing behavior, such as goals and planning, feedback and monitoring and social support. Despite this guidance, few interventions pay close attention to the behaviour change theory and techniques used to design their interventions (National Institute for Health and Care Excellence, 2014). In particular, the poor description of interventions in research protocols and published reports presents a barrier for future design of complex interventions (Michie et al., 2009), as it is difficult to identify the active and effective components of the intervention (Michie et al., 2013). The proliferation of eHealth interventions requires the coding of such interventions to facilitate future research to compare accurately across interventions. With that in mind, this systematic review aims to identify the key BCTs applied in eHealth PA interventions for adults with cardiovascular disease.

Methods

This systematic review is reported in line with the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidance. The inclusion criteria for studies were as follows; human randomised and quasi-randomised controlled trials, published and unpublished, of physical activity eHealth interventions for adults (≥18 years old) clinically diagnosed with cardiovascular disease. Studies were included if the main intervention component was delivered via a computer, smartphone, tablet or phone (e.g. mobile phone App, emails, text messages and phone calls) with the primary or secondary aim of increasing the physical activity level of the user. The interventions could be delivered to groups or individuals. The inclusion criteria was kept quite broad in order to identify as many studies as possible with PA as a primary or secondary outcome, as well as studies which had PA as a component of the intervention.

The Behaviour Change Taxonomy version 1 was used to identify the specific BCTs used within the included studies (Michie et al., 2013). Two researchers coded for the BCTs using the taxonomy.

Outcome measures

A description of the BCTs and their frequency of use in the 23 eHealth interventions reviewed were classified using a BCT taxonomy by Michie and colleagues. Due to the heterogeneous nature of the studies differing in PA outcome measures and time-points, we were unable to carry out a meta-analysis examining the effectiveness of the BCTs in relation to the PA outcomes.

Search methods for the identification of studies

Seven electronic databases were searched, including MEDLINE (via EbscoHost, 2000 to 2016), PsycINFO (via EbscoHost, 2000 to 2016), Academic Search Complete (via EbscoHost, 2000 to 2016), SPORTDiscus (via EbscoHost, 2000 to 2016), CINAHL Complete (via EbscoHost, 2000 to 2016), Scopus (2000 to 2016) and Web of Science (Core Collection) (2000 to 2016).

The search was restricted to studies published in English between 2000 and 2016. The search strategy used keywords relating to physical activity, eHealth interventions, CVD and adults, as well as appropriate synonyms. Boolean operators were used to expand, exclude or join keywords in the search, using the terms "AND" and "OR". In all

databases, the searches were limited to the fields of abstract and title only. The search strategy for all databases is illustrated Appendix A.1.

Selection of studies

Figure 2.1 shows the PRISMA flow diagram of reviewed and included studies. One researcher conducted the database search. All articles identified following the database search were then uploaded to the online systematic review software package "Covidence" (Veritas Health Innovation). Firstly, a title and abstract review of all studies was completed independently by two authors. Any disagreements were discussed until a consensus was reached or a third reviewer helped to resolve the discrepancy. A record was kept of all the articles excluded and the reason for exclusion via Covidence. Second, all articles that met the inclusion criteria went through a full text screening process by the two authors independently. Again, any disagreements between the authors on the eligibility of the studies were reviewed by a third author. Additional studies were also identified for inclusion by reviewing the reference lists of review papers through a hand search.

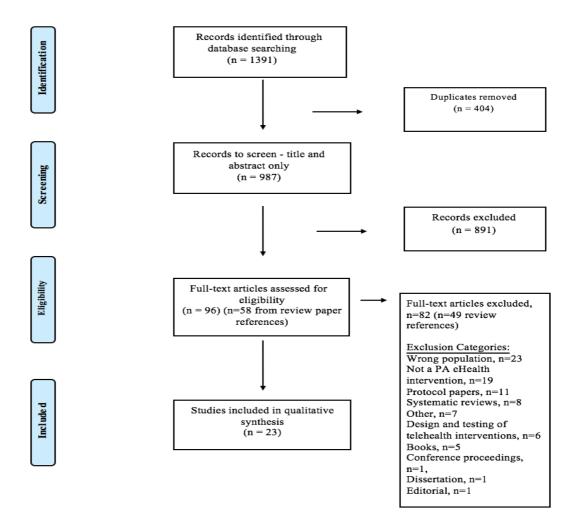


Figure 2.1: PRISMA flow diagram of reviewed and included studies

Data extraction

Data from the studies were extracted independently by two review authors using a data extraction template. Data extracted from the articles included study title, authors, country, year, patient group (sample size), inclusion criteria, study design, technology involvement, assessment, intervention details, outcomes, theory involved, BCTs identified and results. No blinding to study author, institution or journal occurred during the screening process for the study.

If multiple publications of the same study were identified, the team would try to extract and combine all the available data; where there was doubt, the original publication would be given priority. If data seemed to be missing from a study, we tried to obtain the missing data through correspondence with the study authors. The review team resolved any disagreements regarding study eligibility through group discussion.

Assessment of risk bias

Two reviewers assessed each study for risk of bias (high, low or unclear) using the Cochrane risk of bias tool (Higgins et al., 2011). A third review author acted as arbitrator if necessary. The results of the risk of bias assessment were then exported to RevMan to create a visual representation of the publication bias (see figure 2.2).

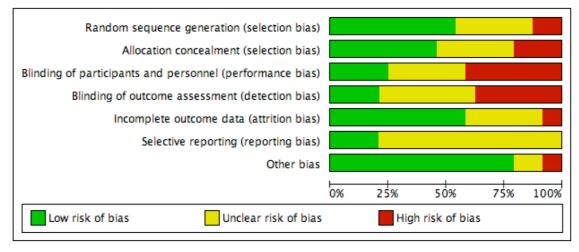


Figure 2.2: Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

Assessing for heterogeneity

Diversity across the studies was assessed qualitatively in terms of eHealth intervention, patient characteristics and outcome measures.

Data synthesis

Following the extraction of data from the studies, careful consideration was given to the appropriateness of conducting a meta-analysis. As the studies were too heterogeneous to combine statistically, the data were synthesised qualitatively.

Behaviour Change Techniques (BCTs)

To gain an understanding of the types of BCTs used in PA eHealth interventions in this patient population, 2 authors screened the included studies and coded the BCTs used in each study using Michie and colleagues BCT taxonomy (Michie et al., 2013).

Results

The search criteria returned 1391 articles through databases searching. A total of 404 duplicates were removed, leaving 987 articles to screen. The articles title and abstracts were then screened by two reviewers, resulting in 891 records excluded for not meeting the inclusion criteria. The authors reviewed the full text of 96 studies, identifying 14 studies for inclusion in this review. From a hand search of review papers references an additional 58 studies were identified as potentially eligible. Following a full text review of these papers, 9 studies were included in the review. Therefore, a total of 23 articles were included in the qualitative synthesis.

Study characteristics

Table 2.1 provides an overview of the included studies and the physical activity results. Of the 23 studies included, 14 comprised an internet/web-based programme and/or smartphone intervention (Ammenwerth et al., 2015; Antypas and Wangberg, 2014; Chow et al., 2015; Dale et al., 2015; Devi, Powell and Singh, 2014; Frederix et al., 2015; Lear et al., 2014; Lindsay et al., 2009; Maddison et al., 2015; Piotrowicz et al., 2014; Reid et al., 2012; Tomita et al., 2008; Varnfield et al., 2014; Widmer et al., 2015), 3 were telephone interventions (Ades et al., 2000; Furber et al., 2010; Hanssen et al., 2007), 2 used a telehealth device (Artinian et al., 2003; Barnason et al., 2009) and 2 consisted of a form of telemonitoring (Lee et al., 2013; Scalvini et al., 2009). Single studies consisting of videoconferencing (Dalleck, Schmidt and Lueker, 2011) and of virtual reality wraparound screens (Chuang et al., 2006) were also found. Of the 20 studies with a control group, 17 involved 'usual care' as the control. Usual care predominately pertained to receiving standard cardiac rehabilitation services (Ades et al., 2000; Artinian et al., 2003; Barnason et al., 2009; Chow et al., 2015; Chuang et al., 2006; Dale et al., 2015; Dalleck, Schmidt and Lueker, 2011; Devi, Powell and Singh, 2014; Frederix et al., 2015; Hanssen et al., 2007; Lear et al., 2014; Lee et al., 2013; Maddison et al., 2015; Reid et al., 2012; Tomita et al., 2008; Varnfield et al., 2014; Widmer et al., 2015). Eight studies were carried out in Europe (Ammenwerth et al., 2015; Antypas and Wangberg, 2014; Devi, Powell and Singh, 2014; Frederix et al., 2015; Hanssen et al., 2007; Lindsay et al., 2009; Piotrowicz et al., 2014; Scalvini et al., 2009), while seven of the studies were conducted in North/South America (Ades et al., 2000; Artinian et al., 2003; Barnason et al., 2009; Lear et al., 2014; Piotrowicz et al., 2014; Tomita et al., 2008; Widmer et al., 2015). Three studies apiece were conducted in Australia (Chow et al., 2015; Furber et al., 2010; Varnfield et al., 2014) and New Zealand (Dale et al., 2015; Dalleck, Schmidt and Lueker, 2011; Maddison et al., 2015) and two studies were conducted in Asia (Chow et al., 2015; Lee et al., 2013).

The majority of participants were recruited from hospitals/medical centres (Ades et al., 2000; Ammenwerth et al., 2015; Antypas and Wangberg, 2014; Artinian et al., 2003; Barnason et al., 2009; Chow et al., 2015; Chuang et al., 2006; Dale et al., 2015; Devi, Powell and Singh, 2014; Furber et al., 2010; Hanssen et al., 2007; Lear et al., 2014; Lindsay et al., 2009; Piotrowicz et al., 2014; Reid et al., 2012; Scalvini et al., 2009; Tomita et al., 2008; Varnfield et al., 2014; Widmer et al., 2015). One study recruited participants from a general practitioner (GP) coronary heart disease (CHD) registry (Lindsay et al., 2009), while another recruited from a CR referral list (Furber et al., 2015). Tomita and colleagues (2008) recruited participants from three hospitals and two health insurance companies. One study recruited participants from primary and community health services (Varnfield et al., 2014). Outcomes were assessed from 3 weeks (Barnason et al., 2009) to 16 months (Hanssen et al., 2007), with the average end-point across the 23 studies at 4.5 months.

Table 2.1: Information on included studies

Author and country	Sample (n) (% males) / Dropout (% DO)	Intervention	Control	PA Measure and Effect
Ades et al., 2000 USA	133 (81.2% male); n=83 in the transtelephonically monitored rehab program and n=50 in the standard on- site rehab program 9% DO	Multiple long-distance phone lines to monitor up to 8 patients at the same time. Patients were given a patient's kit that included bipolar ECG leads, an ECG transmitter unit, a headset, a voice transmitter and a telephone modem. During the exercise sessions, patients were in direct telephone contact with the nurse coordinator and with other participants.	Standard on-site rehabilitation program	No physical activity measurement*
Ammenwerth et al., 2015 Austria	25 (96% male) 0 DO	Tele-monitoring programme is a multi-modal intervention programme to improve lifestyle and medication management of patients with CHD. It includes patient education, self-monitoring with goal-setting and feedback, and regular clinical visits.	No control group	Pedometer (steps) Pre-defined goals for PA were reached in up to 86% ad 73% of days, respectively.
Antypas et al., 2014 Norway	69; n=29 tailored group (76% male) and n= 40 control group (79% male) 27.5% DO	Internet- based intervention-consisting of general information about CVD and self-management, including diet, physical activity, smoking and medication and a discussion forum, augmented by tailored messages.	Received the basic internet intervention. Did not receive messages or feedback.	IPAQ (MET minutes/week) To = C > E, PA, (p=.02) T1m = No PA diff, (p=.38) T3m = E > C, PA, (p=0.02)
Artinian et al., 2003 USA	18 (94% male); n=9 in the intervention group and n=9 in the control group 0 DO	The Med- eMonitor retains medications in individual compartments, and uses an alarm to remind patients daily when to take their medications, which to take, and how many to take. The monitor contained an additional 25 virtual compartments in which daily reminders or questions about other medications, symptoms, monitoring daily weight and blood pressure, reducing salt intake, eating heart healthy, and engaging in physical activity. The monitor sat in a cradle that was connected to a telephone line - patient information was automatically transmitted to the Med-eMonitor server.	Received usual care	No physical activity measurement*

Barnason et al., 2009 USA	280; n=143 in the intervention group and n=137 in the control group 17.1% DO	Tele-health-intervention delivered via the Health Buddy ® telehealth device; for a total of 42 daily sessions. The symptom management intervention provided subjects with strategies designed to address commonly occurring symptoms experienced after recovery from CABS, to improve outcomes (physical activity, functioning); and a long-term outcome of having less healthcare utilization.	Received usual care	Accelerometer, modified 7-day activity interview (baseline PA assessment), physical activity and exercise diary T6m = No sig. diff between exp and control groups in average daily activity counts (p=.20)
Chow et al., 2015 Australia	710; n=352 received text message intervention and n=358 received usual care 1.5% DO	A text message—based prevention program which involved delivery of regular semipersonalized text messages providing advice, motivation, and information that aimed to improve diet, increase physical activity, and encourage smoking cessation (if relevant).	Received usual care - includes community follow- up with the majority referred to inpatient cardiac rehabilitation by their physician	Global physical activity questionnaire (Total PA – MET minutes/week) T6m = E > C, PA (p=.003)
Chuang et al., 2006 Taiwan	24 (100% male); n= 12 received non-virtual reality (VR) intervention and n=12 received VR intervention 16.7% DO	Intervention consisted of virtual reality "wraparound" screens used in CR.	No virtual reality experience during rehabilitation	No physical activity measurement*
Dale et al., 2015 New Zealand	123(81.3% male); n=61 in the intervention group and n=62 in the control group 9.8% DO	Theoretically framed comprehensive program of evidence-based CR guidelines delivered by text message and a supporting website over 24 weeks. Participants received 7 messages per week and had access to a supporting website. Participants were also given a pedometer to self-monitor their physical activity.	Received standard CR services	Godin leisure time physical activity questionnaire Exp. group ↑ adherence to health behaviour from baseline (33%) to 3 months (59%) and plateaued at 6 months (53%). Control group ↑ adherence to health behaviour from baseline (27%) to 3 months (37%) and plateaued at 6 months (39%). Sig. treatment effect in favor of intervention at 3 months (p=.03) but not 6 months (p=.13)

Dalleck et al., 2010 New Zealand	226; n=173 conventional cardiac rehab (58% male) and n=53 in tele-medicine – delivered cardiac rehab (55% male) 0 DO	In the telemedicine site, rehabilitation was delivered via telemedicine using videoconferencing.	Conventional cardiac rehabilitation	No physical activity measurement*
Devi et al., 2014 UK	94 (74.5% male); n= 48 in the intervention group and n=46 in the usual care group 23.4% DO	6-week web-based rehabilitation program contained information about the secondary prevention of coronary heart disease (CHD) and set each user goals around physical activity, diet, managing emotions, and smoking. Participants completed an online exercise diary and communicated with rehabilitation specialists through an email link/synchronized chat room.	Received usual care from their GP	Accelerometer (daily steps) $T6w = E > C, \text{ step count, (p=.02)}$
Frederix et al., 2015 Belgium	140; n=70 intervention group (96% male) and n=70 in control group (79%male) 10% DO	Internet-based telerehabilitation program as well as to conventional centre-based CR. Wore an accelerometer for the duration of the study - uploaded the data at least every 2 weeks to a secure webpage - patients could self-monitor PA via the webpage. Based on the uploaded data a semi-automatic tele-coaching system provided patients with feedback via email and/or SMS. Received dietary and smoking cessation tele-coaching programme.	Conventional cardiac rehab care	Accelerometer (step data) and IPAQ (MET-min/week – Vigorous and/or moderate and/or walking (VMW)) T6w and T6m = Exp. Group, No sig. PA change (p=.24) T6w and T6m = Control Group, No sig. PA change (p=.85) T6m = E>C, leisure VMW, (p=.01)
Furber et al., 2010 Australia	215; n=104 in the intervention group (71.2% male) and n=111 in the control group (68.5% male) 6.5% DO	The intervention comprised a pedometer, a step calendar for self-monitoring, and telephone support which included goal setting and behavioural reinforcement. Goal setting varied from people nominating specific step count targets or a time-based target. Interactions with participants were carried out by mail and telephone.	Sent two PA information brochures by mail after they had completed the baseline questionnaire. The control group participants did not receive any reinforcement telephone calls	Active Australia Questionnaire (Total PA and Walking) T6w = E > C, total PA mins (p=0.027) E > C, total PA sessions (p=0.003) E > C, walking minutes (p=0.013) E > C, walking sessions (p=0.002) T6m = E > C, total PA mins (p=0.015) E > C, total PA sessions (p=0.019) E > C, walking minutes (p=0.002) E > C, walking minutes (p=0.0026)

Hanssen et al., 2007 Norway	288; n= 156 in the intervention group (84.6% male) and n= 132 in the control group (76.5% male) 26% DO	All patients randomized to the intervention group received, in addition to the current clinical practice a structured intervention encompassing telephone follow-up and an open telephone line. The purpose of these calls was to provide patients with information, education, and support based on individual needs and to provide patients with information.	Received current clinical practice care -> one visit to a physician at the outpatient clinic 6-8 weeks after discharge and subsequent visits to the patient's general practitioner	Single item question – How often on an average do you exercise each week? Scale answers. T3m = No sig. diff between exp. and control groups in weekly exercise habits T6m = E > C, PA (p=0.004)
Lear et al., 2014 Canada	78; n=38 in the intervention group (90% male) and n=40 in the control group (80% male) 9% DO	Virtual cardiac rehabilitation programme (vCRP). Participants were also provided with a heart rate and a home blood pressure monitor for the intervention. A webpage displayed the tasks that needed to be completed for each week. The one-on-one chat sessions were used to discuss progress, any change in symptoms, provide exercise prescription, dietary recommendations, and risk factor management. These sessions lasted ≈1 hour; however, participants could also access the vCRP health staff via email.	Received usual care	Minnesota Leisure Time Physical Activity Questionnaire T16m = No sig. diff between exp. group and control group in leisure time PA (p=0.191)
Lee et al., 2013 Korea	60; of the 55 participants who completed the follow-up 85% male in the intervention group and 76% male in the UC group. 8.3% DO	Intervention group received standard medical therapy and a CR programme consisted of educational rehabilitation and exercise training. Participants wore wireless monitoring equipment (HeartCall) to check their heart rate through electrocardiography. A phone call was made to participants once a week for counselling and to minimize risk factors and establish exercise intensity in stages	Usual care	No physical activity measurement*
Lindsay et al., 2009 UK	108 (66% male): n=58 intervention group and n=54 in the control group	Internet health portal accessed via a computer and broadband. Access to project website and could interact in one of five closed groups, with facilitation from the researchers for the first 6 months. The website contained a glossary and information resources about CHD, diet, exercise and smoking. The moderators began discussion topics during the moderated phase. During the moderated phase, there were two forms of communication with moderators: discussion forms and instant messaging. There was an unmoderated phase for 3 months following the 6-month moderated phase.	Received a computer and 1-year broadband subscription like the experimental group however they did not have access to the project portal. Weekly drop-in session and phone support were available.	Exercise frequency measured using a question from the Health Survey for England (days per week moderate exercise: mean + SD) T9m = No sign. diff between exp. and control groups in days per week moderate exercise, (p=.703)

