

The development and co-design of the PATHway intervention: a theory-driven eHealth platform for the self-management of cardiovascular disease.

Background Cardiovascular diseases (CVD) are a leading cause of premature death worldwide.

International guidelines recommend routine delivery of all phases of cardiac rehabilitation (CR).

Uptake of traditional cardiac rehabilitation remains suboptimal, as attendance at formal hospital-based CR programmes is low, with community-based CR rates and individual long-term exercise maintenance even lower. Home-based CR programs have been shown to be equally effective in clinical and health-related quality of life outcomes, and yet are not readily available.

Purpose The aim of the current study was to develop the PATHway intervention (Physical Activity Towards Health) for the self-management of cardiovascular disease. Increasing physical activity in individuals with CVD was the primary behaviour.

Methods The PATHway intervention was theoretically informed by the Behaviour Change Wheel (BCW) and Social Cognitive Theory (SCT). All relevant intervention functions, behaviour change techniques (BCTs) and policy categories were identified and translated into intervention content. Furthermore, a person-centred approach was adopted involving an iterative co-design process and extensive user-testing.

Results. Education, enablement, modelling, persuasion, training and social restructuring were selected as appropriate intervention functions. Twenty-two BCTs, linked to the 6 intervention functions and 3 policy categories were identified for inclusion and translated into PATHway intervention content.

Conclusions. This paper details the use of the BCW and SCT to develop an eHealth intervention for the self-management of CVD. The systematic and transparent development of the PATHway intervention will facilitate the evaluation of intervention effectiveness and future replication.

Keywords: intervention development, person-centred approach, behaviour change wheel, health behaviour change, eHealth, physical activity, cardiovascular disease

Background:

Cardiovascular diseases (CVD) are a leading cause of premature death and disability within Europe and an economic burden worldwide [1]. Importantly, from a behavioural science perspective, approximately 80% of cases are precipitated by the mismanagement of key modifiable risk factors, including physical activity, smoking, diet, alcohol consumption, stress management and medication adherence [2]. Cardiac rehabilitation (CR) is an essential part of the current management of CVD [3]. There are typically three discrete phases of cardiac rehabilitation: Phase 1 (the acute phase), Phase 2 (the reconditioning phase; i.e., hospital-based), and Phase 3 (the maintenance phase; i.e., community or home-based) [4].

Phase 2 or hospital-based CR typically involves risk factor education, supervised exercise training, and psychological support. However, even though CR improves mortality and morbidity rates, uptake of CR remains suboptimal [4]. The main reasons for the low adherence rates include: travel distance, low self-efficacy, perceived body-image and lack of time [5]. Interestingly, home-based CR has been shown to be equally effective in clinical and health-related quality of life outcomes [6,7]. Home-based solutions have most commonly employed programmes with individually tailored exercise prescriptions based on walking with intermittent support from a nurse or exercise specialist [8]. Health professional support can take the form of telephone contact and/or scheduled visits as agreed between patients and their assigned CR team [8] in order to overcome many of the frequently cited barriers to CR participation [5]. Indeed, there are several examples where home-based CR programmes have been introduced as an alternative to both hospital and community-based programmes throughout different phases of CR in order to widen access and participation [9,10,11]. Research indicates that the efficacy of self-management programmes is influenced more by the quality, structure and availability of the follow-up rather than the location [8]. However, despite this, few CR programs offer a remote solution and utilise eHealth interventions even though they may be as effective and implemented on a wider scale. A number of recent interventions have used automated text messaging [12,13,14] as well as other eHealth solutions [15,16] to deliver care. Increasingly, individuals with CVD recognise eHealth interventions as a viable way of delivering this care as their desire and acceptance of technology-delivered CR is increasing [17]. However, the need for dynamic and adaptive eHealth interventions has not been sufficiently addressed to examine issues of long-term maintenance of behaviours with studies often showing initial positive effects which are not sustained [11]. The current intervention aims to address this current gap within home-based CR.

Personalised and adaptive interventions have previously been investigated within the field of Human Computer Interaction (HCI) and more recently Mohr and colleagues have bridged disciplines bringing together expertise from behavioral science and developers through the development of the Behavioural Intervention Technology framework (BITs) [18]. The BITs framework aims to facilitate the documentation and translation of behavioural intervention components into technological features [18]. BITs include clinical aims reflecting the target behaviour and outcome, but importantly also highlights usage aims reflecting user engagement with technology with the BIT during the intervention period.

Incremental stepped approaches to developing and evaluating behaviour change interventions using technology are vital, as per the Medical Research Council (MRC) and Behaviour Change Wheel (BCW) frameworks [19,20]. The BCW and the COM-B model describes an individual's capability, opportunity and motivation as the key 'drivers' leading to behaviour [20]. A key tenet of both the MRC and BCW frameworks is to identify intervention content and mechanisms through the systematic application of theory and evidence-based research. The BCW is a tool used to aid intervention design. It specifies nine intervention functions (coercion, education, enablement, environmental restructuring, incentivisation, modelling, persuasion, restriction, training). These intervention functions are identified as the broad mechanisms through which an intervention can effect change [20]. Seven broad policy categories are also listed (i.e., communication/marketing, environmental/social planning, fiscal measures, guidelines, legislation, regulation and service provision) [20]. These intervention functions are then linked to BCTs, the observable, replicable and irreducible active ingredients of an intervention [20]. At the core of the BCW, the Capability Opportunity Motivation-Behaviour (COM-B) model can be seen, the COM-B describes the catalysts for behaviour that act as a starting point for using the BCW. These catalysts for behaviours are used to aid identification of appropriate target behaviours. Capability is the individual's ability to perform a behaviour and includes both physical capability (e.g. skills) and psychological capability (e.g. knowledge). Opportunity describes the factors that lie outside the individual that facilitate or prompt behaviour and includes both physical opportunity (e.g. affordability) and social opportunity (e.g. cultural norms). Motivation describes the brain processes that energise and direct behaviour and includes both automatic motivation (e.g. habits) and reflective motivation (e.g. cost-benefit decision making) [20]. A recent systematic review and meta-analysis used the BCW framework to determine

the effectiveness of certain behaviour change techniques (BCTs) on CVD risk factors [21]. This review found that the most commonly used techniques in CR were 1) providing information on the consequences of behaviour, 2) providing instruction on how to perform the behaviour, 3) goal setting in relation to the outcome, 4) goal setting in relation to the behaviour, 5) providing information on where and when to perform the behaviour and 6) prompt review of behavioural goals. However, there was no association between specific BCTs and mortality or the number of BCTs used in an intervention [21]. Goodwin and colleagues found evidence for a positive effect of secondary prevention interventions, but it was not possible to identify what the essential ingredients of these behaviour change interventions were [21]. This was due to a number of generic difficulties in reporting and synthesising intervention studies in this area. Unfortunately, this issue can be seen across a number of eHealth interventions with a dearth of adequate intervention design and content reporting [22,23]. Indeed, much of the difficulty in reporting complex interventions is due to the multiple components targeted. The current study seeks to address key concerns that were identified by explicitly reporting all intervention content and the method of delivery. Further description of intervention content, guiding theoretical frameworks and user testing protocols needs to be made available to aid future intervention development [24].

However, explicitly reporting eHealth intervention development, content and operationalisation of that content can be particularly challenging in the area of eHealth [18]. Within an eHealth intervention, a workflow (i.e., a set of rules) determines when and under which conditions each intervention component is delivered to individuals over time and although content is often specified, the availability and decision support rules behind this content is often not available. The BCTs used in the current intervention are embedded within the content of the intervention and eHealth delivery mechanisms are defined. This BCT taxonomy [25] is a fundamental part of describing how interventions move from initial needs analysis to intervention components. Intervention components are operationalised as each BCT is linked with specific intervention features as user interfaces, reminders, or push notifications.

Parallel to intervention development it is crucial to consider the implementation context of the intervention. To enhance the likelihood of intervention implementation, it is important that iterative co-design be recognised as an integral aspect of the preparatory work, with stakeholder consultation as a mandatory step to create a context specific, fit-for-purpose, user-centred intervention. Co-design

goes beyond aiming to adopt a user centred approach; it is a person-centred ethos sought to empower patients to tailor an intervention to suit their own contexts, and partner in creating an intervention that would be appropriate and responsive to their needs [26,27]. This involved iterative processes of user engagement where intervention co-design was viewed as a partnership.

This approach is especially needed within eHealth interventions given that often the target population may not be technologically literate. By adhering to a co-design method, formative research work can shape the intervention appropriately and allow usability testing to move beyond assessing mere technology functionality [22]. This is a core part of eHealth interventions as it must be recognised that technology is not merely a passive agent within an intervention to deliver intervention content, it is an inseparable aspect of eHealth interventions that impacts on patient satisfaction and adherence [28]. Within the field of HCI, human-centred design is not new; it is a design philosophy that seeks to place the end user at the centre of the design while also considering impacts on a broad range of stakeholders [29]. An important consideration within this field are *human factors* which detail the interaction between human capabilities (physical, sensory, emotional, and intellectual) and limitations in the design and development of technology [30]. The implementation of a co-design method allows for testing of identified 'human factors'.

This paper provides a comprehensive description of the PATHway intervention development process, its final structure and content. It describes the steps undertaken to develop a user-centred, dynamic, adaptive, eHealth intervention and the research team have endeavoured to present each development step to facilitate replication of this design process for future complex eHealth interventions.

PATHway aims to empower patients who have CVD to self-manage their CVD risk factors post hospital-based CR. PATHway aims to provide an alternative remote community-based CR programme to patients. It uses an internet-enabled and sensor-based home exercise platform as the core component of a personalized, comprehensive lifestyle intervention programme. This novel programme is set within a collaborative care context and is complementary to CR management applicable in most European countries.

Methods

Participants

1) Applied theoretical framework

This involved evidence synthesis from previous research. No participants were involved in this phase.

2) Engagement with target population

To establish the need for PATHway, a quantitative study was undertaken to explore technology usage and needs among the target cohort using the Technology Usage Questionnaire (TUQ; n=310; 77 % male; mean age $61,7 \pm 14,5$ years). Following this, qualitative research methods were used to further engage with the target population in relation to their needs. 33 one-to one interviews were conducted with CVD patients (male n=26; female n=7; mean age= 60.38 years [one participant did not report age]) . Individuals with CVD were selected based on a variety of cardiac histories (e.g., PCI, stenting, CABG and heart failure), and differing levels of engagement with CR services 1) high attenders of hospital-based CR, 2) low attenders of hospital based CR, 3) high attenders of community-based CR and 4) dropouts from community based CR). Eligible CVD patients were identified by the research team in conjunction with hospital CR and community-based CR staff. All those interested were provided with information sheets. Research staff then followed up with potential participants to confirm interest in participation and for completion of consent procedures. This provided a wide range of perspectives to further understanding the core clinical and technical requirements, this led to the formulation of use-cases for the PATHway system with functional and non-functional requirements.

Subsequently, a further 21 interviews were conducted with healthcare professional stakeholders to provide a deeper understanding of the PATHway end-user requirements. This included representatives from public policy, specifically individuals from the Department of Health (n=2) and from the Health Services Executive (n=1); representatives from the community, specifically general practitioners (GPs) who refer patients to cardiac rehabilitation (n=3), public health nurses (n=1), local patient organisation (n=1), national patient organisation (n=1), representatives from the hospital specifically the cardiac rehabilitation cardiologists (2), hypertension specialist (n=1), specialized cardiology nurses (n=3), physiotherapists/exercise physiologists involved in cardiac rehab phase 2 and 3 (n=4), psychologist involved in cardiac rehab (n=1), technologists with experience of healthcare devices in cardiac rehabilitation (n=1).

3) Iterative participant PATHway design-focus groups

Thirty CVD patients (18 male, 12 female; age 55-75 years, range of CVD history) from a) two hospital-based cardiac rehabilitation programmes and b) two community-based cardiac rehabilitation programmes in Ireland and Belgium were invited to participate in these focus groups. Recruitment

procedures for focus group participation were the same as those for participation in individual interviews. Four focus groups met a total of three times as part of the PATHway co-design process.

Stakeholder expert panel

A stakeholder expert panel (SEP) was held (n=10) to ensure that the views and opinions of the full health ecosystem were included [31]. This SEP met once for a full day feedback workshop where the PATHway intervention was presented and included professionals ranging from cardiologists, cardiac rehabilitation co-ordinators to patient and health service representatives.

4) Usability testing: the 5E approach

Eleven CVD patients took part in this usability phase to test various usability dimensions of the first PATHway prototype.

Procedure

The content and format of the PATHway intervention were developed based on 1) a review of appropriate theoretical frameworks and previous studies investigating cardiac rehabilitation interventions, 2) engaging the target population and health professionals by means of questionnaires and one-to-one individual interviews, 3) Iterative participant PATHway design- (i.e., focus groups and SEP) 4) engaging with a stakeholder expert panel to review the first PATHway prototype 5) further usability testing using the 5E approach [32].

1) Applied Theoretical Framework

The BCW [20] and social cognitive theory (SCT) [33] were chosen as they provide a framework in which to understand the complexities of initiating an eHealth health behaviour change within a chronic disease population [34].