Maddison et al., 2014 New Zealand	171; n=85 intervention group (81% male) and n=86 control group (81% male) 10.5% DO	The HEART (Heart Exercise And Remote Technologies) intervention involved personalised automated package of text messages and a secure website with videos aimed at increasing exercise behaviour over a 24-week period. The intervention group also receive usual CR care.	Directed to receive usual community- based CR	IPAQ (minutes/week): Total PA, leisure time PA (LTPA) and walking T6m = E > C, LTPA (p=0.04) and walking (p=.02) T6m = No Total PA diff between group, (p=0.22)
Piotrowicz et al., 2014 Poland	365 (84% male) 0 DO	4-week home based cardiac telerehabilitation (HTCR) programme based on walking, Nordic walking or cycloergometer training. HTCR was tele-monitored with a device adjusted to register electrocardiogram (ECG) recording and to transmit data via mobile phone to the monitoring center.	No control group	No physical activity measurement*
Reid et al., 2011 Canada	223 (84.3% male); n=115 in the intervention group and n=108 in the control group 30.9% DO	CardioFit is an internet-based expert system and website. Participants received hospital visits from an exercise specialist who delivered a CardioFit personally tailored physical activity plan and instructions on how to access the CardioFit website. Following discharge, participants were asked to log their daily activity on the website and complete a series of five online tutorials. After each tutorial, a new PA plan was developed. Participants received motivational feedback on progress via email.	Usual care intervention: Received PA guidance from their attending cardiologist and an education booklet	Pedometer (steps/day) and Godin leisure time physical activity questionnaire (MVPA min/week) T6m and T12m = E > C, Objective PA, (p=0.023) T6m and T12m = E > C, Subjective PA, (p=0.047)
Scalvini et al., 2009 Italy	47 (87% male) 0 DO	One-month home rehabilitation programme supervised by a nurse-tutor and physiotherapist. Physiotherapy was performed at home with callisthenic exercises and bicycle-ergometer tests. Tele-monitoring and scheduled contacts with a nurse. Tele-assistance if required.	No control group	No physical activity measurement*
Tomita et al., 2009 USA	40 (32.5% male); n= 16 in the intervention group and n=24 in the control group 20% DO	Publicly accessible and secured websites. Informational support included online information on: HF, drugs used to treat HF, effects of alcohol and smoking, depression, prescribed home exercise, nutrition, weight management, and exercise. An exercise instruction program was developed and delivered via streaming video. Participants were asked to access the website daily to record their vital signs and health behaviors. Health care professionals emailed participants feedback for patients' records.	Received usual care	Knowledge questionnaire developed for the study – Exercise frequency question as part of questionnaire T12m = E > C, PA (p=0.001)
Varnfield et al., 2014	120; n=60 in intervention and n=60 in control group	The CAP-CR platform used a smartphone for health (health diary) and exercise monitoring (inbuilt	Traditional centre- based CR	No physical activity measurement*

Australia	36.6% DO	accelerometer). Through the smartphone participants received motivational and educational materials via text messages and there were also preinstalled audio and video files (e.g. understanding CVD, symptoms and managements)		
Widmer et al.,	76; n=25 in CR+PHA group	Intervention groups used an online and smartphone version	Two control groups:	Input PA minutes per day into personal health assistant.
2015	(76% male), n=19 in CR	of a personal health assistant (PHA) during CR and Post-	Usual Mayo clinic	
	group (89% male), n=17 in	CR.	CR group and usual	$T3m = Exp. Group \uparrow PA (p = < 0.0001)$
USA	Post-CR+PHA group (65%		post-CR care group	Control. Group \uparrow PA (p=<0.0001)
	male) and n=15 in post-CR			
	group (53% male)			T3m = No PA diff between groups (p=.24)
				3 ,
	0 DO			

Behavioural change techniques

Only 2 out of the 23 studies explicitly mentioned the BCTs applied (Dale et al. 2015; Devi et al. 2014). From the other studies, two reviewers coded the BCTs from the program description. Table 2.2 outlines the number of BCTs used in each study as well a comprehensive list of the techniques used. The average number of BCTs employed in the included studies was 7.2 (range 1-14). The top three most frequently used BCTs were information about health consequences (78%; 18/23), goal setting (behavior; 74%, 17/23) and joint third, self-monitoring of behavior and social support (practical) (48%; 11/23 each) (Table 2.2). The Text4Heart study conducted by Dale and colleagues (2015) employed the most BCTs out of all the articles, using 14. These were goal setting (behaviour), problem solving, review outcome goals, feedback on behaviour, self-monitoring of behaviour, social support (unspecified), instruction on how to perform the behaviour, information about health consequences, demonstration of the behaviour, social comparison, prompts/cues, graded tasks, credible source and reduce negative emotions. A study by Barnason and colleagues (2009) used the least amount of BCTs of the 23 studies included in the review, employing just one BCT - graded tasks.

The most common BCT group used in the 23 included studies was feedback and monitoring, while the second most common group was goals and planning. This was followed by social support. Four groups did not appear in any of the 23 included studies; identity, scheduled consequences, self-belief and covert learning.

Table 2.2: Behaviour change techniques used in the included studies

]	Beh a	viou	ır C	han	ge T	'echi	niqu	e Co	odes																					
Study	1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	2.1	2.2	2.3	2.4	2.5	2.6	2.7	3.1	3.2	3.3	4.1	5.1	6.1	6.2	7.1	8.7	9.1	10.3	10.4	11.1	11.2	12.1	12.5
Ades et al. (2000)	✓			✓						✓				✓			✓			✓					✓						
Ammenworth et al. (2015)	✓		✓						✓	✓	✓	✓	✓	✓	✓	✓	✓			✓											
Antypas et al. (2014)	✓			✓						✓						✓			✓	✓			✓								
Artinian et al. (2003)	✓			✓				✓			✓	✓		✓	✓					✓			✓		✓						
Barnason et al. (2009)																								✓							
Chow et al. 2015		✓															✓			✓			✓		✓						
Chuang et al. (2006)			✓								✓		✓	✓																✓	✓
Dale et al. (2015)	✓	✓					✓			✓	✓					✓			✓	✓	✓	✓	✓	✓	✓				✓		
Dalleck et al. 2010	✓			✓	✓								✓						✓												

	В	ehav	ioui	r Ch	ang	e Te	chni	ique	Coo	des																					
Study	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	2.1	2.2	2.3	2.4	2.5	2.6	2.7	3.1	3.2	3.3	4.1	5.1	6.1	6.2	7.1	8.7	9.1	10.3	10.4	11.1	11.2	12.1	12.5
Devi et al. 2014	✓				✓					✓	✓									✓				✓			✓		✓		
Frederix et al. (2015)	✓									✓							✓		✓	✓				✓				✓			
Furber et al. (2010)	✓	✓			✓					✓	✓			✓		✓															
Hanssen et al. (2007)	✓																	✓	✓	✓					✓						
Lear et al. (2014)	✓			✓									✓	✓			✓		✓	✓											
Lee et al. (2013)	✓											✓		✓						✓				✓							
Lindsay et al. (2009)																✓	✓			✓											
Maddison et al. (2014)	✓	✓		✓							✓						✓			✓					✓						

	В	eha	viou	ır (Cha	nge	e Te	chni	iqu	e C	ode	S																			
Study	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	2.1	2.2	2.3	2.4	2.5	2.6	2.7	3.1	3.2	3.3	4.1	5.1	6.1	6.2	7.1	8.7	9.1	10.3	10.4	11.1	11.2	12.1	12.5
Piotrowicz et al. (2014)	✓											✓	✓	✓					✓	✓											
Reid et al. (201	✓									✓	✓					✓	✓		✓												
Scalvini et al. (2009)	✓			✓					✓				✓			✓			✓	✓					✓						
Tomita et al. (2009)											✓	✓			✓	✓	✓	✓	✓	✓					✓				✓		
Varnfield et al. (2014)	✓									✓	✓	✓		✓	✓	✓	✓			✓									✓		
Widmer et al. (2015)			✓							✓	✓	✓			✓	✓	✓			✓			✓	✓		✓					

Note: The behaviour change technique codes listed in table 2.2 are the BCTs identified in the 23 studies included in the review. These BCTs are part of the Michie's taxonomy of 93 consensually agreed, distinct BCTs. The following are each of the code names; 1.1 Goal setting (behaviour), 1.2 Problem solving, 1.3 Goal setting (outcome), 1.4 Action planning, 1.5 Review behaviour goal(s), 1.6 Discrepancy between current behaviour and goal, 1.7 Review outcome goals, 1.8 Behavioural contract, 2.1 Monitoring of behaviour by others without feedback, 2.2 feedback on performance, 2.3 Self-monitoring of behaviour, 2.4 Self-monitoring of outcome(s) of behaviour without feedback, 2.6 Biofeedback, 2.7 Feedback on outcome(s) of behaviour, 3.1 Social support (unspecified), 3.2 Social support (practical), 3.3 Social support (emotional), 4.1 Instruction on how to perform the behaviour, 5.1 information about health consequences, 6.1Deomstration of the behaviour, 6.2 Social comparison, 7.1 Prompts/cues, 8.7 Graded tasks, 9.1 Credible source, 10.3 Non-specific reward, 10.4 Social reward, 11.1pharmacological support, 11.2 Reduce negative emotions, 12.1Restructuring the physical environment, 12.5 Adding objects to the environment.

Table 2.3 outlines the frequency of use of the BCTs across the 23 studies, the BCT taxonomy group and an example of how a BCT was incorporated into a study. Only two BCTs were used in over 70% of the studies, these were 5.1 information about health consequences (78%) and 1.1 goal setting (behaviour) (74%). Additionally, 4 BCTs were used in over 40% of the studies; these included 2.2 feedback on behaviour (43%), 2.3 self-monitoring of behaviour (48%), 3.2 social support (practical) (48%) and 4.1 instruction on how to perform the behaviour (43%). Several BCTs, including 10.3 non-specific reward, 12.1 restructuring the physical environment, 12.5 adding objects to the environment, 11.1 pharmacological support, 6.1 demonstration of the behaviour, 6.2 social comparison, 1.7 review outcome goals, 10.4 social reward and 1.8 behavioural contract were only used in one study (Table 2.3).

Table 2.3: Frequency of BCTs used in the included studies

BCT label	BCT group	Example of how the BCT was used	Frequency of use (%)	Studies where found
5.1 Information about health consequences	Natural consequences	"The website contained a glossary and information resources about CHD, diet, exercise and smoking" ¹⁶	18 (78%)	1-4, 6, 8, 10-11, 13-18, 20- 23
1.1 Goal setting (behaviour)	Goals and planning	"Together with a MyCor physician, individuals goal for blood pressure, footsteps and weight were defined" ²	17 (74%)	1-4, 8-15, 17-20, 22
2.3 Self-monitoring of behaviour	Feedback and monitoring	"Following hospital discharge, participants were asked to log their daily activity on the CardioFit website" 19	11 (48%)	2, 4, 7-8, 10, 12, 17, 19, 21-23
3.2 Social support (practical)	Social support	"All participants received detailed programme information and 1h of face-to-face training on technology use" ²²	11 (48%)	1-2, 6, 11, 14, 16- 17, 19, 21-23
4.1 Instruction on how to perform the behaviour	Shaping knowledge	" Tutorials were organised to engage self-control processes including exercise planning, goal-setting, monitoring and self-regulation, and relapse prevention"	10 (43%)	3, 8-9, 11, 13-14, 18-21
2.2 Feedback on behaviour	Feedback and monitoring	" patients were provided an individual, automatic feedback report that was sent to their smartphone once weekly"	10 (43%)	1-3, 8, 10-12, 19, 22-23
2.6 Biofeedback	Feedback and monitoring	"In general, these patients were monitored electrocardiographically for their first 4 to 6 sessions with exercise intensity guided by a progressive heart rate prescription of 65% to 85% of their maximal measured heart rate from the baseline stress test"	9 (39%)	1, 2, 4, 7, 12, 14- 15, 18, 22
3.1 Social support (unspecified)	Social support	"Social reinforcement network that encourages the adoption and maintenance of a healthier lifestyle for improved wellness" ²³	9 (39%)	3, 8, 12, 16, 19-23

9.1 Credible source	Comparison of outcomes	"Role model video vignettes" ¹⁷	8 (35%)	1, 4, 6, 8, 13, 17, 20-21
2.4 Self-monitoring of outcomes of behaviour	Feedback and monitoring	"Each participant was equipped with a smartphone preinstalled with health diary and activity monitoring applications; blood pressure monitor and weight scale"	7 (30%)	2, 4, 15, 18, 21-23
1.4 Action planning	Goals and planning	"The home programme consisted of regular exercise prescription" 17	7 (30%)	1, 3-4, 9, 14, 17, 20
8.7 Graded tasks	Repetition and substitution	"Exercise intensity was 40% weeks 2 to 4, 50% weeks 5 to 6, 60% weeks 7 to 8, 70% weeks 9 to 10, and 80% weeks 11 to 12" 15	6 (26%)	5, 8, 10-11, 15, 23
2.7 Feedback on outcome(s) of behaviour	Feedback and monitoring	"If patients confirmed these values, messages to consult their physician appeared, as these changes in weight, blood pressure, or lab values could represent a potential danger to their health" 23	5 (22%)	2, 4, 21-23
2.5 Monitoring of outcomes of behaviour without feedback	Feedback and monitoring	"Participants were asked to wear their heart rate monitors when exercising and upload their exercise data at least twice per week to the vCRP" 14	5 (22%)	3, 5, 7-8, 24
1.2 Problem solving	Goals and planning	"Participants were asked to develop strategies to overcome barriers to increasing their physical activity"	4 (17%)	2, 6, 13, 23
11.2 Reduce negative emotions	Regulation	"Emotional support was provided on an as needed basis via email" ²¹	4 (17%)	12-13, 16-17
7.1 Prompts/cues	Associations	" Have you gone for your walk today jane?" ⁶ (message)	3 (13%)	6, 8, 10
1.5 Review behaviour goals	Goals and planning	"Baseline and post-programme appointments between the registered dietician and patients at the telemedicine- supported site were conducted by telemedicine"	3 (13%)	3, 16, 23

1.3 Goal setting (outcome)	Goals and planning	"The PHA provides user-friendly and interactive access to targets, plans" 23	3 (13%)	4-5, 7
2.1 Monitoring of behaviour by others without feedback	Feedback and monitoring	"In addition, video-recorders (cassette or DVD) for physiotherapy and 1-lead ECG devices were provided. An electronic health record was prepared for each patients and the patients general practitioner informed" ²⁰	2 (9%)	7, 19
3.3 Social support (emotional)	Social support	"Providing alternative coping strategies when the patient appeared to use inappropriate strategies" 13	2 (9%)	17, 20
10.3 Non-specific reward	Reward and threat	"The PHA provides user-friendly and interactive access to awards that encourages the adoption and maintenance of a healthier lifestyle for improved wellness" 23	1 (4%)	4
12.1 Restructuring the physical environment	Antecedents	"The virtual terrain in our study consisted of a 5-km-long straight (or curved) stretch of road, grass and trees with a mountain background"	1 (4%)	5
12.5 Adding objects to the environment	Antecedents	"The images were projected from behind the viewer through 3 projectors connected with computers"	1 (4%)	5
11.1 Pharmacological support	Regulation	"The smoking cessation tele-coaching program included nicotine replacement therapy" 11	1 (4%)	10
6.1 Demonstration of the behaviour	Comparison of behaviour	"Video role model messages" ⁸	1 (4%)	13
6.2 Social comparison	Comparison of behaviour	"Video role model messages" **	1 (4%)	13
1.7 Review outcome goals	Goals and planning	"You're a few weeks into the program. Well done! Time to add a new goal - maybe you are ready to think about a long-term goal this time" (message)	1 (4%)	13

10.4 Social reward	Reward and threat	Paper listed the behaviour change techniques used in the intervention. Social reward was one of the BCTs used.	1 (4%)	16
1.8 Behavioural contract	Goals and planning	"Provided patients with written information that included the name, frequency and action of their medications" ⁴	1 (4%)	22

Behaviour Change Techniques Linked to Improved Physical Activity Outcomes

Eight of the 15 interventions that had PA as an outcome measure reported statistically significant improvements in physical activity between the experimental and control groups. Goal setting (behaviour) and information about health consequences were the most frequently used BCTs across the eight studies (N=6 each). This was followed by feedback on behaviour and instruction on how to perform the behaviour, which were incorporated in 5 studies each. The following BCTs were also included in the interventions which had an improved PA outcome at the final endpoint; self-monitoring of behaviour, social support (practical), social support (unspecified), credible source, problem solving, review behaviour goals, social support (emotional), prompts/cues, graded tasks, reduce negative emotions, action planning, self-monitoring of outcomes of behaviour, biofeedback, feedback on outcome(s) of behaviour, social reward and pharmacological support (See table 2.4).