The BCW is a useful tool to implement within intervention and is discussed previously. SCT was used to underpin the PATHway intervention. The SCT posits a multi-faceted model whereby individual self-efficacy works in conjunction with knowledge, goals, outcome expectations, and perceived environmental impediments and facilitators in establishment of behavior (e.g., engagement with CR) [33]. Self-efficacy is a mediator of behaviour change [33] and is an outcome of cardiac rehabilitation [35]. Therefore, enhancing self-efficacy was a central part of the PATHway health behaviour change content. Other SCT factors were used (i.e., knowledge, goals, outcome expectations, and perceived environmental impediments and facilitators), these core factors within social cognitive theory work together to initiate and subsequently maintain a target behaviour. The

role of SCT within the intervention spanned and mapped well onto the COM-B. Knowledge of the behaviour and the benefits of engaging/ not engaging with a specific health behaviour were considered, while individuals' outcome expectations were studied given the impact on perceived expected costs and benefits of engaging with a target behaviour and subsequent motivation and goal-setting.

2) Engagement with the target population

To establish the need and acceptability of an eHealth CR intervention for CVD patients and their healthcare providers, quantitative and qualitative data were collected. This included the development, administration and analysis of a Technology Usage Questionnaire [see reference 17 for more details]. Further exploration of the TUQ results, guided by the COM-B model was required to gain a nuanced understanding of the user requirements. Thus, following the TUQ over fifty interviews were conducted with individuals with CVD (n= 33), and other healthcare professional stakeholders (n= 21) to provide a deeper understanding of the PATHway end-user requirements (qualitative findings reported separately; manuscript under review)

3) Iterative participant PATHway design

Once PATHway's clinical and technical requirements were converted into platform ideas, further testing at each development stage from feasibility testing to implementation was performed [22]. To facilitate an iterative process, three separate rounds of focus groups were held with the same cohort. Patients were exposed to parts of the PATHway intervention by the research team, and feedback on that particular part was elicited. Microsoft PowerPoint slideshows composed of PATHway screenshots, videos and hard copy content were used. Researchers also brought the patients through available PATHway prototypes on a large screen to elicit response.

Features explored included content, the user interface, views on remote social interaction and technical support. Patients shared their views on the user interface in terms of visual aesthetics, usability and required IT support, level and tone of content as well as feedback on the novel elements of PATHway (i.e., social interaction while exercising remotely and home-based health and fitness testing). This allowed the research team to assess preliminary functionality, acceptability, user friendliness, and engagement. All focus groups were audio-recorded, transcribed and analysed using content analysis [36]. Key recommendations regarding technical and intervention content were identified for communication to the technical team.

4) Stakeholder expert panel

Following the iterative co-design phase, a stakeholder expert panel (SEP) was held (n=10) to ensure that the views and opinions of the full health ecosystem were included [31]. To facilitate the SEP panel, the research team presented on three core elements 1) the concept of PATHway, 2) prototypes of the PATHway content and 3) the theoretical underpinnings of PATHway. Group discussion and questions were encouraged and any follow up feedback following the SEP panel was taken into account for further refinement of the PATHway intervention.

5) Usability testing: the 5E approach

Following the integration of SEP and user feedback, further usability testing was conducted using the 5E approach [32]. The 5E approach looks at usability requirements and aggregates these requirements into features of the system across five dimensions of usability (i.e., effective, efficient, engaging, error tolerant and easy to learn) [32]. The effective dimension explores how completely and accurately a user task can complete a task. The efficient dimension refers to how quickly the task can be done. The engaging dimension highlights how well the interface guides the user intuitively through the task. The error tolerant dimension assesses how well a system can avoid user generated errors, but also how the system aids the user in overcoming this error. The easy to learn dimension evaluates how the system supports both initial and long-term use. These 5 dimensions are central to the user experience and the 5E approach encourages a clear reporting of user-generated issues [in percentages for ease-of-use). What emerges from using this approach is an understanding of what usability means within a specific context. The testing was approx. 80-90 mins including initial welcome, set up, testing period, filling out reports and closure. Technical partners provided the list of broad features to test (i.e., home platform access, home exercising-single user, exergame, exercise practice, active lifestyle, usage reporting, assessment, behavioural change and preference settings). A customised 5E template was also developed and used, this included further in-depth questions for each of the 'E' dimensions to evaluate each feature. Patients completed this with the aid of the researcher. To ensure consistency within usability testing, a compilation guide of exact features to test was also created.

Results

1) Applied theoretical framework informing intervention development

The target behaviour of PATHway is to increase levels of physical activity. Through the BCW, SCT and previous studies [37-39] key areas were identified to directly address individual's concerns with capability, opportunity and motivation around increasing level of physical activity (the results of this exercise are presented in Table 1). The salient COM-B and SCT constructs were mapped onto a total of twenty-two BCTs which were included within the PATHway intervention. Each related BCT is listed using its corresponding taxonomy number (e.g., 4.1 Instruction on how to perform a behaviour [20]). Key intervention functions of enablement, education, modelling, training and environmental restructuring and persuasion were utilised. Policy functions include guidelines, service provision and social planning. Table 1 identifies all intervention features and eHealth components, then describes each component in full and links all intervention components to the specific behaviour change technique that is applied within that component. For further details see Additional file 1 where Table 1 is further expanded to link each intervention component to the appropriate BCW and SCT construct.

[Insert Table 1 approx. here]

2) Engagement with the target population

The findings from the Technology Usage Questionnaire are reported elsewhere [17], however in brief summary 97% had a mobile phone, 91% used the internet (76% of those using it daily). Heart rate monitors were used by 35% and 68% reported to find heart rate monitoring important when exercising at home. Physical activity monitoring was reported by 12%. Most (77%) indicated an interest in CR support through internet, 68% through the mobile phone, with many reporting interest in game-based CR (67 %) and virtual rehabilitation (58%). Key findings led the PATHway design team to facilitate end users who indicated low physical capability to do the actual exercises, poor psychological capability or readiness to change their behaviour and low technological capability or readiness to engage with a 'high tech' intervention. With regards to opportunity, the main obstacles were around time, space and equipment. Patients identified several factors that influenced motivation for engaging in physical activity including (e.g., goal setting and social interaction).

3) Iterative PATHway Design

Iterative focus groups yielded insights into how PATHway content should be further developed and refined. Following a review of the transcripts, several areas were identified. Feedback is contained within Additional file 2 under the following headings 1) the PATHway feature in question; 2) the participant identified issues; 3) an illustrative quote of the issues and 4) the final resulting action to

refine PATHway development. Important issues which were prioritised were user interface issues (e.g., colours, less busy background, simplified graphs etc.), need for improved exercise repetition counting accuracy, removal of the leader board concept and facilitating people with multiple helpline and support options.

4) Stakeholder Expert panel

Feedback from SEP is reported within Additional file 3 under the following headings 1) Description of Expert feedback; 2) Illustrative quote of the issue and 3) Recommendation/how it is addressed within PATHway system.

Several key issues were identified. The importance of the familiarisation phase to PATHway was seen as a key point of contact and important for participant satisfaction and long-term engagement with the system. The need for on-going support for patients was seen as crucial, with the SEP highlighting that PATHway should aim to be *technology-augmented care*, whereby it would be supplemented with face-to-face meetings. Suggestions for further content development that are not currently within the description of work were also raised by the SEP, particularly in relation to mental health and depression, as well as sexual activity and sexual functioning.

The SEP highlighted some key issues that were previously also identified in the individual interviews conducted such as needing 'whole team buy-in' from senior health care professionals to ensure successful implementation.

5) The 5E approach:

Table 2 contains the result of the usability test performed on the first PATHway prototype. A high level of performance across core areas of effectiveness, efficiency, engaging, error tolerance and ease of learning was found.

[Insert Table 2 approx. here]

Final Intervention structure and content resulting from the previous 5 development phases

The final core intervention content is described below in the following sections and has been designed equally acknowledging the importance of applying appropriate theoretical frameworks as well as user feedback. For further details on the intervention see Additional file 4 where the Template for Intervention Description and Replication (TIDieR) checklist is reported to ensure the completeness

of reporting, and ultimately the replicability, of interventions [40]. For further details on validated tools/questionnaires used within the intervention please see the PATHway RCT protocol [41].

Familiarisation Phase

All PATHway patients are required to attend four face-to-face familiarisation classes in the last four weeks of their cardiac rehabilitation. These classes ensure that all patients are comfortable using the various technology features and functions that PATHway has to offer, prior to being discharged from hospital once CR is complete. They give the participant the opportunity to be taught how to use the system in an individual/small group setting. Patients can then practice using the system at home before the next session, so that any issues can be raised. Examples of the sample lessons are:

Individually tailored exercise programme

Before an individual starts to use PATHway, a consultation on how to use the PATHway system is held with the participant whereby they consider the recommended exercise prescription and agree upon it (see additional file 5 for exercise consultation script). Patients are given the opportunity to explore benefits and barriers to using the PATHway system and how PATHway can enable them to achieve their exercise goals. The exercise program content was based on the current guidelines and recommendations of the European Society of Cardiology e.g., a minimum of 150 minutes of moderate to vigorous physical activity per week [42-48] along with existing evidence based exercise training principles. PATHway presents patients with various ways of achieving their exercise prescription, including Exerclasses and ExerGames where the Patients' movements are captured by MS Kinect camera, and heart rate is sensed by means of the MS Band 2. Based on sensor readings, the program is adapted in real time in order to obtain an optimal and personally tailored exercise program at all times. Moreover, an active lifestyle activity module is available with practical training guides for walking, cycling, gym workouts, and swimming, and with the possibility for any other physical activity to be performed. Patients use these different formats of exercise sessions flexibly through choosing personal preferences for length and types of sessions on any given day. Further sensing technology is also used within the motion capturing component utilising the Microsoft Kinect® sensor which assesses patients' movements during the Exerclass and Exergame sessions in order to give feedback on exercise execution.

Second to the dynamic adaptation process, other safeguards for participant satisfaction and adherence are also in place within PATHway exercise module. The affective response module assesses participant enjoyment via a single item question at each exercise session. Rate of perceived exertion is also measured using the Borg rating of perceived exertion (RPE) scale [49]. The affect and RPE scores allow the PATHway platform to automatically adjust the exercise sessions offline according to the participant's level of exertion and enjoyment, with the purpose of matching the next session even more closely to the participant's needs.

Health behaviour change programme

The health behaviour change content offered by PATHway consists of 1) a lifestyle assessment questionnaire, 2) good habits visualisation, 3) a behavioural change assessment, 4) recommended goals based on participant preference and selection, 5) behaviour change notifications and 6) MyHealthyLifestyle content.

Key modifiable lifestyle behaviours for the management of CVD included physical activity, healthy eating, smoking cessation, alcohol moderation, stress management and medication adherence. Following a lifestyle assessment (a questionnaire to review a participant's lifestyle behaviours; completed at baseline, three and six months) patients receive, through PATHway, a personalised 'Good Habits Visualisation' of their own risk profile. This 'Good Habits Visualisation' is based on the total scores from the lifestyle assessment. This visualises how their current lifestyle fits in relation to CVD self-

management guidelines. This visual graphic displays how each risk factor should be managed, through three simple categories: 'Well Done', 'Room for Improvement' and 'Make a change'. The participant can then choose any of the behaviours to modify throughout the PATHway intervention.

This 'Good habits visualisation' then leads the participant to a behavioural change assessment [50] whereby four questions are asked to ascertain the participant willingness to change that specific behaviour: 1) *Is this behaviour a problem for you?* 2) *Are you distressed by this problem?* 3) *Are you interested in making a change?* 4) *Are you ready to change now?* This method is known as the 'traffic light assessment' which uses a behavioural change counselling or motivational interviewing

approach [33]. This assessment assigns the participant to a group appropriate to their behaviour change stage. Patients were deemed 'ready for change [green category]' if they had 4 yes answers, 'ambivalent towards change' [yellow category] if they had 2-3 yes answers and 'not ready to change' [red category] if they had 0-1 yes answers.

PATHway then shows pre-specified text for each category (for all healthy lifestyle behaviours) based on their readiness to change (e.g., the 'green' category for physical activity will be shown the following text "Excellent! You are ready to start-here is an exercise goal just for you," the 'yellow' category is seen as 'ambivalent towards change' and is prompted through the PATHway flow to engage in decisional balance activities which proposes common reasons of why an individual may/may not want to engage in the selected behaviour. The 'red' category are deemed to not be ready for change and are directed to engage with the provided educational and support content and consider change in the future.

Importantly, this behavioural assessment also targets perceived self-efficacy which is an important factor within the intervention SCT framework. Assessing a participant's readiness to change is an important part of setting health behaviour change goals, even for those patients who are not yet ready to change. A readiness assessment recognises the reality of a non-linear process of health behaviour change whereby some behaviours may be more problematic for patients. This assessment empowers patients to make those choices and directs the user to the most appropriate content for them at that time (e.g., educational material on risk factors rather than goal-based recommendations).

To maintain consistent engagement with PATHway even when not actively using the system, tailored behaviour change notifications are also delivered to the participant via SMS or email depending on participant preference. These messages are linked to the patients chosen health behaviour goals and are rule-based messages linked to participant weekly performance. Targeted lifestyle content is also delivered irrespective of performance. The full library of behaviour change notifications (n=829 messages available in both English and Dutch) are mapped to BCTs to enhance reporting and evaluation of this component (see additional file 6 for sample text messages).