Table 2.4: Frequency of behaviour change techniques (BCTs) used in studies with improved PA outcome

inproved 171 odecome	Total number of studies n=8
BCT label	studies II=0
	N (%)
1.1 Goal setting (behaviour)	6 (75)
5.1 Information about health consequences	6 (75)
2.2 Feedback on behaviour	5 (62.5)
4.1 Instruction on how to perform the behaviour	5 (62.5)
2.3 Self-monitoring of behaviour	4 (50)
3.2 Social support (practical)	4 (50)
3.1 Social support (unspecified)	3 (37.5)
9.1 Credible source	3 (37.5)
1.2 Problem solving	2 (25)
1.5 Review behaviour goals	2 (25)
3.3 Social support (emotional)	2 (25)
7.1 Prompts/cues	2 (25)
8.7 Graded tasks	2 (25)
11.2 Reduce negative emotions	2 (25)

1.4 Action planning	1 (12.5)
2.4 Self-monitoring of outcomes of behaviour	1 (12.5)
2.6 Biofeedback	1 (12.5)
2.7 Feedback on outcome(s) of behaviour	1 (12.5)
10.4 Social reward	1 (12.5)
11.1 Pharmacological support	1 (12.5)
1.3 Goal setting (outcome)	0 (0)
1.7 Review outcome goals	0 (0)
1.8 Behavioural contract	0 (0)
2.1 Monitoring of behaviour by others without feedback	0 (0)
2.5 Monitoring of outcomes of behaviour without feedback	0 (0)
6.1 Demonstration of the behaviour	0 (0)
6.2 Social comparison	0 (0)
10.3 Non-specific reward	0 (0)
12.1 Restructuring the physical environment	0 (0)
12.5 Adding objects to the environment	0 (0)

It is worth noting that those interventions that did not did demonstrate a significant increase in PA (N=5) were at par with the level achieved in standard CR, as no significant differences between the control and experimental groups were found. This is an important finding as it highlights the fact that the eHealth interventions were at par with or were significantly better at improving PA levels of cardiac patients when compared to standard cardiac services. This emphasizes the potential of eHealth interventions in a CR setting.

To further examine the efficacy of the individual BCTs the interventions were grouped into four groups depending on whether physical activity was measured objectively or subjectively and whether there was a difference between experimental and control groups. Once the interventions were grouped we sought to examine if there were any common BCTs used across the studies (Table 2.5). This task allowed us to examine if there were any similarities between the interventions in terms of the BCTs they employed.

Objective and self-report studies with no difference between experimental and control groups were the only groups with similarities in the BCTs they employed. Social support (practical) and information and health consequences were employed in all self-report studies where there was no PA difference between the experimental and control groups. Goal setting (behaviour) and feedback on behaviour were employed in all PA objectively measured intervention where no significant difference was found between groups at the final endpoint. However, there were no similarities in the BCTs used across all the effective interventions, regardless of whether PA was measured objectively or subjectively. Furthermore, the average number of BCTs used across significant interventions did not differ, as studies that increased PA versus those that did not increase PA employed an average of seven BCTs.

Table 2.5: Link between Interventions and Behaviour Change Techniques

a) Self-report studies with no difference between experimental and control groups

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Study																															
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Widmer et																															
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al. (2015)																															

^{*}Highlighted cells indicate that the BCTs were used in all the interventions

b) Objective studies with no difference between experimental and control groups

												Beh	avio	ur C	hang	ge T	ech	niqu	ie C	odes											
Study	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	2.1	2.2	2.3	2.4	2.5	2.6	2.7	3.1	3.2	3.3	4.1	5.1	6.1	6.2	7.1	8.7	9.1	10.3	10.4	11.1	11.2	12.1	12.5
Barnason et al. (2009)																								√							
Tomita et al. (2009)											✓	✓			✓	✓	✓	✓	✓	✓					✓				✓		

c) Self-report studies with difference between experimental and control groups

												Beh	avio	ur C	hang	ge T	ech	niqu	e Co	des											
Study	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	2.1	2.2	2.3	2.4	2.5	2.6	2.7	3.1	3.2	3.3	4.1	5.1	6.1	6.2	7.1	8.7	9.1	10.3	10.4	11.1	11.2	12.1	12.5
Chow et al. 2015		✓															√			✓			✓		√						
Frederix et al. (2015)	✓									✓							✓		✓	✓				✓				✓			
Hanssen et al. (2007)	✓																	✓	✓	✓					✓						
Reid et al. (2011)	✓									✓	✓					✓	✓		✓												

d) Objective studies with a difference between exp. and control groups

d) Objective state	1105	** 1011	u u	11101	CIICC		W CC1	т сир	. unc	. 00	1101		1	viour	Chan	ge T	'echr	niaue	Code	es											
																- 5															
Study	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	2.1	2.2	2.3	2.4	2.5	2.6	2.7	3.1	3.2	3.3	4.1	5.1	6.1	6.2	7.1	8.7	9.1	10.3	10.4	11.1	11.2	12.1	12.5
Ammenworth et al. (2015)	✓		✓						✓	✓	✓	✓	✓	✓	✓	✓	✓			✓											
Antypas et al. (2014)	√			✓						✓						✓			✓	✓			✓								
Devi et al. 2014	✓				✓					✓	✓									✓				✓			✓		✓		
Furber et al. (2010)	✓	√			✓					✓	✓			✓		✓															
Reid et al. (2011)	✓									✓	✓					✓	✓		√												

^{*}Highlighted cells indicate that the BCTs were used in all the interventions

Discussion

This systematic review consisted of 23 studies reviewing the use of BCTs in PA eHealth interventions for adults with cardiovascular disease. To our knowledge, this is the first review that aimed to identify the use of Michie and colleagues behaviour change taxonomy in physical activity eHealth intervention studies among this population. The findings of the review indicate that an average of 7.2 BCTs were employed in the 23 studies. Information about health consequences was the most frequently used technique, with 78% of studies incorporating this technique into their intervention. This was followed closely by goal setting (behaviour), which was used in 74% of the studies, with self-monitoring of behaviour and social support (practical) employed in 48% of the studies.

Although Michie's behaviour change technique taxonomy is made up of 93 different techniques, the maximum amount of techniques used in a single intervention was 14 (Dale et al., 2015). These were goal setting (behaviour), problem solving, review outcome goals, feedback on behaviour, self-monitoring of behaviour, social support (unspecified), instruction on how to perform the behaviour, information about health consequences, demonstration of the behaviour, social comparison, prompts/cues, graded tasks, credible source and reduce negative emotions. The minimum number of techniques used in a study was one - graded tasks (Barnason et al., 2009). A failing of the studies included in this review was the poor description of the intervention components. Only two papers in the review specifically mentioned the BCTs incorporated in their interventions (Dale et al., 2015; Devi, Powell and Singh, 2014). However, even though the paper by Devi and colleagues (2014) listed the BCTs used, it failed to link the BCTs used to the intervention functions or components. In the study by Dale (2015) the researchers provided only examples of text messages linked to BCTs. Neither study gave a full account of the BCTs used in their studies and how these were linked to the intervention components. This finding is in line with previous research, where reviews of nearly 1,000 behaviour change outcome studies found that interventions were fully and accurately were described in only 5% to 30% of experimental studies (Dane and Schneider, 1998; Gresham et al., 1993; Moncher and Prinz, 1991; Odom et al., 2003). Overall this lack of robust and detailed information on the intervention functions provide a significant barrier to better understanding the effects and mechanisms of behaviour change interventions, to inform the development of more effective interventions in the future (Frederix et al., 2015).

Another key issue relating to the poor description of behaviour change interventions is the inconsistent use of terminology. This variation in terminology used makes the coding of the techniques used even more difficult when reviewing behaviour change interventions. For example, social support (unspecified) was coded for in 39% of the studies included in the review by the reviewers. Terminology varied across the studies where social support was coded, for example, one study used a social reinforcement network (Antypas and Wangberg, 2014), another incorporated mentors into their intervention (Varnfield et al., 2014), while another study involved tutorials in their intervention (Reid et al., 2012). The reviewers coded these examples as social support (unspecified) however, this BCT was not specifically mentioned in any of the studies. Therefore, there is a need to have consistent terminology and sufficient information on intervention components to allow for the replication of interventions that have been found to be effective. The lack of such information appears to be particularly problematic in behavioural interventions rather than for pharmacological ones (Michie et al., 2009). In a workshop 26 multi-disciplinary researchers were presented with behavioural or pharmacological intervention protocols and were asked if the protocol provided sufficient information so that the study could be replicated in a practice setting. The researchers were less confident that they could replicate the behavioural interventions compared to the pharmacological interventions (t = 6.45, p < 0.0001) and concluded they would need more information to replication the behavioural interventions (U = 35.5, p=0.022) (Michie et al., 2005).

This review provides new and important information regarding the use of BCTs in eHealth PA for adults with CVD, highlighting the frequent use of the following BCTs; information about health consequences, goal setting (behaviour), self-monitoring of behaviour and social support (practical). However, it is clear that more robust and comprehensive interventions are needed, which systematically and coherently detail the behaviour change techniques used in the interventions. Identifying the active ingredients of the interventions will enable researchers to examine the effectiveness of these key intervention components, ensuring that the most effective BCTs are used regarding eHealth physical activity interventions for adults with cardiovascular disease.

Strengths and Limitations

A major strength of this review was the authors attempt to identify all relevant studies by using a comprehensive search strategy and multiple databases. The authors' also hand

searched review paper references to identify any additional studies which may have been relevant to the review. All articles identified following the database search were then uploaded to the online systematic review software package "Covidence" (Veritas Health Innovation). This allowed for a systematic and comprehensive approach to screening the articles and coding the reasons for exclusion. This software also enabled the screening for risk of bias in a simple and efficient way. From this, a visual representation of the publication bias was produced using RevMan.

A limitation of this review was the wide variability among the studies included, with study designs ranging from RCTs, to feasibility studies and pilot trials. However, it was necessary to include all studies and not just RCTs to identify as many physical activity eHealth interventions as possible. There was also a lack of consistency in the measurement of physical activity across the studies, from subjective to objective assessments. The follow-up duration also varied significantly from 3 weeks to 16 months. This meant it was impossible to pool the results in a meta-analysis.

Many studies measured the physical fitness of their participants, as opposed to their physical activity levels. Although all the interventions had a physical activity/exercise component to their eHealth intervention, some studies did not directly measure the physical activity level of participants. We can therefore only infer from the studies that by increasing physical activity behaviour that the physical fitness outcome improved. This inference of a causal relationship between physical activity and physical fitness is a limitation to these studies. Another limitation is the variety of methods used to measure physical activity, meaning that comparison between studies is challenging and therefore determining the impact of specific BCTs is impossible.

Implications for research and practice

This systematic review highlights the need for more robust and comprehensive eHealth physical activity interventions for adults with CVD. Although the most frequently used BCTs were identified, it is worth noting that the majority of studies did not specifically detail the active ingredients of their interventions. Further work is also needed to determine what is the most appropriate measurement of physical activity among this population so that interventions use the best subjective and/or objective measurements ensuring comparisons can be easily drawn across studies. The review also highlights the importance of identifying the BCTs used within a study and their link to the intervention

components in order to understand the ingredients that bring about the desired behaviour change. It is only by identifying these mechanisms of change that we can understand why an intervention was found to be effective or not.

CHAPTER 3

Development of the MedFit Application: A behaviour change theoretically informed mobile application for patient self-management of cardiovascular disease

Chapter 3 Study 2

The overall aim of this study was to develop a behaviour change, theoretically informed exercise rehabilitation mobile application for adults with cardiovascular disease, by following the early stages of the formative research; development and feasibility/piloting.

Purpose of the chapter

The purpose of this study was to develop to mobile application following the early stages of the formative research process. The content and format of the MedFit app were developed based on theory, usability testing, and content design. Following the systematic review the first/alpha version of the app was created. The app was then tested in focus group with adults with cardiovascular disease to provide feedback on the app. This feedback was translated into technical improvements through close collaboration with the technical team, who adapted the app based on the focus group feedback.

Candidates' contribution to the publication

The lead author (OD) undertook the following activities:

- Developed the questionnaire and analysed the results.
- Used the questionnaire results to develop the focus group script.
- Recruited and conducted focus groups with participants from HeartSmart in MedEx.
- Transcribed the focus group scripts verbatim.
- Coded all the text and identified themes.
- Wrote the paper and made changes based on feedback from the other authors.

Contribution of other authors to the publication

All authors read, reviewed and approved the final paper.

- DW and CW reviewed and provided feedback on the questionnaire and focus group script.
- Validation of the coding was undertaken by OD and DW where they independently coded the same piece of transcription and compared notes.
- CW, DW and BF revised and provided feedback on the drafts on the manuscript.
 KW and NOC also provided feedback on the manuscript.

Abstract

Background

The MedFit application is designed to facilitate people with cardiovascular disease (CVD) to participate in an exercise-based rehabilitation programme remotely. This paper details development of the formative research process outlined by the Medical Research Council. The content and format of the MedFit app were developed based on (1) a systematic review of the use of behaviour change techniques in physical activity eHealth interventions (study 1), (2) engaging the target population in app usability focus group testing and (3) technical team expertise and translation of feedback.

Methods

This study was conducted following the creation of the first prototype of the app. The first prototype was developed based on the results from the systematic review. In the next stage of the development process, the feasibility and acceptability of the prototype application was tested in focus groups. The focus group script was developed using a questionnaire (N=119 MedEx participants; 64.7% male; mean age 65 ± 8.86 years) based on usability theory (UTAUT2). The questionnaire identified constructs which impacted participants acceptance and use of apps. These constructs were used to develop the focus group script. Focus group participants were recruited from the HeartSmart programme in MedEx. MedEx is an exercise rehabilitation programme for people with chronic illness run in Dublin City University (DCU). Twenty-six people took part in the five focus groups (65% male; mean age 64 ± 8.2 years) to provide feedback on the prototype app. Focus groups were transcribed verbatim and in-depth content analysis was performed.

Results

The results of the questionnaire revealed that performance expectancy, social influence, hedonic motivation, behavioural intention, effort expectancy and facilitating conditions all rated highly among a majority of respondents. These construct were used to develop the focus group script. Usability feedback included; retrieve password function, play exercise video continuously and remove leaderboard function. Following in-depth content analysis of the acceptability section, four main themes were identified; support, app as a mentor/guide, translation of activity from gym to home and technology knowledge gap. Support was further split into three subthemes, learning/familiarisation process, family/friends and technical support. The familiarisation process was extremely important to participants as well as the availability of technical support. This tied into the

theme of technology knowledge gap. Overall participants believed they would receive support/encouragement to use the app from family/friends. The app was viewed as a mentor/guide providing instruction and on the exercise. Additionally, the app allowed for the 'translation activity from gym to home' because it can be used anytime and anywhere. This feedback was translated into feasible technical improvements through close collaboration with the technical team, who adapted and made modifications to the app based on this co-design process.

Conclusion

The formative research process of the app development was undertaken to develop the MedFit app. This work will provide guidance for future research aiming to develop mobile applications by incorporating a best practice framework for mHealth intervention development and a user-centered design approach.

Introduction

Cardiovascular disease is the leading cause of mortality worldwide, accounting for 17.3 million deaths per year, which is expected to rise to more than 23.6 million by 2030 (American Heart Association, 2015). With the prevalence of CVD on the rise, secondary prevention methods to battle this condition have never been so important. Cardiac rehabilitation (CR) is a secondary prevention programme. It is defined by the World Health Organisation (WHO) as the 'sum of activity and interventions required to ensure the best possible physical, mental, and social conditions so that patients with chronic or post-acute cardiovascular disease may, by their own efforts, preserve or resume their proper place in society and lead an active life' (World Health Organisation, 1993). Cardiac rehabilitation involves exercise training, education on heart-healthy living and counselling to reduce stress and help return to an active lifestyle. As physical activity has been shown to improve quality of life and reduces mortality in patients with CVD, physical activity counselling and exercise training are the core components of the programme. A Cochrane systematic review of exercise-based CR found that cardiovascular mortality was reduced and there was a reduction in hospital admissions and improvements in health-related quality of life (Anderson et al., 2016). Cardiac rehabilitation has also been associated with improvements in psychological wellbeing and quality of life (Dalal, Doherty and Taylor, 2015).

Although the benefits of CR have been well documented, adherence to these programmes is generally suboptimal. Across a number of surveyed countries only 14-43% of cardiac patients participate in rehabilitation programmes (Balady et al., 2007; Graham et al., 2007; Stone et al., 2005). Poor uptake of cardiac rehabilitation has been attributed to several factors such as physicians' reluctance to refer some patients, particularly women and people from ethnic minorities or lower socioeconomic classes and a lack of resources and funding (Ades, 2001). Furthermore, less than 50% of those who participate in CR maintain an exercise regime for as long as 6 months after completion of the programme (Daly et al., 2002; Moore et al., 2003). Results from a Cochrane systematic review revealed that common barriers to adherence to CR programmes include accessibility and parking at local hospitals, a dislike of group environments and work or domestic commitment (Dalal et al., 2010). This suggests that current cardiac rehab programmes do not suit all patients and that alternative modes of rehabilitation should be available.

mHealth (mobile health) technologies may hold the key to this new mode of CR delivery. mHealth is a component of eHealth defined as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants and other wireless devices" (World Health Organisation, 2011, p.6). According to Kailias and colleagues (2010) there are more than 7000 documented smartphone health apps available to the public (Kailas, Chong and Watanabe, 2010). mHealth technologies use techniques and advanced concepts from a multitude of disciplines such as computer science, electrical and biomedical engineering, health sciences and medicine (Baig, GholamHosseini and Connolly, 2015). Technology-enabled health behaviour change interventions are designed to engage people in health behaviours that prevent or manage disease (Free et al., 2013). Literature in the area of internet and mobile-based health interventions has found that such tools can be useful in supporting the self-management of chronic disease (Fanning, Mullen and McAuley, 2012; Omboni et al., 2013). The Institute of Medicine's has called to increase the design and testing of health technologies (Corrigan, 2005), while Michie and colleagues called for the identification of intervention active components so that the effects and mechanisms of behaviour change interventions can be better understood (Michie et al., 2013).

MedFit Theory and Development

MedFit is an mHealth application and is designed to allow people with CVD to participate in an exercise-based rehabilitation programme remotely through an Android App. MedFit offers the potential to make exercise-based rehabilitation programmes more effective by making them more accessible, more personalised and more interactive, by providing real-time support and feedback for participants.

The development of the MedFit app has been underpinned by social cognitive theory and the behaviour change wheel. These models of health behaviour change have been used to design how the best practice guidance and content will be delivered to the end user.

Social Cognitive Theory

Social cognitive theory (SCT) is multi-component theory, whereby individual self-efficacy works in conjunction with knowledge, goals, outcome expectations, perceived environmental impediments and facilitators in the establishment of behaviour (Luszczynska and Schwarzer, 2005). The core determinants of SCT include knowledge of health risks and benefits of different health practices, perceived self-efficacy that one

can exercise control over one's health habits and the outcome expectations about the expected barriers and benefits for different health habits. Other key determinants include health goals and the concrete plans and strategies for realizing them, and the perceived facilitators and social and structural impediments to the changes they seek (Luszczynska and Schwarzer, 2005). These core factors of social cognitive theory work together to initiate and subsequently maintain a target behaviour.

The COM-B and Behaviour Change Wheel (BCW)

The COM-B model and behaviour change wheel were developed by Michie, Atkins and West (2014) as a systematic method of understanding behaviour and linking this understanding to behaviour change techniques. The COM-B model is a behaviour system whereby an individual's capability, opportunity and motivation interact to generate behavior and in turn that behaviour influences these components (Michie, Van Stralen and West, 2011). This model provides a basis from which interventions aimed at behaviour change, such as the MedFit app can be designed. The model ensures that an individual's capability, opportunity and motivation are targeted in order to initiate behaviour change.

The BCW is an approach to developing behaviour change interventions, beginning with identifying a target behaviour needed to change. The intervention is then designed to consist of intervention functions and behaviour change techniques, as well as the delivery mode, which takes into account policy categories. The BCW consists of three layers. The hub of the wheel is formed by the COM-B model, which identifies the sources of behaviour which may be prime targets for the intervention. The next layer comprises of nine intervention functions to choose from depending on the particular COM-B analysis one arrives at. The outer layer is made up of seven types of policy that can be used to deliver the intervention functions (Michie, Atkins and West, 2014).

Michie and colleagues (2013) also developed a behaviour change technique taxonomy that links to the behaviour change wheel, identifying 93 hierarchically clustered techniques that are the active components of behaviour change interventions. The core components of these techniques are 1) shaping knowledge, 2) comparison of outcomes, 3) comparison of behaviour, 4) self-belief, 5) natural consequences, 6) social support, 7) antecedents, 8) goal setting and planning, 9) feedback and monitoring, 10) associations, and 11) repetition and substitution. The use of behaviour change techniques forms a

crucial part of the current evidence based development and delivery of mHealth interventions. It provides researchers with a systematic way of developing and characterizing interventions that enables their outcomes to be linked to mechanisms of action and it can also help to diagnose why an intervention may or may not have achieved its desired outcome (Michie et al., 2013).

The mHealth development and evaluation framework (Chapter 1, figure 1.1) has been used to guide the development and evaluation process applied to the MedFit app. This framework follows an iterative process for developing technology-based interventions, it facilitates and encourages end-user engagement and has been used in previous research of this nature with CVD patients (Dale et al., 2014; Whittaker et al. 2012). The purpose of this paper is to detail the development work through the early stages of the formative research process. This process is important to undertake as it provides a best practice framework for mobile application design and development, allowing the app to be developed in an iterative process with users central to the design. This iterative design process with end-users ultimately allows for the custom design and creation of a truly patient-centric home-based exercise-rehabilitation CVD platform.

Methods

The mHealth development and evaluation framework (Figure 1.1) has been used to develop the app. The framework begins with the conceptualization phase. This phase in the MedFit applications development involved conducting a systematic literature review. The systematic review aimed to identify what BCTs are used in physical activity eHealth interventions for people with cardiovascular disease. From this review, the app content was designed and developed in line with the most frequently used groups of BCTs in the effective interventions. Another phase of the app's development involved recruiting an advisory panel to review the proposed course of action and to make recommendations. Regular brainstorming sessions on how to best translate the theory and evidence into practical methods and techniques were also held.

MedFit App Alpha Version Description

Following the conceptualization phase, the first/alpha version of the app was developed with expertise in app design from the technical team (Figure 3.1). The app was created to

work in conjunction with a FitBit watch and was comprised of three central sections; 'exercise', 'progress' and 'my healthy lifestyle'. Within the exercise section of the app, preset exercise programmes were incorporated into the app. These programmes consisted of a warm-up, main phase and cool down, all of which can be performed in the comfort of the user's own home. Local muscular endurance (LME) exercises as well as stretches were also incorporated into the programmes. The exercise section contained a 'test yourself' function whereby users could do a 6-minute walk test to test their progress. The 'progress' section of the app contained user feedback displayed in charts and graphs so that the users could track their progress over time e.g. track step count. The 'my healthy lifestyle' of the app provided tips and recommendation on lifestyle factors, such as healthy eating, alcohol consumption, physical activity, stress management, medication adherence, smoking cessation and sexual functioning.

The alpha version of the app was then tested in focus groups to ascertain the usability and acceptability of the app among potential end-users.



Figure 3.1: Screenshots of the alpha version of the MedFit app as shown to participants in focus groups

Design of Current Study

The aim of the current study was to explore the usability and acceptability of the MedFit app in line with the mHealth development and evaluation framework. This study has received ethical approval from the DCU ethics committee (DCUREC/2015/038). Following initial development of the MedFit app, further work on individual acceptance and use of information technology was conducted. An explanatory sequential design was used, whereby the quantitative questionnaire results informed the qualitative focus group script (Doyle, Brady and Byrne, 2016). Specifically, a questionnaire was used to identify the core constructs which impact the acceptance and use of apps by participants. Following this, focus groups were held to further explore these constructs in relation to the MedFit app and to collect usability feedback. This use of mixed methods research (i.e., questionnaire and focus groups) has numerous benefits. This approach gives a voice to participants and ensures that the findings are grounded in the participants' views and experience (Wisdom and Creswell, 2013). While the quantitative results from the questionnaire allowed the research team to identify the constructs which are deemed important to participants acceptance and use of technology, the qualitative focus group work allowed participants to expand their views on the constructs. This ensured that very specific and tailored app content can be created based on the users' needs and wants.

Material Development

Focus Group Script Development

To develop a theoretically informed focus group script the 'Unified Theory of Acceptance and Use of Technology 2' model (UTAUT2) was used (Venkatesh, Davis and Morris, 2007). This model outlines the critical factors and contingencies related to the prediction of behavioural intention to use a technology and technology use. The core constructs related to this model include:

- ➤ Performance expectancy: The degree to which an individual believes that using the system will help him or her to attain gains in job performance.
- ➤ Effort expectancy: The degree of ease associated with using a given technology system or application.
- Social influence: The degree to which an individual perceives that people who are

- important to them should use the new system
- ➤ Facilitating conditions: The degree to which an individual believes that an organisational and technical infrastructure exists to support use of the system (Venkatesh et al., 2003).

Further development of the predictors of behavioural intention led to an extended UTAUT2 incorporating three new constructs: hedonic motivation, price value and habit.

- ➤ Hedonic motivation is defined as the fun or pleasure derived from using a technology. It has been previously shown to play a role in determining technology acceptance and use (Brown and Venkatesh, 2005).
- Price value: The degree to which an individual perceives the technology as good value for money has a significant impact on whether an individual uses a given technology.
- ➤ Habit is viewed as prior behaviour (Kim, Malhotra and Narasimhan, 2005) and is measured as the extent to which an individual believes the behaviour to be automatic (Limayem, Hirt and Cheung, 2007).

Compared to the original UTAUT model, the extensions proposed in UTAUT 2 produced an improvement in the variance explained in behavioural intention (56% to 74%) and technology use (40% to 52%) (Venkatesh, Thong and Xu, 2012). The role of the questionnaire within this study was specifically to develop a theoretically informed focus group script, which would pose questions relating to the core constructs identified as impacting on the acceptance and use of apps by participants.

A questionnaire [adapted from a questionnaire developed by Venkatesh and colleagues (2012)] entitled the 'Acceptability of mobile phone applications among adults with chronic illness'. The questionnaire comprised of two sections (see appendix B.3). Section 1 asked respondents about tablet computers and smartphones, asking if participants have either and whether they use mobile phone apps. Section 2 sought to obtain opinions regarding the importance of mobile applications using questions based on the UTAUT 2 model relating to participant opinions on factors such as 'facilitating conditions', 'effort expectancy', 'social influence', 'performance expectancy' and finally 'hedonic motivation'. Respondents were asked to indicate the extent to which they agreed or disagreed with statements using a seven point Likert scale response framework [(1) = strongly disagree; (2) =disagree; (3) = somewhat disagree; (4) = neutral; (5) = somewhat

agree; (6) agree; (7) = strongly agree].

Focus Group Script Development Participants

An adapted version of the UTAUT2 questionnaire was completed by MedEx Wellness participants. MedEx Wellness is a community-based exercise rehabilitation programme for chronic illness located at Dublin City University (DCU). It offers supervised exercise classes to individuals with a range of chronic conditions, including cardiovascular disease, pulmonary disease, diabetes, and cancer.

A total number of 119 MedEx participants completed the UTAUT 2 questionnaire. 64.7% of the respondents were male, with the average age of the group (n=116) 65 ± 8.86 years (range 38-84 years). The duration of attendance in MedEx ranged from ≤ 1 month (12.7%), 2-5 months (22.9%), 6-12 months (15.3%), 1-3 years (27.1%), ≥ 3 years (22%).

Questionnaire Analysis

Analysis was conducted using SPSS 23 (IBM, 2013). Correlations were carried out between behavioural intention and UTAUT2 constructs. In order to decipher what constructs were ranked most important to the participants, the research team set a criteria for inclusion whereby factors were rated positively if participants scored \geq 15 on the three item constructs and \geq 20 on the four item constructs on the positive end of the likert scale; somewhat agree (5) / agree (6) / strongly agree (7).

Focus groups

Focus group participants

Participants were recruited from the HeartSmart programme in MedEx Wellness, which caters individuals with cardiovascular disease. In total 26 HeartSmart participants took part in the focus groups (65% male; mean age 64±8.2 years).

Focus Group Procedure

There were five focus groups. Each focus group lasted approximately 1.5-2 hours in duration with a maximum of six people per group. The researcher aimed to balance the groups in terms of gender. The focus group was led by a moderator, who guided the interview, while an assistant moderator took notes on the ensuing discussion. The focus group had two main strands. The first focused on the usability of the MedFit app where

the researcher presented the different functions of the app and the participants could follow along using a Samsung Galaxy S5 Neo on which the app was downloaded (See appendix B.4). Participants were asked to give their feedback and opinions on the prototype app components. The second strand of the focus group concentrated on the acceptability of the app with questions relating to the main constructs identified in the questionnaire which impacted participant's acceptance and use of apps.

Focus Group Data Analysis

The focus groups were transcribed verbatim. The data was analysed using content analysis (Neuendorf, 2016). An initial list was generated of ideas about the data and what was interesting about it. An initial set of codes were generated for each focus group based on the data. This coding was done manually by going through the content of the entire data set and linking the information to particular codes. The researcher was left with a list of codes identified from the dataset. Validation of the coding was undertaken whereby two members of the research team independently coded the same piece of transcription and then compared notes. The codes were sorted into broader themes, so that all the codes across each of the 5 focus groups, belonging to a particular theme were grouped together. This stage was performed in excel whereby the researcher created a sheet for each focus group. From here the potential themes were given separate columns and the corresponding codes were placed underneath the theme, along with participant quotes. In phase 4 the themes were revised and refined. All the coded data extracts were also reviewed to ensure they are appropriately coded to a given theme. The themes were then reviewed to ensure they accurately reflected the dataset and codes. The final phase involved defining and further refinement of the themes and sub-themes (Braun and Clarke, 2006).

Results

Focus Group Script Development Results

A total number of 119 MedEx participants completed the UTAUT 2 questionnaire. 74.1% of participants had a tablet computer and 75.2% owned a smartphone. A high percentage also revealed that they have used mobile applications on their smartphones (72.3%).

The results revealed that performance expectancy, social influence, hedonic motivation, behavioural intention, effort expectancy and facilitating conditions all rated highly among

a majority of respondents. More than 50% of respondents scored a total of 15 or more on performance expectancy, social influence, hedonic motivation, behavioural intention (3 item constructs; table 3.1). Greater than 50% of respondents scored a total 20 or more on the two 4 item constructs, effort expectancy and facilitating conditions (Table 3.2). A total of 73.5% of respondents from MedEx believed that they had the necessary conditions to facilitate the use of apps in their lives.

Table 3.1: % respondents scoring ≥15 on the three item constructs

3 Item Constructs			
Construct	Score ≥15	Range (min-max)	
Performance expectancy	58.6%	18 (3-21)	
Social Influence	54.7%	18 (3-21)	
Hedonic Motivation	56.4%	18 (3-21)	
Price Value	40.2%	16 (5-21)	
Habit	18.9%	16 (4-20)	
Behavioural Intention	56.6%	18 (3-21)	

Table 3.2: % respondents scoring ≥20 on the four item constructs

4 Item Constructs			
Construct	Score ≥20	Range (min-max)	
Effort expectancy	59.8%	24 (4-28)	
Facilitating Conditions	73.5%	23 (5-28)	

Only 18.9% of respondents scored \geq 15 on the Habit construct indicating that end-users did not perceive habit as playing a significant role in the acceptance and use of mobile apps amongst this cohort. 40.2% of respondents scored a total of 15 or more on the price value construct, indicating that perhaps price value does not play as significant a role as some of the other constructs.

The results of the questionnaire were used to inform and develop the usability focus group script (see appendix B.4). Questions were developed based on the constructs that rated highly among participants (i.e. performance expectancy, social influence, hedonic motivation, behavioural intention, effort expectancy and facilitating conditions), while habit and price value were not incorporated into questions and these were not deemed as important to the participants based on the criteria set.

Focus Groups Results

Usability of the MedFit App

The first section of the focus groups involved participants providing feedback on the app components. Table 3.3 provides a list of the feedback from the focus groups based on each app component and the translation of this feedback in app content. Updated screenshots of the app based on participant feedback can be found in appendix C.1.

Table 3.3: Participants usability feedback on the alpha version of the app

	Feedback on the App components	Translation of focus group feedback
Login	 Need a password clue If the wrong password is inputted, have a link to retrieve password See letters come up on screen as you type your password 	 to app content Characters appear onscreen as person types in password Simple retrieve password function
Home screen	 Confusion regarding the 'burger' menu – many wouldn't know to click on it Change burger menu to the word 'menu' 'My healthy lifestyle' should not have the word my in it as this tab contains generic information Change 'My healthy lifestyle' icon 	 Changed the 'burger menu' to the word 'menu' Removed the word 'My' from the title 'My healthy lifestyle' Changed the healthy lifestyle icon
Exercise tab/exercise programme	 Play video continuously under the timer Have a pause function in the exercise programme Play music with a beat. Option to mute the music Ability to log activity not picked up by FitBit. 	 Video plays continuously under timer Ability to log activity not tracked by FitBit in new section called 'Log my activity'
Progress	 Need to see results/progress from the 'Test yourself' section Daily progress statistics should be the default screen Have range for the group attendance and duration but don't attach any personal identification - this would give people an idea of where they are in relation to the min and max Remove the group leaderboard 	 Daily progress results are set as the default screen Removed identification from the group part of the app Removed the leaderboard
Healthy Lifestyle	 Happy with the information provided Use visuals to depict information Different levels of information – basic info, recent research, reference section to publications, links to additional sites for more information. 	 More pictures used throughout the content Different levels of information provided to cater for all
My MedFit group	 Ability for users to add events to the event list or send them to the researchers via a comment box on the app Opt in/opt out function regarding the group chat function Potential to have a chat function/ comment box where users could message for tech support Small group chats (5-6 people) Remove the leaderboard 	MedFit group to be created in the version after the Beta version of the app. Feedback from the focus groups for this section of the app will then be incorporated into the app

Menu	 Video tutorial FAQ section Comment box Contact details for technical support Leave your details and a message and someone can get back to you (i.e. leave a comment) 	Video tutorial, contact details and FAQ all added to the menu function
Feedback notifications	 No more than 4 messages per week Suggestion to turn off notifications 	Maximum of 4 message sent per week

Acceptability of the MedFit App

Following in-depth content analysis, four main themes emerged. These were; support, the app as a mentor/guide, translation of activity from gym to home and technology knowledge gap.

Support

Support was split into three sub-themes based on the focus group feedback; learning/familiarisation process, support from family/friends and technical support.

Learning/familiarisation process

Participants placed huge emphasis on an initial familiarisation and set up process. As many participants weren't familiar with using apps on a regular basis participants said that it would be very important to have a familiarisation period where they would be taught how to use the app the either in a one-to-one training session "one-to-one would be great" (FG2) or in "Small groups" (FG2). It was reiterated across the groups that learning how to use the app would occur over time, using a "trial and error" method (FG1). However, at the initial introduction to the app participants would need to be shown how to use the app in a simple, step-by-step manner "And it's the lady bird approach. Right from the start, don't assume any knowledge" (FG3). Participants felt that they would also need written instructions/ guide to help them learn how to use the app. This would also be helpful if they forgot how to use the app at home as they would something to look at for guidance. "Well a guide is always good... and that's the only reason so if you don't use something often you can come back to it without having to go miles to find out" (FG5). These instructions/guide could also come in video format as this format will be familiar to them from cardiac rehabilitation "or even a video. I mean that's what they use in cardiac rehab instead of doctors talking" (FG5).

Family/friends support

Overall, most participants believed they would get support from family and/or friends to use the app. This support would come in the form of encouragement to use the app. Most people have families who are interested in their loved ones' health and would therefore provide encouragement to use the app if they believed it would benefit their health. "Most families, most people are lucky enough to have people interested in them. When you get sick, the first thing they do, if there's anything they can do to help you get better. If it's just to encourage you to exercise, they'd be all too happy to do it" (FG1).

There were differing views in the groups as to whether friends/family could provide technical support to use the app. Some believed their family, particularly their children would have the knowledge and skills to help them use the app "There's a lot that we don't understand we ask the kids about, you know, and they show us" (FG1). One participant thought their family wouldn't take an interest in the app, that they have their own apps and interests to worry about, however, their friends might because they are of a similar age and interest level.

Technical support

In terms of technical support most participants agreed that they would need a contact for technical support in case they had an issue than neither themselves nor their family/friends could solve. The participants provided numerous suggestions as to what format the technical support should come in. Some suggested the use of a comment box where you could leave a message on the app regarding your query either straight to the technical team or to other users of the app. "Probably the comment box is the best" (FG4).

Participants agreed that the best form of technical support would be the availability of contact number that participants would ring during set hours. "Well if you have your contact details there that if you are stuck, eh you can ring in" (FG2).

App as a mentor/guide

The theme 'app as a mentor/guide' was present in all five focus groups. Participants believed the app would provide instruction and knowledge on how to exercise correctly.