User dashboard

A wrist worn HR/physical activity monitor (Microsoft band 2) will collect data on both physical activity and sedentary behaviour. This data will be synthesized and displayed via the participant's personalised dashboard. This will provide accessible summaries of physical activity data which can

also be accessed by health care professionals. As mentioned previously, the band will also dictate the patients individually tailored exercise programme based on live streaming of heart rate recordings.

All information pertaining to an individual's exercise prescription is available on the landing page of the dashboard (e.g., minutes of physical activity achieved so far, how many ExerClass left to do etc.). More detailed information on each exercise session can also be viewed (e.g., heartrate ranges during a session, and analysis by warm up, aerobic and cool down phases).

Other sections of the dashboard include 'MyHealthyLifestyle' which is a content-based module of PATHway which gives patients further information on cardiovascular disease healthy lifestyle behaviours (i.e., physical activity, smoking cessation, alcohol reduction, healthy eating, stress management and medication adherence) [48]. All content is aimed at allowing the individual to self-manage their cardiovascular disease. Each section is structured uniformly including 1) key recommendations and basic content, 2) further advanced information and 3) interactive content video/audio content.

Social interaction

Given the importance of social interaction and support [51], PATHway contains a social connectivity module to further facilitate social interaction, connection and support. This aims to create a community of practice and enable small groups of remote patients to interact and schedule multi-player exercise opportunities with one another. This is made possible by means of a live chat function. An online calendar will also allow patients to create and promote local and personal events and to invite others to join.

Health data management system and clinical front-end

PATHway maintains two types of Health Data Management Systems (HDMS). The first is for approved health care providers that only have access to participant data from the local healthcare facility. This data is participant record-oriented, diagnosis and treatment-focused. This is the clinical front-end and allows access to individual participant information and data (i.e., clinical diagnosis, health behaviour change data, dashboard information, exercise prescription and notification preferences). The second is a research HDMS environment where all raw participant data from

patients is held. These data, where necessary, will be transformed to comply with data protection requirements.

Discussion

This paper describes the methods used to systematically develop a multi-component complex e-health intervention to facilitate the self-management of cardiovascular disease and to specifically target the behaviour of increasing/maintaining physical activity within individuals with CVD. Our results show that the system requirements were possible to associate with theoretically derived BCTs using the taxonomy established by Michie and colleagues [25].

PATHway has extended behavioural science methodology by using both the BCW and SCT to develop its intervention for the self-management of CVD in a BIT. The use of a systematic approach from the perspective of person centred formative research, as well as a systematic application of theory and standardised language across multiple disciplines including health, disease management, behaviour change, technology and exercise science has led to a novel intervention. The learning that has been made throughout its development will allow the PATHway intervention, whether effective or not, to contribute to implementation science and intervention design research. Indeed, PATHway is one of the few interventions to target and measure multiple behaviours, mirroring traditional CR while utilising sensed data to create an adaptive personalised intervention. Interventions addressing multiple healthy lifestyle behaviours are increasing. Effective intervention development examples for targeting multiple behaviours is necessary. This is an important area of future research for CR research as there are a constellation of behaviours that need to be addressed for optimal patient outcomes. Indeed, the recommended healthy lifestyle behaviours within PATHway are also risk factors for other chronic conditions, therefore, the potential impact of research targeting such multiple behaviours may be greater given shared risk factors [52]. Further research is needed to compare outcomes of more basic eHealth interventions (e.g., text messaging interventions) with more complex approaches particularly as there may be cost and scalability difference [11]. In particular, given some evidence for successful CR programmes delivered exclusively through the Internet requiring minimal resources [53]. The results of the PATHway RCT design will allow investigation of some of these issues (PATHway trial registration number: NCT02717806).

Michie et al. [24] highlighted how a major strength of the BCW approach is that it encourages full consideration of all intervention options prior to implementation. This is especially useful when

developing an eHealth intervention given the wide array of features and possibilities available. This highlights the need to consider not only what could be possible to implement but also what is wanted or needed by the end-user. Current findings extend previous eHealth interventions by integrating sensed data and BCTs to allow for greater individual tailoring and improved bi-directional communication with health care providers. Dale and colleagues [11] advised this approach as a potential future direction for consideration when their text message intervention found initial positive effects that were not sustained at 6 months follow up. However, advanced features may not be context appropriate or effective in addressing the target behaviour. This is where an approach such as the BCW allows in-depth consideration of the suitability of intervention functions, behaviour change techniques and policy categories.

Importantly, context and user-centred design were core aspects of the person-centred approach to PATHway development. PATHway development exemplifies how iterative co-design can result in a more nuanced approach to the identification of appropriate BCTs. All qualitative data were synthesised, prioritised and implemented within a theoretical framework. This approach addresses previously identified limitations of intervention development whereby top-down decisions can be made unilaterally by the research team during the development of large and complex interventions [54]. The current paper proposes that this can be limited if there is a commitment to a person-centred approach throughout development [22]. However, it must be noted that this method presents practical challenges for a multi-disciplinary team, moreover this approach can be time-consuming and challenging with regard to, for example, the difficulty involved in changing technology features during technology components development and integration. This type of multidisciplinary issue is somewhat unique to eHealth interventions due to the pace of development, interoperability concerns and the need for compliance with regulatory, ethical, and security requirements [55].

Limitations

Obstacles for transparent intervention development and reporting can occur during certain phases of using the BCW framework. In line with findings from McSharry and colleagues [55], it was found that the selection of policy level categories was less well-defined and practical than the other BCW steps. The identification of policy categories is currently described as step 6 of the BCW process, between the identification of intervention functions and the identification of BCTs, which is not always the next intuitive step in intervention design. In addition, policy categories appear to be

more applicable to large-scale public health projects rather than individual health behaviour change interventions.

It must also be noted that there is a growing need to consider adopting methods from other disciplines rather than using deployment-evaluation cycles [54]. Theories, models, and methods to support this approach can be found in engineering and related sectors (e.g., use of factorial or fractionated evaluation designs which have been utilised well within the HCI sphere) [56].

Conclusions

To improve self-management for a wide range of individuals it is important to consider other options beyond the traditional approaches to CR. In looking towards newer approaches, it is important to appropriately design these eHealth solutions. The BCW approach provides a systematic, explicit and pragmatic framework for intervention development with the use of an in-depth co-design process embedded in theoretical approaches. This article illustrated the steps involved in the development of eHealth interventions combining theory from both behaviour change and HCI to improve not only usability but efficacy. This multi-disciplinary approach to intervention development contributes to future collaborative efforts across disciplines in the development of eHealth-based behaviour change interventions. This will facilitate the evaluation of intervention effectiveness and future replication and contribute to behavioural and implementation science.