"I think it'll be useful in my life because... I'll go to the gym and I have this to do my warm-up... shows me what weights to do, you know, ... Because when you go sometimes you just haven't a clue and you're kind of doing stuff and you could hurt yourself, you could overdo it, it's perfect, you know exactly what you're doing and... keeps you healthy" (FG1).

Feedback and monitoring on their progress while using the app was viewed as important to the participants. "It's important to get feedback" (FG5). Participants liked the idea of "keeping up on things as they're happening" (FG4) and expressed an interest in monitoring their progress on the app. "It would be kinda interesting watching what you're putting in and seeing the progress or the opposite" (FG4).

Participants also believed that the app would heighten awareness to exercise and provide motivation to exercise in the form of prompts/cues (e.g. push notifications). "Because, I mean first of all it would motivate you, and it would also give you correct information and guide you where you're going" (FG5). " I think we sit down a lot more than we realise, we drive a lot more that we realise, you know, I personally speaking and I think it would be sort of a wakeup call to me anyway. To actually see it in black and white " (FG4).

The code 'app as a tool' came under the theme 'app as a mentor/guide' as participants thought the app has a job/function to do and did not necessarily have to be fun. "It's good to have something there to support you but for me, personally it doesn't need to be fun. It just needs to do what it says on the box, as they say" (FG1). "No it's a tool.... It's there to do a job" (FG4).

The app would also motivate their family members to exercise having seen their family member use the app. Participants could see the benefit the app would have to the health of their family not just themselves. "I think it would benefit my own family. I have two teenage daughters that do like to sit down a lot when they're at home, so I think if they saw me using the app at home they'd probably, probably slag the hell out of me but they'd probably eventually come out and join in and do something" (FG2).

"Yeah. I would say the only thing to do would be to try and include the family, in the programme" (FG4).

Translation of activity from gym to home

Overall the majority of participants agreed that the app would create an option for people to exercise who are housebound or for those who for one reason or another can't make it to a structured exercise class.

"Well I bring Mary from Rush but I have my own business so sometimes I can't come and if I can't come well Mary would have her app on her phone and I'd have it myself where you'd get a few minutes in the day where you can exercise, as I said rather than just saying ah I can't go today I'll sit down and have a rest" (FG2).

"I'm living in Skerries, it's not a great job having to get in but if Bridget is gone off in the car well I have to take a bus so eh, well now that makes me think about it again, use that or a bus? I think that would come out first and I would find myself using it" (FG3).

Participants viewed the app as part of building a healthy lifestyle "Like I'd see this as part of building up a healthy lifestyle" (FG5). The app would work in conjunction with structured programmes, allowing for flexibility and planning, providing no excuse not to exercise. "It means I can do it at home and I don't feel like I'm slacking off" (FG1). Participants thought the app could be used in tandem with the gym/structured exercise classes. For the days that they don't go to the gym, the app could be used instead in order to build up their activity to meet the guidelines.

"Yeah sure you can make the sessions here what happens if you don't make the sessions here but you but you know you've a period in the day where you can exercise... now you know what you can do and even if you go into a gym you're going to go in and do something without damaging yourself" (FG1).

"I would use it in tandem with the gym. I'd be more inclined to try and keep up with the gym but where I couldn't do the gym, I would do it so. I might find that I got to the gym twice and use this once" (FG1).

Technology knowledge gap

Participants acknowledged that there is a generation gap when it comes to technology. Participants came from a generation where there were no smartphones and were therefore new to concept of smartphones and their use of them. In comparison it was acknowledged that today's youth are familiar with technology and have little difficulty using smartphones. "And I mean that stuff is all so easy to the younger generation, even the seven year old granddaughter can use the bloody phone better than I can" (FG1).

"Well I think you see you have a generational problem, here like...You're talking to people who weren't brought up with smartphones and apps" (FG3).

One woman also pointed out that they are not part of the "throw away generation" (FG3). She described this as where the older generations are more cautions than young people in trying out new technology in fear that they make break it, whereas younger generations have no fear associated with technology. Older generations came from a time where there was limited use of technology in their working lives and therefore are not up to speed with current smartphone advances.

It was also said that there may be a 'fear of the unknown' associated with the use of apps on smartphones, as smartphones weren't available as they grew up. "I'm totally illiterate with this stuff, I just... no matter how many times I'm shown I can't do it" (FG1).
"No no, well I'm just saying that like, I'm just anxious about it" (FG2).

However it was also acknowledged by a participant that smartphones are part of life and have multiple purposes. "The smartphone is part of my life. I look at football and everything on it" (FG5).

Summary

In summary participants responded well to the MedFit app and were positive towards its potential use by people to continue their cardiac rehabilitation following hospital based rehabilitation. However, four main themes were identified from the focus groups which would potentially impact participants' acceptance and ultimate use of the app. Figure 3.2 provides a summary of the key themes and subthemes found following the content analysis of the focus group transcriptions. In the following section a description of how the app content was modified based on these themes and the participants' usability feedback, as well as how the themes relate to the underpinning theory is detailed.

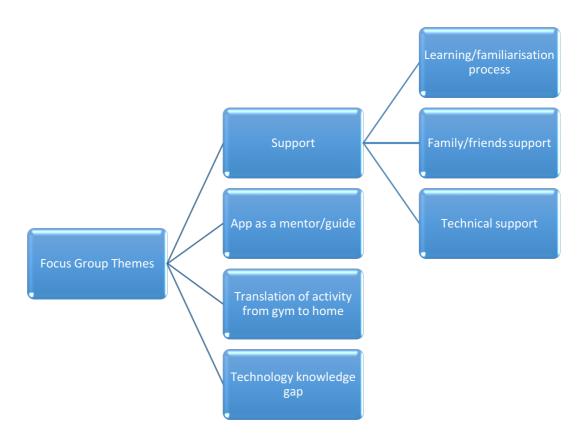


Figure 3.2: Summary of focus group themes and subthemes

Synthesis of app development procedure

Table 4 depicts the phases of intervention development and how the underpinning theory is related to the behaviour change techniques used, the focus group feedback, ultimately leading to the app content. The first column represents the constructs from the social cognitive theory, which have been mapped to the behaviour change wheel and behaviour change techniques. Feedback from the focus groups is then linked to the underpinning theory, culminating in the app components and content. Appendix C.1 provides visual representations (i.e. screenshots) of the beta version of the app based on this development work.

Table 3.4: Development process of the MedFit App

Social Cognitive Theory	Behaviour change wheel- intervention Functions)	BCTs (code number and title of BCT)	Co-design feedback (focus group themes)	App content developed as a result of feedback and theory
Knowledge	Education, Training, enablement	4. Shaping Knowledge4.1 Instruction on how to perform a behaviour9. Comparison of outcomes9.1 Credible source	Support: Technical Support, Technology knowledge gap App as a mentor/guide	 Healthy lifestyle – Tips and recommendation on healthy lifestyle components Exercise – Video and teaching points are used to guide participants through each exercise. These have been developed with guidance from literature and instructors working in community based CR Progress – Feedback on activity level
Perceived self- efficacy	Education, Training, Modelling	 6. Comparison of behaviour 6.1 Demonstration of the behaviour 6.2 Social comparison 15. Self-belief 15.1 Verbal persuasion about capability 15.3 Focus on past success 	App as a mentor/guide Support: Technical, family and friends, and the learning and familiarisation process	 Exercise - Demos of exercises, tests and feedback on tests and activity performed Social Interaction – Provide support to participants by encouraging social interaction through the 'MedFit group'.
Outcome expectations	Education, training, persuasion, modelling.	5. Natural Consequences5.1 Information about health consequences5.6 Information about emotional consequences	App as a mentor/guide	 Healthy lifestyle – Tips and recommendation on healthy lifestyle components Notifications – to help initiate and maintain the behaviour change

Perceived facilitators/impediments	Education, Training, Enablement, Environmental restructuring, persuasion	3. Social support 3.1 Social support (un-specified) 3.2 Social support (practical) 3.3 Social support (emotional) 12. Antecedents 12.1 Restructuring the physical environment 12.2 Restructuring the social environment	Translation of activity from gym to home Support: Technical, family and friends, and the learning and familiarisation process	 Social interaction - Provide support to participants by encouraging social interaction through the 'MedFit group'. Contact us – Technical support number and information Exercise – Ability to exercise anywhere and at any time
Goals	Education, persuasion, training.	1. Goal setting and Planning, 1.1 Goal setting (behaviour), 1.2 Problem solving 1.3 Goal setting (outcome), 1.4 Action planning, 1.5 Review behaviour goal (s), 1.7 Review outcome goal (s), 2. Feedback and Monitoring, 2.2 Feedback on behaviour 2.3 Self-monitoring of behaviour, 2.4 Self-monitoring of outcome (s) of behaviour, 2.6 Biofeedback, 2.7 Feedback on outcome (s) of behaviour, 7. Associations, 7.1 Prompts/ cues, 8.3 Habit formation, 8.7 Graded task	App as a mentor/guide	 Progress – Individual, personalised goal given to get participant. Results and feedback provided on activity. Notifications – to provide encouragement and support to users to reach their PA goal Exercise – Classes adapted based on person's ability and needs

Discussion

This study describes the development of a mobile application for exercise rehabilitation, for adults with CVD in line with the mHealth Development and Evaluation Framework. The early stages of the formative research process, development and feasibility/piloting in line with the Medical Research Council's framework, were used to design this complex mHealth intervention. To develop the alpha version of the app the most appropriate theories we chosen to underpin the app, a systematic review was conducted to identify what BCTs to include in the app and the technical design team gave their feedback on the content and design of the app. This study predominantly focused on the gaining feedback on the alpha version of the app through focus group testing. This co-design process was crucial to the user validation of the app.

The creation of eHealth technologies is often led by a technology-driven approach as opposed to the user-centred approach. To date a large proportion of mHealth technologies are designed on the basis of health system constructs which may potentially not be as effective as development which involves end users in the design process (Verhoeven et al., 2010). Furthermore, technical design teams often base their ideas on assumptions that are not validated by end user needs and wants (McCurdie et al., 2012). Studies have shown that the full potential of eHealth and mHealth technologies can only be exploited when developed by a multi-disciplinary team who apply a human-centred co-design approach with the specific context of the technology's use in mind (Pagliari, 2007; Heeks, 2006). This user-centred design approach plays a key role achieving user engagement which in turn can improve the likelihood that the intervention will be effective (McCurdie et al., 2012).

With this in mind, the research team aimed to develop a theoretically informed app with potential cardiac patients at the heart of the design. This design process was undertaken by a multi-disciplinary team of health psychologists, physical activity specialists and technology specialists. The team used a novel approach to application development whereby health behaviour change theory and the unified theory of acceptance and use of technology (UTAUT2) was used to guide app development, with the patient voice at the heart of the mobile applications development.

Some interesting themes emerged from the focus groups. Support appeared to be a critical theme to participant's acceptance and use of the app. Support was split into three subthemes, learning/familiarisation process, family/friends support and technical support. Participants explained how came from a generation that did not use technology and would therefore need technical support and training on how to use the app. This tied into the theme of 'technology knowledge gap' as the participants were not overly familiar with smartphones and particularly mobile apps. However, participants expressed a willingness to learn how to use the app as long as they had the availability of technical support. A user guide as well as a contact number for support were suggested methods of technical support by the groups. This need for technical support for older adults using new technologies is in line with findings from previous research (Aula, 2005; Steele et al., 2009). Older adults may need face-to face training as well as a written manual when learning how to use new technology (Demiris et al., 2004). It may also be helpful to provide use cases and scenario analysis when teaching older adults to use technology (Lee and Coughlin, 2014).

Overall participants believed they would receive support/encouragement to use the app from family/friends. The A lack of support may increase feelings of complication and anxiety and decrease the likelihood of using the technology (Igbaria, Parasuraman, & Baroudi, 1996). Social support is therefore an important factor to consider when developing mobile applications. The fact that participants believed that they would receive support to use the MedFit app is a positive finding.

The app was viewed as a mentor/guide providing instruction and on the exercise. The availability of personalised feedback and monitoring was viewed as a major positive to participants. This finding is in line with a review of smartphone applications for promoting physical activity conducted by Coughlin and colleagues (2016) which found that participants preferred apps that coach and motivate them and provide tailored feedback toward personalised goals. Additionally, the MedFit app allowed for the 'translation activity from gym to home' because it can be used anytime and anywhere. Participants viewed this flexibility as another benefit to the app.

This feedback was translated into feasible technical improvements through close collaboration with the technical team, who adapted and made modifications to the app based on this co-design process. The feedback was then linked to the underlying

behaviour change theory and techniques to create theory driven, user centered content.

In relation to the mechanisms of behaviour change, it is important to use theory to inform intervention design and to specify the BCTs are used (Webb et al., 2010). It has been well documented that behaviour change interventions are poorly described in accurate and sufficient detail for readers to truly understand, evaluate and/or replicate the intervention reported (Glasziou et al., 2008). Many mHealth cardiac rehabilitation studies to not specifically address the behaviour change strategies in their design (Beatty et al., 2013). This was reiterated in our systematic review whereby only two studies specifically mentioned the BCTs included in their interventions. However, neither study gave a full account of the BCTs used in their studies and how these were linked to the intervention components. It is also apparent that interventions based on behaviour change theory are more effective than those lacking a theoretical basis (Glanz and Bishop, 2010; Michie and Johnston, 2012). Armed with this knowledge, we aimed to describe in detail the active ingredients of our intervention, so that the applications development was easy to understand, evaluate and replicate for future research.

The next step is the evaluation of the MedFit app. The beta version of the app will be trialed in a feasibility study. We propose recruiting community-based cardiac rehabilitation participants (N=20) and providing them with a Samsung Galaxy Neo, on which the MedFit app will be downloaded for a two-week period. The participants will be asked to trial all components of the app. Following this, further focus groups will be conducted to explore the MedFit user experience. Again, this feedback will be provided to the technical team who will translate the feedback into technical improvements in the app in collaboration with the clinical team. Following this a full-scale intervention will be carried out to test the effectiveness of the MedFit app.

Summary

This paper details the development of a mobile intervention for cardiovascular disease patients. The development work has been carried out in a systematic approach from theory, to user-testing and technical team design expertise. This paper highlights the importance of transparency when designing mHealth interventions using BCTs and theory, so that interventions are easily understood, evaluated and reproduced. The researchers have also demonstrated a novel way to examine the usability and acceptability of a mobile app within a focus group setting to ensure long-term technology adoption and

use. Overall it is hoped that the MedFit app will encourage the adoption of the mobile application to improve health behaviours, in particular the physical activity levels of people with cardiovascular disease.

Strengths and limitations

A key strength of this study was the development of the app in line with the mHealth development and evaluation process and the MRC's formative research process. These provided a best practice and systematic process to developing an mHealth intervention. Furthermore the inclusion of potential end-users in the development and design process was a huge strength to this study. Incorporating the needs and wants of users ensured that app was designed specifically for adults with cardiovascular disease, increasing the likelihood of adherence to the app.

A potential limitation to this study was the fact that the findings from the focus group are not generalizable to the wider public, as these were the thoughts and responses of a small sub-sample of community based cardiac rehabilitations participants. The findings do however provide potential strategies and guidance to enhance the likelihood that cardiac rehabilitation mHealth interventions will be engaging to end-users. Another limitation of the study was the difficulty we had recruiting women to take part in the focus groups (65% male). However it must be noted that this does reflect the fact that women are significantly less likely to participate in and complete CR (Oosenbrug et al., 2016). This is reflective of the population we had to recruit from the cardiac rehabilitation programme in DCU, hence why we had a larger number of men than women involved in the study.

CHAPTER 4

Conclusion

Conclusion

Cardiac rehabilitation is crucial to the management of cardiovascular disease and is a cost-effective way to improve patients physical and psychological health (Bethell et al., 2009) (Eshah et al., 2009). The aim of cardiac rehabilitation is to stabilise, slow or even reverse the progression of CVD and hence reduce the risk of future cardiac events (Balady et al., 2011). The main components of CR include patient assessment, nutritional counseling, risk factor management (i.e., lipids, hypertension, weight, diabetes mellitus, and smoking), psychosocial and vocational counseling, and physical activity counseling and exercise training (Balady et al., 2011). Although CR has been shown to improve mortality rates, reduce hospital admissions and improve psychological well-being and quality of life, uptake of CR ranges from 20% to 50% worldwide (British Association for Cardiovascular Prevention and Rehabilitation, 2012). Adherence to CR is also suboptimal at less than 50% (Bjarnason-Wehrens et al., 2010). Several barriers to CR have been cited in the literature. These include poor referral rates particularly regarding women, people from ethnic minorities and elderly people. As well as barriers regarding living in rural settings, being from low socioeconomic classes, having multiple morbidities and lack of leave from work to attend CR sessions (Dalal et al., 2015).

Mobile technology has the ability to overcome some of these barriers to cardiac rehabilitation and may be a useful tool for increasing participation (Beatty et al., 2013). One of the most significant opportunities in the health domain that mHealth offers is that it allows patients to actively engage in and self-manage their condition (Handel, 2011). The MedFit app offers the potential to make exercise-based rehabilitation programmes more effective by making them more accessible and more personalised, by providing real-time support and feedback for participants. The mHealth development and evaluation framework was used to guide and aid the development and evaluation of the app (Dale et al., 2014).

Many eHealth interventions are designed on the basis of existing healthcare system constructs and may not be as effective as those that involve end-users in the design and development process (Verhoeven et al., 2010). The World Health Organisation advocates that user evaluation be incorporated into the mHealth project lifecycle to ensure effective outcomes (World Health Organisation, 2011). Within the context of this project the research team sought to engage potential users in the development and design process so

that the intervention would ultimately address the needs, wants and preferences of the users.

To our knowledge, our systematic review was the first systematic review conducted solely researching BCTs in physical activity eHealth interventions for cardiovascular disease patients. A total of 23 interventions were identified which met the inclusion criteria. The average number of BCTs employed in the included studies was 7.2 (Range 1-14). The top three most frequently used BCTs were identified as information about health consequences (78.3%), goal setting (behaviour) (73.9%) and self-monitoring of behaviour (47.8%). While we had sought to identify the effectiveness of the BCTs, we did not find any evidence that the techniques contributed to the overall effectiveness of the interventions. This was due to the wide range of BCTs used in the studies, as there may have been a synergistic effect between the techniques. It would therefore be impossible to determine the individual effect a given BCT may have had on the overall outcome of a trial. A review by Goodwin and colleagues noted similar findings in that they could not determine the effectiveness of the BCTs due to the fact that the BCTs do not work in isolation of each other. It was also impossible to conduct a meta-analysis due to the heterogeneous nature of the physical activity outcome measures.

To date there has been little focus on the use of BCTs in cardiac rehabilitation programmes, particularly regarding e- & mHealth technologies for cardiac rehabilitation. To ensure that cardiac rehabilitation programmes are easily implementable and reproducible it is important that the active ingredients of an intervention are clearly identified and logged. Understanding which BCTs are used allows the exploration of causal pathways, which allows for intervention refinement (Heron et al., 2015). The research team found very few interventions which clearly identified the active ingredients of their intervention. This was a major short coming to the studies included in the review where the majority of trials were poorly specified, preventing high-fidelity replication. Future research should give precise specification and descriptions of the intervention; identifying the behaviour(s) to be changed, the BCTs used and the competences required to deliver them (Dixon et al., 2011). There was also an issue relating to the inconsistent terminology used in the description of behaviour change interventions. A lack of consistency in the terminology used made the coding of techniques difficult to perform. It is therefore imperative that future studies use consistent terminology and provide sufficient information on the intervention content to allow for replication of effective

interventions. To combat the limitations cited above the MedFit app has been developed with behaviour change theory and techniques at the heart of its design. Behaviour change theory (social cognitive theory and the behaviour change wheel) has been used to design how best practice guidance and content will be delivered to the end user. This development process was mapped from the theoretical constructs to specific behaviour change techniques which were implemented within the MedFit app. These theories were used in conjunction with focus group feedback to design the app to meet the needs and wants of end-users.

Although e- and mHealth interventions have been yielding promising results, a quarter of all app downloads are only used once (Localytics, 2011). Consumers often do not use a mobile app which does not engage them from the outset, therefore undermining the intervention's potential effectiveness. In a review by Zhao and colleagues (2016) which aimed to examine the effectiveness of mobile phone apps in achieving health-related behaviour change, the retention of participants to the mobile app interventions was examined. Retention was defined as the proportion of participants who remained in the study on completion. Only 10 out of 17 studies achieved the retention rate of >80% in the intervention group. Personalisation and adaption in real time appeared to be the key elements which impacted participant engagement with the app (Zhao et al., 2016). A study by Varnfield and colleagues (2014) had a 77% completion rate (46/60) in the home care cardiac rehabilitation app intervention group. This was approximately 30% more than the control group. The intervention group consisted of scheduled telephone consultations with experts who provided personalised feedback on progress according to participants' goals. This personalised feedback based on their progress towards a goal was likely to have contributed to the high level of participant retention compared to the control group. Additionally, our systematic review of behaviour change techniques in physical activity eHealth interventions for adults with CVD found that goal setting (behaviour) and self-monitoring of behaviour were two of the most frequently used BCTs in the interventions.

A reoccurring theme in the focus group analysis was the notion of app as a mentor/guide providing instruction on the exercise. The app would also provide motivation to exercise using notifications. This idea of the app as a mentor/guide was viewed as particularly important to the participants. The fact the app can provide instruction on how to exercise and that it would be personalised to the individual made it appealing to the groups. This feedback on activity level was viewed as a fundamental and essential part of the app.

Research suggests that personalised feedback about objectively measured physical activity may increase an individual's awareness of physical activity (DiClemente et al., 2001; Proper et al., 2003). These factors are worth noting for future mobile apps particularly regarding this population, in an exercise context.

Based on these findings from the literature and the fact that focus group participants acknowledged the importance of monitoring and providing feedback on their progress towards a goal, this was incorporated as a component of the MedFit app. Participants will be provided with a personalised physical activity goal and will be able to check their progress towards this goal via a 'progress section' on the app. Participants will also be able to self-monitor their progress by taking part in the '6 minute walk test' and 'sit to stand test', as part of the 'test yourself' section on the app.

Other suggested features of effective dietary and physical activity app interventions found by Zhao and colleagues in their review were self-monitoring, goal setting, feedback and social networking. These features were all found in the MyFitnessPal app which was included in the review and it is worth noting that this app received the highest possible rating from app store reviewers (5/5 stars). Numerous technology based studies have found that the inclusion of a social interaction component had a positive effect in increasing physical activity levels (Lin et al., 2006; Albaina et al., 2009; Cornejo, Favela and Tentori, 2010) or at least reduced participant attrition rates even if it did not increase the average physical activity levels (Richardson et al., 2010). As social interaction has been found to be an effective feature of eHealth interventions in the literature, the MedFit app will incorporate a social interaction component in a later version of the app. Considering the focus group feedback and app design expertise this social interaction component will come in the form of an events page and the ability to create groups in the MedFit app. The app will have an events page where participants can create and invite other participants to take part and where local physical activity events will be signposted for participants. Participants will also be able to interact with each other via groups on the app and will be able to send comments within the groups.

Our focus groups provided additional strategies to encourage the acceptance and use of the MedFit app. Following in-depth content analysis four main themes were identified; support, app as a mentor/guide, translation of activity from gym to home and technology knowledge gap. Support was split into three subthemes, learning/familiarisation process,

family/friends and technical support. Participants placed huge emphasis on an initial familiarisation and set up process. As many participants weren't familiar with using apps on a regular basis participants said that it would be very important to have a familiarisation period where they would be taught how to use the app in a one-to-one training session or in small groups. With most participants not regular app users, they felt they would need technical support in the form of a contact number which they could ring if they had a problem. This is an important finding for future mHealth research aiming to cater to the needs of older adults. It was reiterated throughout the groups that they were not brought up in a smartphone and app generation and it would therefore be imperative to get training and support on how to use the app. This tied in to the theme of technology knowledge gap. However, it was encouraging to note that the participants were all willing to learn how to use the app. This is in line with previous literature which found that because older adults were brought up in an era where technology experience and training was unavailable, technical support and proper teaching/coaching is essential for adoption (Demiris et al., 2004; Poynton, 2005; Wang et al., 2010). It is therefore essential to provide technical assistance throughout the lifestyle of the technology, from the purchase, to installation, learning, operation and maintenance (Lee and Coughlin, 2015). Technical support for older adults including in person training and written manuals must cater for the needs of the population (Aula, 2005; Demiris et al., 2004; Steele et al., 2009). As older adults rely heavily on written manuals these should be written in plain language and in a clear readable way (Tsai, Rogers, and Lee, 2012).

These findings from the focus groups backed up by literature have been implemented into the design of the MedFit app. Participants will be shown how to install the app on their phone and will be given a short presentation on how to use it prior to commencing any future trials. The research team have also created a user manual and a frequently asked questions (FAQ) guide in hard copies that participants will have to refer to if needed. The FAQ guide will also be available to read on the app, as well as a video tutorial on how to navigate through the app. Participants will also be provided with a contact number which they can ring if they require technical support.

Overall the participants also believed they would receive support and encouragement to use the app from their family and friends. This was a significant finding as previous research in the area suggests that older adults social support groups play an important role in the adoption of new technology, acting as "technology champions" (Wang et al., 2010).

Older adults' family and friends can support them to use technology and also increase their awareness of the benefits of its use (Walsh and Callan, 2010).

Additionally, the app allowed for the 'translation activity from gym to home' because it can be used anytime and anywhere. The app would create an option for people to exercise who are housebound or for those who for one reason or another can't make it to a structured exercise class. The participants also believed the app could be used in conjunction with structured exercise classes whereby they could use the app to reach their goal, along with going to gym classes. This was an interesting finding which perhaps indicates that exercise applications should be developed not in isolation or as an alternative to attending the gym but rather as working in conjunction with additional physical activity outlets to create a healthy lifestyle. This blended model approach between mHealth technologies and structured physical activity classes may offer a solution for cardiovascular patients to participate in community based cardiac rehabilitation depending on their preference on mode of delivery.

Future Directions

Upcoming work in this project (beyond the scope of this masters) will involve evaluating the first complete version of the MedFit app in a feasibility trial. This trial will be conducted to pilot the intervention components and to assess acceptability, likely rates of recruitment, retention of participants and to calculate appropriate sample sizes (Craig et al., 2008). Approximately 20 MedEx participants will take part in the study in groups of six, with each group trialing the app for a two-week period. Participants will be provided with a Samsung neo smartphone on which the app will be downloaded. Following the trial participants will be invited to take part in a debrief focus group to provide their opinion and feedback on the app components. Such research may identify any methods or protocols which need modification and how changes might occur (Bowen et al., 2009). This process will then inform the development of the MedFit intervention to evaluate the mobile application's effectiveness. Participants who have just completed in hospital cardiac rehabilitation will be invited to participate in this trial in Autumn 2017. The participants will trial the app for an 8-week period. Pre- and post-testing will involve participants completing a 6-minute walk test, accelerometry, health behaviours questionnaire and process measures. Participants will also be asked to take part in a debrief focus group to get specific feedback on the app and their experience using it.

Recommendations

It is hoped that research will highlight the benefit of and need to follow best practice guidance for mHealth intervention development; emphasising the importance of following a systematic and coherent process to app development and evaluation. To our knowledge, our systematic review was the first attempt to identify the BCTs used in physical activity eHealth interventions for adults with CVD. We showed that it is possible to use a taxonomy to code interventions however the coding of BCTs was dependent on the reported content, which was limited in some cases. Future work must clearly identify the active ingredients of interventions so that effective interventions can be easily understood and replicated. A possible limitation to this work was the wide variability among the studies included in the review, with study designs ranging from randomised controlled trials, to feasibility studies and pilot trials. Due to the wide variability in study designs and outcome measures a meta-analysis could not be conducted. Potentially future work should narrow inclusion criteria so that the data can be pooled together into a meta-analysis.

The importance of conducting user-centred design was highlighted throughout this project. Involving the user in the design and development of the app through focus group testing ensured the app would meet the needs, wants and competencies of the end user. This user-centred design process was a major strength of this study. Due to the importance of this work perhaps it would have been worth incorporating more potential users views and opinions at the conceptualisation phase to truly design an intervention that meets participants' requirements. Future work should incorporate end-users at each stage of the mHealth development and evaluation process.

Overall it is clear that following a systematic development process from conceptualisation to formative research, pre-testing, trial and qualitative follow-up is needed if we are to truly design mHealth interventions which are grounded in theory yet driven by user needs.

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APPENDICES

Appendix A Paper 1 supporting documents

Appendix A.1: Keyword Searches

Title: Systematic review of the use of behaviour change techniques (BCTs) in eHealth interventions for adults with cardiovascular disease.

Databases: EBSCOhost (MEDLINE, PsycINFO, Academic Search Complete, SPORTDiscus with Full Text, CINAHL Complete), Scopus and Web of Science (Core Collection)

Limited to Published date: 2000-2016

Searched: 10.02.16

<u>Ebscohost - MEDLINE, PsycINFO, Academic Search Complete, SPORTDiscus with</u>
Full Text. CINAHL Complete

Search	Search Terms	Results
No.		
S5	S1 AND S2 AND S3 AND S4	649
S4	TI ("physical activity" or "activity level" or "sedentary	1,034,549
	behaviour" or "sedentary behavior" or exercise or walking or	1,00 1,0 19
	running or recreation or "fun and games" or sport or pastime)	
	OR AB ("physical activity" or "activity level" or "sedentary	
	behaviour" or "sedentary behavior" or exercise or walking or	
	running or recreation or "fun and games" or sport or pastime)	0.700.007
S3	TI (intervention or education or information or train or coach	9,732,085
	or skills or program* or counsel or mentor or support or "health promotion" or lifestyle or advocacy or communicate	
	or empower or therapy or intensive or manage or psycho* or	
	treat or rehabilitation or "disease management" or "disease	
	treatment") OR AB (intervention or education or	
	information or train or coach or skills or program* or counsel	
	or mentor or support or "health promotion" or lifestyle or	
	advocacy or communicate or empower or therapy or intensive	
	or manage or psycho* or treat or rehabilitation or "disease	
G2	management" or "disease treatment")	550 (12
S2	TI ("coronary heart disease" or chd or "coronary artery disease" or cvd or cardiovascular) OR AB ("coronary heart	552,613
	disease" or chd or "coronary artery disease" or cvd or	
	cardiovascular)	
S1	TI ("mobile phone" or "cell phone" or "cellular phone" or	1,516,069
	smartphone or "smart phone" or "mobile technology" or	
	telemedicine or mHealth or eHealth or wireless or "personal	
	digital assistant" or computer or technology or digital) OR	
	AB ("mobile phone" or "cell phone" or "cellular phone" or	
	smartphone or "smart phone" or "mobile technology" or	
	telemedicine or mHealth or eHealth or wireless or "personal	
	digital assistant" or computer or technology or digital)	

<u>Scopus</u>

Search No.	Search Terms	Results
S5	S1 AND S2 AND S3 AND S4	85
S4	TITLE-ABS("physical activity" or "activity level" of "sedentary behaviour" or "sedentary behavior" or exercise or walking or running or recreation or "fun and games" or sport or pastime)	28,263
S3	TITLE-ABS (intervention or education or information or train or coach or skills or program* or counsel or mentor or support or "health promotion" or lifestyle or advocacy or communicate or empower or therapy or intensive or manage or psycho* or treat or rehabilitation or "disease management" or "disease treatment")	7,172,380
S2	TITLE-ABS ("coronary heart disease" or chd or "coronary artery disease" or cvd or cardiovascular)	371,781
S1	TITLE-ABS ("mobile phone" or "cell phone" or "cellular phone" or smartphone or "smart phone" or "mobile technology" or telemedicine or mHealth or eHealth or wireless or "personal digital assistant" or computer or technology or digital)	2,481,098

Web of Science (Core Collection)

Search	Search Terms	Results
No.		
S5	S1 AND S2 AND S3 AND S4	784
S4	TS=("physical activity" or "activity level" or "sedentary behaviour" or "sedentary behavior" or exercise or walking or running or recreation or "fun and games" or sport or pastime)	710,150
S3	TS=(intervention or education or information or train or coach or skills or program* or counsel or mentor or support or "health promotion" or lifestyle or advocacy or communicate or empower or therapy or intensive or manage or psycho* or treat or rehabilitation or "disease management" or "disease treatment")	6,878,918
S2	TS=("coronary heart disease" or chd or "coronary artery disease" or cvd or cardiovascular)	422,096
S1	TS=("mobile phone" or "cell phone" or "cellular phone" or smartphone or "smart phone" or "mobile technology" or telemedicine or mHealth or eHealth or wireless or "personal digital assistant" or computer or technology or digital)	1,668,653

Note: TS= Title, Abstract, Author Keywords and Keywords Plus®

Appendix A.2: Table of the outcomes and results of included studies

Study	Outcomes	Results
Ades et al. 2000	 Peak Vo2 and Peak workload (w) -> exercise stress test Quality of Life weight 	 No significant differences between groups in any of the outcome measures. Patients in the home-based monitoring program increased peak aerobic capacity to a similar degree as patients who exercised on site (18% vs. 23%). Quality of life domains improved similarly in both groups.
Ammenwerth et al. 2015	 Patient survey based on the Information System Success Model Quality of life Patient adherence -> log files of health diary data- Data was aggregated to calculate number of daily measurements that were documented per patient per week Health condition -> The % of patients reaching their goals was calculated for phase 1 and phase 2. Goals were uniformly set at: steps>3,000 per day, BP <140/90 mmHg and heart rate <70 beats per minute. Data were aggregated to obtain the number of times the goals were reached per patient per week Medication adherence 	 Patients reported feelings of self-control, motivation for life- style changes, and improved quality of life. Adherence to daily measurements was high with 86% in phase 1 and 77% in the telemonitoring phase 2. Adherence to medication was high with 87% in phase 1 and 80% in phase 2 (range 5,833-7,148 median steps per day). Pre-defined goals for physical activity were reached in up to 86% and 73% of days, respectively. Quality of life improved from 5.5 at study entry to 6.3 at the end (p< 0.01; MacNew questionnaire). Reductions in blood pressure and heart rate or an improvement in reaching defined goals could not be observed.
Antypas et al. 2014	 Maintenance of physical activity, measured through self-report (IPAQ). Self-efficacy Perceived social support Anxiety and depression Stage of change = URICA-E2 scale Perceived tailoring = 4 items from Dijkstra 	 One month after discharge, the tailored intervention group (n=10) had a higher median level of overall physical activity (median 2737.5, IQR 4200.2) than the control group (n=14, median 1650.0, IQR 2443.5) -> No significant difference (Kolmogorov-Smirnov Z=0.823, P=.38, r=.17). At 3 months after discharge, the tailored intervention group (n=7) had a significantly higher median level of overall physical activity (median 5613.0, IQR 2828.0) than the control group (n=12, median 1356.0, IQR 2937.0; Kolmogorov-Smirnov Z=1.397, P=.02, r=.33).