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Table 1: PATHway features mapped to BCTs

PATHway feature	Description	BCT used
PATHway consultation and familiarization phase	At 0 months (approx.. 4 weeks prior to the end of hospital based cardiac rehabilitation) 1-1 consultation with PATHway team on how to use the PATHway system. Further, initially 4 classes within hospital based cardiac rehabilitation where participants learn to use the PATHway system during their usual CR classes. This includes remote use of PATHway at home with homework assignments discussed in class.	4.1 Instruction on how to perform a behaviour 6.1 Demonstration of the behaviour 9.1 Credible source 3.2 Social support (practical) 3.1 Social support (un-specified) 9.1 Credible source 1.1 Goal setting (behaviour) 1.2 Problem solving 1.3 Goal setting (outcome) 1.4 Action planning 5.1 Information about health consequences 5.6 Information about emotional consequences 15.3 Focus on past success
Practice individual exercise	Function to practice each exercise in slow motion with the avatar. Can choose any exercise. Teaching points available.	4.1 Instruction on how to perform a behaviour 6.1 Demonstration of the behaviour
PATHway technical support	Provision of a helpline number and PATHway support website to address any user issues encountered.	3.2 Social support (practical)
PATHway training videos/manual	Training videos and step guides for all components provided ready loaded on PATHway laptops.	4.1 Instruction on how to perform a behaviour 6.1 Demonstration of the behaviour
Sensor instructions	On-screen animations and instructions for wearing prior to use.	4.1 Instruction on how to perform a behaviour 6.1 Demonstration of the behaviour
On-screen visual/Verbal avatar instructions	Avatar issues audio and text instructions prior to exercise.	4.1 Instruction on how to perform a behaviour 6.1 Demonstration of the behaviour
Exercise prescription	Exercise prescription is available for participants on personal dashboard.	9.1 Credible source 1.1 Goal setting (behaviour) 1.3 Goal setting (outcome) 1.4 Action planning
PATHway exerclass/exergame/active lifestyle	Different PA options (i.e., a traditional exercise class, an exercise based game or active lifestyle options.)	6.1 Demonstration of the behaviour

PATHway multi-player class	Multi-player class of up to 4 people. Allows participants to speak before, during and after exercise to facilitate social interaction.	6.1 Demonstration of the behaviour 12.2 Restructuring the social environment 3.1 Social support (un-specified)
On-screen positive reinforcement during Exerclass (exercise accuracy)	Visual cues on exercise accuracy during ExerClass through different levels of positive reinforcement.	2.2 Feedback on behaviour
End of Exercise summary feedback	Summary at the end of an exercise session including duration, average HR, exercise accuracy.	2.2 Feedback on behaviour
MyHealthy Lifestyle content	Basic and advanced content on each healthy lifestyle area	5.1 Information about health consequences 5.6 Information about emotional consequences
MyHealthyLifestyle content (Ask the Expert videos, Peer videos)	Video content from experts in each healthy lifestyle area.	9.1 Credible source 5.1 Information about health consequences 5.6 Information about emotional consequences
Sensor physiological feedback (i.e., Microsoft band 2, Blood pressure monitor).	Physiological feedback (e.g., heart rate, steps, kcal, blood pressure,).	2.6 Biofeedback 7.1 Prompts/ cues 2.3 Self-monitoring of behaviour 2.2 Feedback on behaviour
Exercise adaptation	Individually tailored exercise programme, both in terms of exercise type and exercise intensity, delivered through PATHway decision support system.	2.6 Biofeedback 8.7 Graded task
Health behaviour change notifications	Optional SMS/emails/ notifications sent to participant. Notifications available for all lifestyle behaviours. Advice and tailored feedback provided.	(full library created with individual notifications mapped to BCTs)
Lifestyle Assessment	Questionnaires to assess if a lifestyle change should be recommended to the participant.	1.6 Discrepancy between current behaviour and goal
Good Habits visualization	Visual display of all risk factors allocated into categories (Well done, Room for improvement, Make a change) to exhibit what behaviours are deemed priorities from the lifestyle assessment.	1.5 Review behaviour goal (s) 2.2 Feedback on behaviour
Behavioural change assessment	4 questions available through the system to assess a participants' readiness to change a selected behaviour.	1.2 Problem solving
Health behaviour change Goal Selection	Following the behavioural change assessment, a goal is suggested by the PATHway system? If we add this, do we need to add for all?	8.7 Graded task 1.1 Goal setting (behaviour) 1.3 Goal setting (outcome) 15.3 Focus on past success
PATHway dashboard (Front end)	Visualisation of data on a personalised dashboard (exercise information, goal information etc.)	2.6 Biofeedback 8.7 Graded task 2.2 Feedback on behaviour

visualisation of PATHway use)		
Calendar logging of health behaviours	Function available on the dashboard to log smoking and healthy eating behaviour.	2.3 Self-monitoring of behaviour 15.3 Focus on past success
Health and fitness assessment	Three-monthly timed assessment at rest and during step test available to allow self-monitoring of progress.	1.7 Review outcome goal (s) 2.4 Self-monitoring of outcome (s) of behaviour 2.7 Feedback on outcome (s) of behaviour
PATHway calendar for events/exercise sessions	Calendar to create, notify and respond to exercise sessions and events for group participation.	1.1 Goal setting (behaviour) 7.1 Prompts/ cues

Table 2. Results of the usability test performed on the first prototype.

	Effectiveness	Efficiency	Engaging	Error Tolerance	Ease of Learning
Home Platform Access	98,2%	100,0%	100,0%	100,0%	100,0%
Home Exercising - Single User ExerClass	88%	99%	66%	93%	84%
Home Exercising - ExerGame	85%	96%	64%	80%	87%
Home Exercising - Exercise Practice	100%	98%	86%	97%	98%
Home Exercising - Active Lifestyle Activity.	60%	93%	85%		100%
Usage Reporting	100%	100%	100%		100%
Assessment	99%	92%	80%	63%	88%
Behavioural Change	87%	88%	74%	100%	100%
Preference Settings	100%	98%	93%	100%	97%
Average	91%	96%	83%	90%	95%

Additional file 1: Theory mapping-linking each PATHway feature with appropriate theory and techniques