	 Adherence rate = duration of use of the website in days Total page views (i.e. visits to the website) User evaluation = Based on whether participants would recommend the site to a friend and whether they found each of the components useful. Participants were also asked what components they found most and least useful 	 The median adherence was 45.0 (95% CI 0.0-169.8) days for the tailored group and 111.0 (95% CI 45.1-176.9) days for the control group; however, the difference was not significant (P=.39). No statistically significant differences between the 2 groups in stage of change, self-efficacy, social support, perceived tailoring, anxiety, or depression.
Artinian et al. 2003	 Self-care behaviours total quality of life physical quality of life emotional quality of life 6-minute walk distance (in feet) NYHA FC perceived experience of living with the MedeMonitor 	 At baseline and at 3 months, there were no differences between the compliance device group and the usual care group in self-care behaviors, pill counts, 6-minute walk-test distance, or Functional Class. Quality of life improved significantly from baseline to 3-month follow-up (ANOVA, P=.006). This difference was due to an improvement in quality of life for the monitor group (P=.002) but not the usual care only group (P=.113). Patients in the compliance device group had a 94% medication compliance rate, 81% compliance with daily blood pressure monitoring, and 85% compliance with daily weight monitoring as compared to 51% for blood pressure monitoring and 79% for weight monitoring in the usual care group.
Barnason et al. 2009	 Physical activity, physiological and psychosocial functioning health care utilization 	 Physiological and psychosocial functioning: No significant (p<.05) interactions or main effects for group. Physical activity: No significant interaction or time effect for EEE (average kcal/kg/day expended) using the diary; however, there was a significant group effect F(1,177)=8.2, p<.01. There were significant time effects [F(3, 459)= 17.3, p<.01] for the RT3 average daily activity counts, with daily activity counts increasing over time. Similarly, the total group had significantly [F (3, 531) =12.9, p<.01] increased levels of moderate or greater activity, as measured by the diary, over time. Health care utilization: Very similar rates of rehospitalisations, ED visits and clinic visits for cardiac-related problems for the groups

Chow et al. 2015	 Level of plasma LDL-C at 6 months Systolic blood pressure BMI Total cholesterol level Waist circumference Heart rate Total physical activity Smoking status Proportion achieving guideline levels of modifiable risk factors Utility and perceived acceptability of textmessage support programme by intervention participants 	 At 6 months, levels of LDL cholesterol were significantly lower in intervention participants, with simultaneous reductions in systolic blood pressure and BMI, significant increases in physical activity, and a significant reduction in smoking. The majority reported the text messages to be useful (91%), easy to understand (97%), and appropriate in frequency (86%).
Chuang et al. 2006	 maximum load during the work sessions target oxygen consumption target heart rate (beats per minute) number of training sessions required to reach rehabilitation goals. 	 At the end of the 20 sessions, only 4/10 control subjects reached the HR target goal of 85% HRmax. In comparison 9/10 in the VR intervention reached the goal by 9 or fewer training sessions. Using 75% VO2 peak as the training goal, all 10 subjects in the VR intervention reached their target after 2 training sessions. In comparison it wasn't until the 15 training sessions that a cumulative number of 9 control subjects reached this goal.
Dale et al. 2015	 Adherence to healthy guidelines for smoking habit, fruit and veg intake, alcohol intake and physical activity measured as a binary variable using a self-reported composite health behaviour score based on the European Prospective Investigation into Cancer (EPIC)-Norfolk Prospective Population Study at 3 and 6 months. Clinical outcomes - systolic and diastolic blood pressure, lipid profile, weight, body mass index, waist-to-hip and CHD risk probability Medication adherence - Morisky 8-item medication adherence questionnaire Psychological measures -> Self- efficacy for Managing Chronic Disease 6-item scale, the Brief 	 A significant treatment effect in favor of the intervention was observed for the primary outcome at 3 months (AOR 2.55, 95% ci 1.12-5.84; P=.03, but not at 6 months (AOR 1.93, 95% CI 0.83-4.53; P=.13). The intervention group reported significantly greater medication adherence score (mean difference: 0.58, 95% CI 0.19-0.97; P=.004). Most intervention participants reported reading all their text messages (52/61, 85%). The number of visits to the website per person ranged from zero to 100 (median 3) over the 6-month intervention period.

	 Illness Perception Questionnaire and the Hospital Anxiety and Depression Scale Serious adverse event data collected at 6 months Fidelity to the intervention was assessed using an author-derived questionnaire and calculating website and response text message usage statistics 	
Dalleck et al. 2010	 Body mass index Stress score Dietary intake score Energy expenditure Systolic and diastolic blood pressure Total cholesterol HDL LDL Triglycerides 	No significant difference (p>0.05) in the change from baseline to post- programme values between the conventional and the telemedicine groups
Devi et al. 2014	 Daily average step count change at 6-week follow up Energy expenditure Duration of sedentary activity (DSA) Weight Systolic and diastolic blood pressure Body fat percentage Fat and fiber intake Anxiety and depression Self-efficacy Health-related quality of life (QOL) 	 Change in daily steps walked at the 6-week follow-up was +497 (SD 2171) in the intervention group and -861 (SD 2534) in the control group (95% CI 263-2451, P=.02). Significant intervention effects were observed at the 6-week follow-up in EE (+43.94 kcal, 95% CI 43.93-309.98, P=.01), DSA (-7.79 minutes, 95% CI -55.01 to -7.01, P=.01), DMA (+6.31 minutes, 95% CI 6.01-51.20, P=.01), weight (-0.56 kg, 95% CI -1.78 to -0.15, P=.02), self-efficacy (95% CI 0.30-4.79, P=.03), emotional QOL score (95% CI 0.01-0.54, P=.04), and angina frequency (95% CI 8.57-35.05, P=.002). Significant benefits in angina frequency (95% CI 1.89-29.41, P=.02) and social QOL score (95% CI 0.05-0.54, P=.02) were also observed at the 6-month follow-up. Of the 48 intervention group participants, 19 (40%) completed the intervention and 29 (60%) did not progress past stage 3. The mean number of log-ins to the program was 18.68 (SD 13.13, range 1-51), an average of 3 log-ins per week per participant.

Frederix et al. 2015	 Peak aerobic capacity Daily physical activity measured by triaxial accelerometry and self- report questionnaire (IPAQ) Heart-related quality of life Hemoglobin A1c (HbA1c), glycemic control and lipid profile assessed by blood sampling Intervention group gave feedback via a form on the cardiac telerehabilitation system at the end of the study period 	 Mean VO2 peak increased significantly in intervention group patients (n=69) from baseline (mean 22.46, SD 0.78 mL/[min*kg]) to 24 weeks (mean 24.46, SD 1.00 mL/[min*kg], P<.01) versus control group patients (n=70), who did not change significantly (baseline: mean 22.72, SD 0.74 mL/[min*kg]; 24 weeks: mean 22.15, SD 0.77 mL/[min*kg], P=.09). Between-group analysis of aerobic capacity confirmed a significant difference between the intervention group and control group in favor of the intervention group (P<.001). At 24 weeks, self-reported physical activity improved more in the intervention group compared to the control group (P=.01) as did the global HRQL score (P=.01). No significant within-group differences were found for weight, BMI and systolic and diastolic BP in the intervention group and control group. No between group differences either. Fasting glucose levels, HbA1c and LDL cholesterol did not change for the intervention or control group during the study. Total cholesterol increases in both treatment groups but no between group differences were found (P=.97) Qualitative feedback -> 97% found the telerehabilitation motion sensor easy to read and easy to use. 95% were satisfied/very satisfied with the telerehabilitation program. 89% were willing to use the system after the study was completed.
Furber et al. 2010	 Total physical activity per week Psychosocial status (self-management, strategy use and psych distress) 	• After 6 weeks, improvements in total physical activity time ($p = 0.027$), total physical activity sessions ($p = 0.003$), walking time ($p = 0.013$) and walking sessions ($p = 0.002$) in the intervention group were significantly greater than the control group after adjusting for baseline differences, and remained significant at 6 months.
Hanssen et al. 2007 Norway	 Health related quality of life -> SF-36 Lifestyle factors -> exercise and smoking status 	 In both groups, health-related quality of life improved significantly over time on most subscales. A statistically significant difference in favour of the intervention group was found on the 36-item Short Form Health Survey Physical Health Component Summary Scale (P = 0.034) after 6 months. No difference was found between the groups on the Mental Health Component Summary Scale. Significant difference with respect to frequency of physical activity in favour of the intervention group after 6 months (P = 0.004).

Lear et al. 2014 Canada	 Exercise capacity Total cholesterol High-density lipoprotein cholesterol Triglycerides Blood glucose Blood pressure - Smoking status - self-report BMI Waist circumference Leisure time physical activity (LTPA) Diet Hospital admissions and emergency room visits were identified by patient self-report and confirmed through collection of medical records. 	 More participants in the intervention group than the control group had stopped smoking at the 6-month follow-up (P = 0.055). Participants in the vCRP had a greater increase in maximal time on the treadmill by 45.7 (95% confidence interval, 1.04–90.48) seconds compared with the usual care group during the 16 months (P=0.045). There was a non-signicant greater number of unique patients with ≥1 emergency room visit or major event in the usual care group compared with the vCRP (30% ver- sus 18%; P=0.275). There were 22 events in the usual care group compared with 8 in the vCRP group. Total cholesterol (-7.3%; P=0.026), low-density lipoprotein cholesterol (-11.9%; P=0.022), and dietary saturated fat (-1.4% kcal/d; P=0.018) were lower in the vCRP group, whereas dietary protein (1.6% kcal/d; P=0.044) was higher. The lower saturated fat and higher protein intake remained significant after adjusting for confounders, 1.5% kcal/d (P=0.03) and 1.9% kcal/d (P=0.018), respectively. Participants perceived the vCRP to be an accessible, convenient and effective way to deliver healthcare services. A key benefit was seen to be the easy access to vCRP health professionals.
Lee et al. 2013 Korea	Exercise capacityQuality of life	 Change of metabolic equivalent of the tasks, maximal exercise time and QOL were signicantly increased (+2.47 vs +1.43, P = 0.021; +169.68 vs +88.31 sec, P = 0.012; and +4.81 vs +0.89, P = 0.022, respectively) Change of submaximal rate pressure product, and of submaximal rate of perceived exertion were signicantly decreased (-28.24 vs -16.21,P = 0.013; and -1.92 vs -1.62, P = 0.018, respectively) in the CR group compared to the UC group after 12 weeks.
Lindsay et al. 2009 UK	Differences in health behaviours between the experimental and control groups. Health behaviours include = days per week of moderate exercise, cigarettes smoked per day,	• At 6 months follow-up (based on the moderated phase), there was a significant difference between the experimental group and the controls in terms of self-reported diet (eating bad foods less often). This change in behaviour was not sustained during the 3-month unmoderated phase.

Maddison et al. 2014 New Zealand	social support, diet (frequency of bad foods) and number of health care visits Peak oxygen uptake (PVO2) f Physical activity (IPAQ) Self-efficacy and motivation to exercise Health related quality of life Economic evaluation	 During the unmoderated phase of the intervention, the experimental group had significantly more health care visits compared with the controls. There was no significant difference between the two phases for either group in terms of exercise, smoking or social support. No significant difference in PVO2 between the two groups (difference 0.21ml kg 1min 1, 95% CI: 1.1, 0.7; p =0.65) at 24 weeks. Significant treatment effects for selected secondary outcomes, including leisure time physical activity (difference 110.2min/week, 95% CI: 0.8, 221.3; p=0.05) and walking (difference 151.4 min/week, 95% CI: 27.6, 275.2; p=0.02). Significant improvements in self-efficacy to be active (difference 6.2%, 95% CI: 0.2, 12.2; p= 0.04) and the general health domain of the SF36 (difference 2.1, 95% CI: 0.1, 4.1; p=0.03) at 24 weeks. The HEART programme was considered likely to be cost-effective for leisure time activity and walking.
Piotrowicz et al. 2014 Poland	 BMI 6 minute walk test -> distance and RPE post test Primary outcome: Physical capacity -> exercise time (s), maximal workload (MET) and maximal workload (Watt) Heart rate -> rest and max effort (bpm) Systolic and diastolic blood pressure -> rest and max effort (mmHg) Double product -> rest and max effort (mm Hg/min) Adherence to HTCR -> Adherence defined as the % of participants who carried out the prescribed training Acceptance of HTCR -> acceptance questionnaire Safety of HTCR 	 No safety issues with HTCR Acceptance of HTCR -> 98% reported the system user-friendly. 39% missed doing an exercise training session due to the mobile phone network operator unavailable. 1/3 reported poor sound quality from the voice communication in the EHO mini device. Contacting the monitoring centre everyday motivated particiapnts to exercise. Felt safer exercising during the HTCR than unsupervised at home. Most patients physical and mental daily activities increased (80% and 77.1% respectively). Adherence to HTCR -> Only 3 non-adherent patients. Physical capacity -> Significant improvements after HTCR in 6-MWT distance (561.9 + 77.9 m; P=.0001), exercise duration (573.9 + 207.0 s; P=.0001), maximal workload (9.8 + 1.9 METs; P=.0001), HR maximal effort (127.0 + 16.9 bpm; P=.0001 and double product max effort (22947.00 + 4909.54; P=.0064).
Reid et al. 2011 Canada	 Physical activity Heart disease health-related quality of life 	• The CardioFit internet-based physical activity expert system significantly increased objectively measured ($p = 0.023$) and self-reported physical activity ($p = 0.047$) compared to usual care.

		• Emotional (p = 0.038) and physical (p = 0.031) dimensions of heart disease health-related quality of life were also higher with CardioFit compared to usual care.
Scalvini et al. 2009 Italy	 6 minute walk test distance Effort test (Watts, beats/min and mmHg) Patient satisfaction 	 There was a significant increase in the 6-minute walking test distance at the end of the programme compared to the baseline (404 m vs. 307 m, P=0.001). In the effort test, the maximum workload, peak heart rate and systolic arterial pressure were 111 W (SD= 30), 107 beats/ min (SD 1/4 26) and 164 mmHg (SD=28), respectively. The global satisfaction – measured on a scale from 0 to 100 – was 90 (SD= 9). Patients were very satisfied with the nurse-tutor support (98%) and the education in hospital (96% good/very good). The nurse-tutor intervention during emergencies was considered effective by 95% of patients. The equipment was considered easy-to-use by 72% of patients.
Tomita et al. 2009 USA	 Adherence to the program Knowledge of heart failure and related health behaviours Heart-failure specific syptoms (fatigues, dyspnea and emotional function) and general health indicators Quality of life Health care utilisation 	 The treatment group had a high (85%) adherence to the intervention. Only the treatment group showed a significant improvement in the knowledge level (p 0.001), amount of exercise (p = 0.001), and quality of life (p = 0.001), and reduction in HF related symptoms (dyspnea, p = 0.001; fatigue, p = 0.003; functional emotion, p 0.001), blood pressure (systolic, p = 0.002; diastolic, p 0.001), frequency of emergency room visit, and length of hospital stay (both p = 0.001).
Varnfield et al. 2014 Australia	 Uptake of a CR programme Adherence to the CR programme Completeion of the programme Nutrition - DHQ Functional capacity – 6-minute walk test Mental health Clinical indices - Systolic and diastolic blood pressure, heart rate, weight and waist circumference Lipid profile - Total cholesterol, LDL, HDL and triglycerides Quality of Life 	 CAP-CR had significantly higher uptake (80% vs 62%), adherence (94% vs 68%) and completion (80% vs 47%) rates than TCR (p<0.05). Both groups showed significant improvements in 6-minute walk test from baseline to 6 weeks (TCR: 537±86–584±99 m; CAP-CR: 510±77–570±80 m), which was maintained at 6 months. CAP-CR showed slight weight reduction (89 ±20–88±21 kg) and waist circumference (p=0.04) also demonstrated significant improvements in emotional state (K10: median (IQR) 14.6 (13.4–16.0) to 12.6 (11.5–13.8)), and quality of life (EQ5D-Index: median (IQR) 0.84 (0.8–0.9) to 0.92 (0.9–1.0)) at 6 weeks. CAP-CR and TCR participants has significant improvements in dietary intake (fat, fibre, salt), mental health (DASS-depression) and triglycerides.

		Between group differences for changes in 6MWT, low-density lipoprotein, high-density lipoprotein, EQ5D-Index or K10 were not significant at 6 months.
Widmer et al. 2015	 Systolic and diastolic blood pressure, mmHg Weight, kg BMI kg/m2 Total cholesterol, mg/dL LDL cholesterol, mg/dL HDL cholesterol, mg/dL Glucose, mg/dL Weekly exercise, min Exercise capacity Current smoking ED visits and rehospitalisation 	 Patients using the digital health intervention (DHI) during cardiac rehabilitation had significant reductions in weight (-4.0 + 5.2 kg, P=.001) and blood pressure (-10.8 + 13.5 mmHg, P=.0009). The group using the DHI after 3 months of CR had significant reductions in weight (-2.5 + 3.8kg, P=.04) and systolic blood pressure (-12.6+ 12.4 mmHg, P=.001) compared to the control groups. Both DHI groups had significant reductions in rehospitalisations and emergancy department visits (-37.9%, P0.01 and -28%, P=.04, respectively).

JOURNAL OF MEDICAL INTERNET RESEARCH

Duff et al

Original Paper

Systematic Review of the Use of Behaviour Change Techniques in Physical Activity eHealth Interventions for People with Cardiovascular Disease

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Abstract

See manuscript file.

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KEYWORDS

Systematic review; physical activity; behaviour change techniques; eHealth intervention; cardiovascular disease

Acknowledgments

See manuscript file.

Conflicts of Interest

See manuscript file.

Authors' Contributions

See manuscript file.

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Appendix B Paper 2 supporting documents

Appendix B.1 Plain Language Statement

Plain Language Statement

DUBLIN CITY UNIVERSITY

MedFit: Acceptability of Mobile Phone Applications among Adults with Chronic Illness.

Principal Investigator: Orlaith Duff, School of Health and Human Performance and Insight Centre for Data Analytics.

Other Investigators: Dr. Catherine Woods, School of Health and Human Performance and Dr. Deirdre Walsh, School of Health and Human Performance and Insight Centre for Data Analytics.

Details of what involvement in the Research Study will require

Involvement in this study would require me to complete a short questionnaire.

Following this, I may be asked to take part in a focus group with a member of the research team. The focus group will be audio recorded and will last approximately 1 hour. As part of this focus group I will be asked for my opinions and views on the first prototype of a mobile application for cardiovascular rehabilitation (CR), called MedFit.

Potential risks to participants from involvement in the Research Study (if greater than that encountered in everyday life)

There are no risks with this project above those of normal everyday living.

Benefits (direct or indirect) to participants from involvement in the Research Study

This study will explore participant's acceptance and use of mobile phone applications in order to aid the development of a mobile phone application for CR, that allows remote participation (i.e. at home) in CR exercise programs at any time and in any place.

Advice as to arrangements to be made to protect confidentiality of data, including that confidentiality of information provided is subject to legal limitations

Confidentiality is an important issue during data collection. Participant's identity, or other personal information, will not be

revealed or published. Questionnaires are anonymous. All data will have names removed and a code attached to them. All data will be dealt with in a strictly confidential basis. All raw data will only be available to the research team. In accordance with DCU policy all data will be kept on-site in DCU in a locked secure area.

Advice as to whether or not data is to be destroyed after a minimum period

After a 5 year period all data will be destroyed in accordance with DCU policy.

Statement that involvement in the Research Study is voluntary

If at any point during your participation in the study you feel as if you wish to withdraw, this is not a problem. You are under no obligation to stay involved if you do not wish to. In the focus group, please note that once the audio recording starts your input cannot be removed from the recording. Please make sure to contact the investigators if you are unable or unwilling to continue in the project so as we can address any issues within the project.

If participants have concerns about this study and wish to contact an independent person, please contact:

The Secretary, Dublin City University Research Ethics Committee, c/o Research and Innovation Support, Dublin City University, Dublin 9. Tel 01-7008000.

Patient Informed Consent



DUBLIN CITY UNIVERSITY

MedFit: Acceptability of Mobile Phone Applications among Adults with Chronic Illness.

Principal Investigator: Orlaith Duff, School of Health and Human Performance and Insight Centre for Data Analytics.

Other Investigators: Dr. Catherine Woods, School of Health and Human Performance and Dr. Deirdre Walsh, School of Health and Human Performance and Insight Centre for Data Analytics.

The purpose of this study is to better understand participant's acceptance and use of mobile phone applications. Involvement in this study will require me to complete a short questionnaire assessing my acceptance and use of mobile phone applications. I may be asked to take part in a focus group with a member of the research team. The focus group will be audio recorded and will last about 1 hour. As part of this focus group I will be asked for my opinions and views on the first prototype of a mobile application for cardiovascular rehabilitation (CR), called MedFit.

<u>Participant - please complete the following (Circle Yes or No for each question)</u>

I have read the Plain Language Statement (or had it read to me) Yes/No

I understand the information provided Yes/No

I have had an opportunity to ask questions and discuss this study Yes/No

I have received satisfactory answers to all my questions Yes/No

If at any point during your participation in the study you feel as if you wish to withdraw this is not a problem. You are under no obligation to stay involved if you do not wish to. In the focus group, please note that once the audio recording starts your input cannot be removed from the recording. Make sure to contact the investigators if you are unable or unwilling to continue in the project so as we can address any issues within the project.

Dublin City University will protect all the information about me, and my part in this study. My information in the focus group will be assigned a unique code which all will protect my identity. All my information will be stored securely and saved in a password

protected file in a computer at DCU. My identity or personal information will not be revealed or published.

The study findings may be presented at scientific meetings and published in a scientific journal but my identity will not be divulged and only presented as part of a group. I am aware that the confidentiality of information provided can only be protected within the limitations of the law. It is possible for data to be subject to subpoena, freedom of information claim or mandated reporting by some professions.

If I have questions about the research project, I am free to call Orlaith Duff at 01-7007653.

I have read and understood the information in this form. My questions and concerns have been answered by the researchers, and I have a copy of this consent form. Therefore, I consent to take part in this research project:

Participants Signature:	
Name in Block Capitals:	
Witness:	
Date:	

Appendix B.3: 'Acceptability of mobile phone applications among adults with chronic illness' questionnaire





ACCEPTABILITY OF MOBILE PHONE APPLICATIONS AMONG ADULTS WITH CHRONIC ILLNESS

Questionnaire

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- 1) Please answer ALL questions in ALL sections.
- 2) Completion of this form will take 5-10 minutes.
- 3) The contents of this questionnaire will be kept strictly confidential.

Demographic Profile:

Name:		
> Date of Birth:		<u>.</u>
Gender (Please circle a	ppropriately): Male/Fo	emale
How long have you bee	n attending MedEx? (F	Please tick one box only)
0-1 month 2-5 months years	6months - 1 year	1-3 years 3+

Tablet Computer and Smartphone:

Q1. Do you have a tablet computer e.g. Apple iPad, Kindle etc.? (A tablet is a wireless, portable personal computer with a touch screen interface. A tablet is typically smaller than a notebook computer but larger than a smartphone.)

than a smartphone.)		
Please circle ONE answer only		
Yes	No	
Q2. Do you have a smartphone e.g., S (Smartphones allow you access the interest of the state of	~ ~ ~	•
Please circle ONE answer only		
Yes	No	
Q3. If yes, is it an:		
O Android phone		
O iPhone (i.e. Apple iPhone) O Other Smartphone: Please list		
Q4. Do you use mobile applications of Gmail, YouTube, Facebook? (A mobile developed specifically for use on smart app you download it from an app store ►)	ile app is a soft tphones and ta	tware application blets. To access an
Please circle ONE answer only		
Yes	No	

Section A: UTAUT 2

This section is seeking your opinion regarding the importance of mobile applications (apps) e.g. Skype, WhatsApp, Twitter. Respondents are asked to indicate the extent to which they agreed or disagreed to the following statements using the 7 Likert scale [(1) = strongly disagree; (2) = disagree; (3) = somewhat disagree; (4) = neutral; (5) = somewhat agree; (6) agree; (7) = strongly agree] response framework.

<u>Please circle one number per line</u> to indicate the extent to which you agree or disagree with the following statements.

No	Questions	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
PE	Performance Exp	pectano	e y					
PE1	I would find mobile apps useful in my daily life.	1	2	3	4	5	6	7
PE2	Using mobile apps would help me to accomplish things more quickly.	1	2	3	4	5	6	7
PE3	Using mobile apps would increase my productivity.	1	2	3	4	5	6	7

No	Questions	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
EE	Effort Expectanc	y						
EE1	Learning how to use mobile apps would be easy for me.	1	2	3	4	5	6	7
EE2	My interaction with mobile apps would be clear & understandable.	1	2	3	4	5	6	7
EE3	I would find mobile apps easy to use.	1	2	3	4	5	6	7
EE4	It would be easy for me to become skillful at using mobile apps.	1	2	3	4	5	6	7

No	Questions	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
SI	Social Influence							
SI1	People who are important to me think that I should use mobile apps.	1	2	3	4	5	6	7
SI2	People who influence my behaviour think I should use mobile apps.	1	2	3	4	5	6	7
SI3	People whose opinions that I value prefer that I use mobile apps.	1	2	3	4	5	6	7

No	Questions	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
FC	Facilitating Cond	itions						
FC1	I would have the resources necessary to use mobile apps.	1	2	3	4	5	6	7
FC2	I would have the knowledge necessary to use mobile apps.	1	2	3	4	5	6	7
FC3	Mobile apps would be compatible with other technologies I use.	1	2	3	4	5	6	7
FC4	I would get help from others when I have difficulties using mobile apps.	1	2	3	4	5	6	7

No	Questions	Strongly Disagree	Disagree	Somewh at	Neutral	Somewh at Agree	Agree	Strongly Agree
HM	Hedonic Motivation							
HM1	Using mobile apps would be fun.	1	2	3	4	5	6	7
HM2	Using mobile apps would be enjoyable.	1	2	3	4	5	6	7
НМ3	Using mobile apps would be very entertaining.	1	2	3	4	5	6	7

No	Questions	Strongly Disagree	Disagree	Somewha t	Neutral	Somewha t Agree	Agree	Strongly Agree
PV	Price Value							
PV1	Mobile apps are reasonably priced.	1	2	3	4	5	6	7
PV2	Mobile apps are good value for money.	1	2	3	4	5	6	7
PV3	At the current price, mobile apps provide a good value.	1	2	3	4	5	6	7

No	Questions	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
HT	Habit							
HT1	The use of mobile apps would become a habit for me.	1	2	3	4	5	6	7
HT2	I would become addicted to using mobile apps.	1	2	3	4	5	6	7
HT3	I must use mobile apps.	1	2	3	4	5	6	7

Section B: Behavioural Intention

This section is seeking your opinion regarding the importance of mobile applications (apps). Respondents are asked to indicate the extent to which they agree or disagree to the following statements using the 7 Likert scale [(1) = strongly disagree; (2) = disagree; (3) = somewhat disagree; (4) = neutral; (5) = somewhat agree; (6) agree; (7) = strongly agree] response framework.

<u>Please circle one number per line</u> to indicate the extent to which you agree or disagree with the following statements.

No	Questions	Strongly disagree	Disagree	Somewha t Disagree	Neutral	Somewha t Agree	Agree	Strongly Agree
BI	Behavioural Inter	ntion						
BI1	I intend to continue using mobile apps in the future.	1	2	3	4	5	6	7
BI2	I will always try to use mobile apps in my daily life.	1	2	3	4	5	6	7
BI3	I plan to continue to use mobile apps frequently.	1	2	3	4	5	6	7

	Would you	be interested	in participating	; in fol	low up	focus g	roups?
If ye	s, please pro	ovide a contac	t number.				

O Yes	Contact Number:	
O No	•	

Thank you very much for taking part.

Should you have any further questions or if you would like to withdraw from the study, please do not hesitate to contact the researcher.

Orlaith Duff: 01-7007653

Appendix B.4: Focus Group Script

- Run with 5-6 people of mix gender and ages
- No more than 2 hours long with 10 minute a tea/coffee break in between
- Introductions (Hello and welcome, as you are aware this is a session to provide feedback on MedFit, a mobile app for cardiovascular rehabilitation)
- Explain how the focus group will work

Usability Section

FitBit

- Show participants the FitBit and its charger. Have the FitBit charged in advance so that they can see the different features of the FitBit.
- Ask participants to try the FitBit on to see what they think of it.
- Feedback screen What would be the top three pieces of information shown on the screen e.g. heart rate, step count, flights of stairs climbed?

<u>App name:</u> Does anyone have any suggestions for the name of the app? MedFit is currently the demo name.

App components

Log in screen

- Show the participants the app login in screen.
- Are the visuals appealing and easy to interpret?
- Explain to participants that the initial setup will be on a laptop for security purposes and that they will then be given a login and password to access the app.
- Ask participants do they would find the process of typing in their login and password. Would it be easy? If not, what would be difficult about setting up an account?

Home page

- The home page includes the sections, exercise, progress and my healthy lifestyle. What do participants think of the home screen? Does it look too busy or is it laid out clearly?
- Can the participants decipher what is in each section before clicking into them? i.e. is the name of each section self-explanatory?

Exercise

- Explain the format of the exercise programme i.e. warm up, main phase, cool down and stretching and show the participants videos of how to do the exercises.
- Explain how each exercise is counted down i.e. 30 seconds
- Ask the participants What do you think about this? What do you like? What do you not like? What would you change? Any other comments?
- Test yourself explain the <u>6 minute walk test</u> and <u>sit to stand test</u>. (Don't clink into each just explain that the test are similar to those completed in MedEx)What do you think about this? What do you like? What do you not like? What would you change? Any other comments?
- How do you think you would follow the exercises? Where would you place the phone? (Deirdre demo the exercises)

Progress

 Facilitator to show the participants feedback visualisation on the big screen to get feedback and goes through each piece of feedback on the dashboard systematically.

My Exercise Statistics

- My Activity bar chart (active mins per day): do you understand the information?
 Is there anything else you would like to see here? Any other comments?
 Anything you would change?
- Daily step count (progress bar indicates how many steps you have taken from 0 to 10,000): do you understand the information? Is there anything else you would like to see here? Any other comments? Anything you would change?
- Daily Heart Rate Information (average HR): do you understand the information?
 Is there anything else you would like to see here? Any other comments?
 Anything you would change?
- Weekly exercise goal: This is a prescribed goal which you can alter, which could potentially be based on step count and/or exercise sessions on the app. What do you think of this idea?
- Weekly exercise goal: In terms of the visuals on the screen, do you understand the information? Is there anything else you would like to see here? Any other comments? Anything you would change?
- Weekly workout time (hours and minutes): do you understand the information?
 Is there anything else you would like to see here? Any other comments?
 Anything you would change?
- Total exercise sessions: do you understand the information? Is there anything else you would like to see here? Any other comments? Anything you would change?

My Group's Exercise -> Found by clicking on the burger menu on the top right hand corner

- Group exercise duration: do you understand the information? Is there anything
 else you would like to see here? Any other comments? Anything you would
 change?
- Group attendance (sessions): do you understand the information? Is there anything else you would like to see here? Any other comments? Anything you would change?

Feedback Notifications: Go through handout

- Go through the examples of the rules
- What do you think of the idea of getting messages based on your progress/feedback and/or messages providing tips and recommendations during the week? Which would you be in favour of (i.e. progress or tips) and why? Would you like a combination on both types of messages? Any other comments?

My Healthy Lifestyle

- Show the screens for the health behaviours. Each section (e.g. physical activity) has recommendations and tips, as well as peer mentor videos and ask the expert videos. It could potentially have links to other relevant sources e.g. websites. What do you these ideas? Would you use this function? What do you like about it? What do you not like about it? What would you change about it?
- In terms of the peer mentor/ ask the expert videos: Would you watch them? What do you like about them? What do you not like about them? Would you use them as well as the text content? Instead of? Do they have any advantages/disadvantage above the text content?

Questionnaires

• Show the participants the example questionnaire on the iPad and how it will be filled in. What do you this of this? Do you think it would be easy/ difficult to answer the questions on a phone? Why or why not?

My MedFit Group

- Show the participants what is envisaged as part of this section i.e. events, message board, leader board.
- How would you expect to interact with other participants using mPATHway, if at all? What would you like about it? What would you not like about it?
- There will be an <u>events page</u> which will list local and national physical activity events. What do you think of this idea? Would you use this function? What do you like about it? What do you not like about it? What would you change about it?
- <u>Message board/chat function</u>? Explain briefly what we imagine the available social interaction features to be. Show an example of 'boards.ie'. What do you

- think of this concept? Would you use this function? What do you like about it? What do you not like about it? What would you change about it?
- <u>Sample of Leader board</u> Explain the concept of a leader board. Participants would be able to see the physical activity minutes/ step count of other users. Are there any other suggestions about what could be shown on a leader board?
- Would users be willing to have their name on a leader board or would you prefer to have an anonymous leader board with nicknames or I.D.'s for example?
- What do you think of the leader board? Would you use it? What do you like? What do you not like? What would you change? Any other comments?

Contact us

- Explain what is envisaged in this section e.g. video tutorials on how to navigate through the app and a section of frequently asked questions
- What do you think of this idea? Is there anything else you would like to see in this section? What do you like? What do you not like? What would you change? Any other comments?

Acceptance and use questions based on the UTAUT2

Performance Expectancy

- 1. Do you think you would find this app useful in your daily life? Why do you think that? If not, what do you think would make the app more useful?
- 2. Do you think this app would help you achieve the goals you set out in cardiac rehabilitation more efficiently? In what way do you think it will/will not help?
- 3. Do you think you would be more productive if you had this app to help you with your cardiac rehabilitation? Why do you think that?

Effort Expectancy

- 1. Do you think you would find learning to use this app easy? Why/ what parts of the application do you think make the app easy to use? If not, what could we do to make the app easier to use?
- 2. Do you think your interaction with this app would be clear and understandable? If not, what could we do to ensure that you could clearly understand and use the app?
- 3. In its current form do you think this app would be easy to use? If yes, what in particular makes it easy to use? If no, what suggestions/ feedback could you provide us with to make the app easier to use?
- 4. Do you think you could become skillful at using this app? Do you think it would take long to be able to understand and work the app properly yourself? Is there anything we could do that would help you to become skillful at using the app?

Social Influence

- 1. Do you think your family and friends would encourage you to use this app?
- 2. Why do you think they would encourage you to use the app? / Why would they not encourage you to use the app?
- 3. How could we make the app more appealing to your family and friends?
- 4. Is it important to you that your family/friends encourage you to use the app?

Facilitating Conditions

- 1. Do you think you have the resources necessary to use the app? E.g. money, time skill etc. If not, is there anything that could be done to facilitate easy use of the app?
- 2. Would you have the necessary knowledge to use the app? If not would you need detailed instructions on how to use the app e.g. instruction manual/ video tutorial?
- 3. Would the app be compatible with other technologies you use?

4. If you had difficulty using the app would you get help from family or friends? Do you think you would need IT support from our team in case you have a problem using the app? What form do you think this IT support should come in? (e.g. phone number for support) When should the IT support be available? (e.g. 9am-5pm Mon-Fri)

Hedonic Motivation

Do you think it would be fun/enjoyable/entertaining to use the app?
 Why/Why not? Is there anything that would make the app more enjoyable to use?

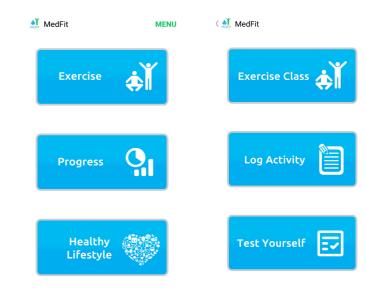
Behavioural Intention

- 1. Could you see yourself using the app regularly? Why/Why not?
- 2. Do you think you would try to use the app in your daily life? Is there anything that could be added/changed to make the app more appealing to use regularly?

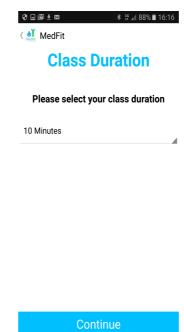
Appendix C: Visuals of app content

Appendix C.1: MedFit App Screenshots



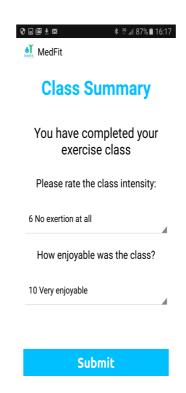


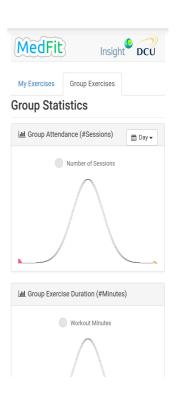




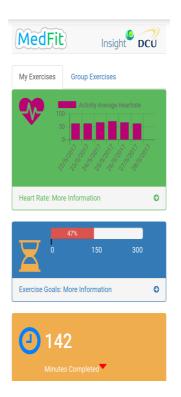
















MENU

MENU



Physical Activity

Being active helps keep your heart healthy.

You're in control - by taking ten minutes a few times a day to get active, you could change your

Being active helps lower your risk of a secondary cardiac event because it:

- Exercises your heart, helping to keep it strong.
- · Helps lower your cholesterol: a fatty substance in your blood which can cause your arteries to clog up.
- Helps lower your blood pressure, which means your arteries are less likely to clog up.



Medication Adherence

Medicines are taken to help keep your symptoms under control or to prevent or treat a heart condition.

Understanding your medication:

It's important to know what you're taking, why you are taking it, and how it will affect you.

When you're given a new prescription, speak to your doctor about:

- the medication prescribed for you and its potential benefits and risks
- · how to take it safely
- nossible side effects and what to do if your





Sexual Functioning

Sexual activity is a major quality of life issue for men and women with cardiovascular disease and their partners.

Men and women with stable cardiovascular disease who have no or minimal symptoms during routine activities can engage in sexual activity.

People with unstable cardiovascular disease or whose symptoms are severe, should be treated and stabilized before having sex.

What you need to know according to the **American Heart Association:**

· Ask your doctor to evaluate you before resuming sexual activity.



MENII



Healthy Eating

Even if you already have a heart condition, a healthy diet can benefit your heart. You should aim for a well-balanced diet. The best way to understand a well-balanced diet is to think of foods in food groups.

Try to eat:

- plenty of fruit and vegtables.
- · Plenty of starchy foods such as bread, rice, potatoes and pasta. Choose wholegrain varieties wherever possible.
- · some milk and dairy products.
- some meat, fish, eggs, beans and other non-dairy sources of protein.