PATHway feature	Description	COM-B	BCW- Intervention functions	Policy categories	BCTs used	SCT construct
PATHway familiarization phase	Phase within hospital based cardiac rehabilitation where participants learn to use the system during their usual CR classes prior to remote use at home.	Capability-physical Capability-psychological Opportunity-social	Training Enablement, Education Modelling	Guidelines Service provision	4.1 Instruction on how to perform a behaviour 6.1 Demonstration of the behaviour 9.1 Credible source 3.2 Social support (practical) 3.1 Social support (un-specified)	Knowledge Perceived self-efficacy
Practice individual exercise	Function to practice each exercise in slow motion with the avatar. Can choose any exercise. Teaching points available.	Capability-psychological	Training Education	-	4.1 Instruction on how to perform a behaviour 6.1 Demonstration of the behaviour	Knowledge Perceived self-efficacy Perceived facilitators/impediments
PATHway technical support	Provision of a helpline number to address any user issues encountered	Capability-psychological	Training,	Service provision	3.2 Social support (practical)	Knowledge Perceived self-efficacy Perceived facilitators/impediments

PATHway training videos/manual	Training videos and step guides for all components provided ready loaded on PATHway laptops.	Capability- psychological	Training, Education	Guidelines	4.1 Instruction on how to perform a behaviour 6.1 Demonstration of the behaviour	Knowledge Perceived self-efficacy Perceived facilitators/impediments
Sensor instructions	On-screen animations and instructions for wearing prior to use.	Capability- psychological	Training	-	4.1 Instruction on how to perform a behaviour 6.1 Demonstration of the behaviour	Knowledge Perceived self-efficacy Perceived facilitators/impediments
On-screen visual/Verbal avatar instructions	Avatar issues audio and instructions prior to exercise.	Capability- psychological	Education Modelling	-	4.1 Instruction on how to perform a behaviour 6.1 Demonstration of the behaviour	Knowledge Perceived self-efficacy Perceived facilitators/impediments
Exercise prescription	Exercise prescription is available for participants on personal dashboard.	Motivation- reflective	Enablement	Guidelines	9.1 Credible source 1.1 Goal setting (behaviour) 1.3 Goal setting (outcome) 1.4 Action planning	Goals Outcome expectations
Face to face exercise consultation	At 0 months exercise consultation is conducted.	Capability- psychological Motivation- reflective	Enablement, Education	Service provision	9.2 Credible source	Goals Perceived facilitators/impediments

					1.3 Goal setting (behaviour) 1.4 Problem solving 1.3 Goal setting (outcome) 1.4 Action planning 5.1 Information about health consequences 5.6 Information about emotional consequences 3.1 Social support (un-specified) 15.3 Focus on past success	Outcome expectations
PATHway exerclass/exergame/active lifestyle	Different PA options (i.e., a traditional exercise class, a exercise based game or active lifestyle options.)	Opportunity	Enablement	-	6.1 Demonstration of the behaviour	Perceived facilitators/impediments
PATHway multi-player class	Multi-player class of up to 4 people. Allows participants to speak before, during and after exercise to facilitate social interaction.	Opportunity-social	Enablement, Environmental restructuring Modelling	-	6.1 Demonstration of the behaviour 12.2 Restructuring the social environment	Perceived facilitators/impediments

					3.1 Social support (un-specified)	
On-screen positive reinforcement during Exerclass (related to exercise accuracy)	Visual cues on exercise accuracy during ExerClass through different levels of positive reinforcement (Good Job, Well Done, Excellent)	Motivation-automatic	Persuasion	-	2.2 Feedback on behaviour	Perceived facilitators/impediments Perceived self-efficacy
End of Exercise summary feedback	Summary at the end of an exercise session including (minutes, HR.....)	Motivation-reflective	Education Persuasion	-	2.2 Feedback on behaviour	Goals Outcome expectations
MyHealthy Lifestyle content	Basic and advanced content on each CVD risk factor.	Motivation-reflective	Education Enablement	Guidelines	5.1 Information about health consequences 5.6 Information about emotional consequences	Knowledge Perceived self-efficacy
MyHealthyLifestyle content (Ask the Expert videos)	Video content from experts in each CVD risk factor area.	Motivation-reflective	Education	Guidelines	9.1 Credible source 5.1 Information about health consequences 5.6 Information about emotional consequences	Knowledge Perceived self-efficacy
Sensor physiological feedback (i.e., Microsoft band 2,	Physiological feedback (e.g., heart rate, steps, kcal, blood	Motivation-automatic Capability-physical	Enablement Education	-	2.6 Biofeedback 7.1 Prompts/ cues	Knowledge Perceived facilitators/impediments Perceived self-efficacy

Blood pressure monitor, Zensor).	pressure, heart rhythm).				2.3 Self-monitoring of behaviour 2.2 Feedback on behaviour	Goals Outcome expectations
Exercise adaptation	Heart rate controlled exercise programme delivered through decision support system.	Motivation-automatic Capability-physical	Enablement	-	2.6 Biofeedback 8.8 Graded task	Perceived self-efficacy
Health behaviour change notifications	SMS/emails/PATHway notifications (depending on preference) sent to participant. Notifications available for all risk factors. Advice and tailored feedback provided.	(full library created with individual notifications mapped to BCTs)	Enablement Persuasion	-	(full library created with individual notifications mapped to BCTs)	Knowledge Perceived facilitators/impediments Perceived self-efficacy Goals Outcome expectations
Lifestyle Assessment	Questionnaires to assess if a lifestyle change should be recommended to the participant.	Motivation-reflective	Education	-	1.6 Discrepancy between current behaviour and goal	Goals Outcome expectations
Good Habits visualization	Visual display of all risk factors allocated into categories (Well done, Room for improvement, Make a change) to exhibit what behaviours are deemed priorities from the lifestyle assessment.	Motivation-reflective Motivation-automatic	Persuasion, Education	Guidelines	1.5 Review behaviour goal (s) 2.2 Feedback on behaviour	Goals Outcome expectations

Behavioural change assessment	4 questions to assess a participants readiness to change a selected behaviour.	Motivation-reflective	Persuasion, Enablement	-	1.2 Problem solving	Goals
Health behaviour change Goal Selection	Following the behavioural change assessment, a goal is suggested.	Motivation-reflective	Enablement	-	8.8 Graded task 1.2 Goal setting (behaviour) 1.3 Goal setting (outcome) 15.3 Focus on past success	Goals Outcome expectations
PATHway dashboard (Front end visualisation of PATHway use)	Visualisation of data on a personalised dashboard (exercise information, goal information etc.)	Capability-psychological Motivation-reflective	Education, Persuasion	-	2.7 Biofeedback 8.7 Graded task 2.2 Feedback on behaviour	Goals Outcome expectations
Calendar logging of health behaviours	Function available on the dashboard to log smoking and healthy eating behaviour.	Motivation-reflective	Education	-	2.3 Self-monitoring of behaviour 15.3 Focus on past success	Goals Outcome expectations
Health and fitness assessment	Monthly timed step test available to allow self-monitoring of progress.	Motivation-reflective	Education Persuasion	Guidelines	1.7 Review outcome goal (s) 2.4 Self-monitoring of outcome (s) of behaviour 2.7 Feedback on outcome (s) of behaviour	Goals Outcome expectations

PATHway calendar for events/exercise sessions	Calendar to create, notify and respond to exercise sessions and events for group participation.	Motivation-automatic Opportunity-social	Environmental restructuring	Social planning	1.2 Goal setting (behaviour) 7.1 Prompts/cues	Goals Outcome expectations

Additional file 2: Selected Iterative PATHway Design feedback

PATHway feature	Participant identified issue	Illustrative Quote	Final resulting action
Round 1			
Avatar	Needs to look more human	'I don't know what's wrong with it [too rectangular, strange angle in the legs]'	Further refinement in visualisation techniques

PATHway background	Need to make the background less distracting	'it doesn't have to be blank completely because; also it can be pleasant, just it shouldn't distract us'.	Graphic features not relevant for an exercise room (e.g., car in background) were removed
On-screen text	Improve clarity of on-screen writing	'To be honest with you I think the purpose of this is to give information, not to have a pretty design necessarily. So I think whatever makes the information stand out the most should be what's regarded'.	Greater contrast between text and background
ExerGame	Unclear how to play the game	'I'd like a page where there's the instructions of how to play the game before the game starts because you had to tell us what was going to happen there; how would we know otherwise unless we had some kind of...lead in to it'.	Instructions available prior to ExerGame start
Exercise accuracy	Threshold too high for participants new to exercise	'To have somebody telling you that your quality is low is negative; I think it should try and get you to, encourage you to improve it rather than tell you that'.	Reduce accuracy thresholds
Dashboard progress display	Speedometer style feedback along with the traffic light concept	'You're measuring the same thing right through you know? And a bar...The red to fifty per cent and orange then to [green], Researcher: So in one arch we'd have the three colours?] Yes'.	One speedometer recommended for ease-of-use, rather than three separate ones for red, orange and green
Dashboard Graphs	Traffic light colours being used in regular graphs where no meaning is associated with the colour is confusing.	'The colour needs to mean the same thing throughout. To me if I look at that, green means I've achieved something, amber means I haven't quite achieved something and I'm confused why blue is there in that event'	Any colours on graphs not associated with the traffic light concept, should not be green, red or orange.

Icons used in progress section	Icons can be too negative and demotivating	'I don't like the thumbs down things there because I think are people who mightn't be capable of doing 10000 so 6000 for them would be very good, I know they're random figures but I don't think the thumbs down is helpful'	Remove thumbs down icons
Calendar Function	Would like the calendar to be used to timetable exercise	'I find this interesting. I am still working, so if I can really plan my exercise at 14h, it will help me do it'	Allow calendar for exercise scheduling
Social interaction	Concerns over speaking with strangers	'I have no need to talk with each other directly, but I can imagine younger people would like this'	Multi-player classes optional
Leader board	Issues of anonymity and comparison with others who are at a different level.	' would look to my score in comparison with other players. Ideally it would be players with my age, gender...'	Removal of leader board feature
Upload of data from sensors	Difficulty having the discipline to upload data	'If it works with Wi-Fi or blue-tooth and you don't have to do a thing then patients don't care that data are synced daily with their PC.'	Make this process as stream-lined as possible
MyHealthylifestyle	Recipes missing from the content	'It would be interesting to know what kind of products are better to use for cooking'	Inclusion of recipes into Healthy eating content
Round 2			
PATHway feature	Participant identified issue	Illustrative Quote	Final resulting action
Exergame	The sensor is too sensitive	'You have to be fast with that little hand, there is not much time to move it away'	Removal of feature, use keyboard instead
MyHealthy lifestyle	Need more targeted advanced information	'Theory and practical tips. I want the complete picture'	Provide tab with advanced information as well as the basic content

Videos in MyHealthyLifestyle section	Videos need to be relatable	'you'd have to have different ones you know. More than one video. Maybe one from an older person's point of view'	Several videos made available
Health Behaviour change notifications	Do not want to be bothered by messages which are too frequent	'I don't want to hear every day that I still did nothing'	Can choose the medium to be contacted by in user preferences (i.e., on the PATHway system, SMS or email).
	Tone of the message	'Well done is fine but I think it's a little bit patronising or something. Even congratulations is fine...It's just...It'd be alright for kids...It's like telling a baby to clap hands, I don't know what it does to me...'	Create library content with user requirements in mind esp. ensure that 'Applaud' messages are not patronising
	Only positive feedback	'If I was you I wouldn't play for police. Only positive feedback should be given.'	Do not include any negative feedback
	What happens if you were away and didn't want to receive messages	'You never know the exact reason why someone didn't train. Maybe someone close died.'	Allow participants to turn on/off the notifications
Round 3			
PATHway feature	Participant identified issue	Illustrative Quote	Final resulting action
Avatar	Speed of the exercises	'Can you change the speed of the exercises? One exercise was really fast and the next one was rather slow'	Calibrate this during user testing with participants. Mixed feedback on exercise speed.
Zensor during health and fitness assessment	Need to be able to understand the readings	'You could print them off and bring them to the GP, I know my go does mine for me and I know she would be able to look at it and say 'I'm not happy with this'	Zensor data available to view on the clinical interface

ExerGame	Would like the levels to move quickly, would rather a shorter time period for the game.	'I think it being shorter for game purposes is probably better, 'cos the object of any game [now I wouldn't be into games myself] is to get through the levels as quickly and efficiently as you can and if you start dragging it out they could sort of lose some of the interest'.	ExerGames recommended to be shorter in duration
Home progress testing	Necessary to see how they really think about the system	'When we could test it at home for a longer period of time, the real bugs/problems would become clear'	In-built familiarisation phase into the intervention period for both patients and staff
Health and fitness assessment	Mixed opinion on having a monthly exercise progress test (step test/ 6MWT)	'If it is a part of long-term follow-up I would prefer a scheduled appointment with a professional once in a while' 'Can't the system estimate my fitness by giving me the same session once in a while and assess my heart rate during those exercises?'	Have reminders, but these are optional
Training manual	Want hard copy and electronic version	'It's always better to have it in hard copy rather than on a screen'	Both versions available to participant upon recruitment
	Step by step guide	'You would want to do the 'ladybird' version [children's books] with simple one liners'	available to participant upon recruitment
	Getting started section	'With anything you usually get a basic 'get you started section', just with a page at the start about connections and they are usually quite easy to follow...'	available to participant upon recruitment
	Need IT support	'Either that [support over the phone] or by email or both, just someone you can contact'	Available to participant. Exact nature of IT support pending budget
	Need FAQ section	'There absolutely has to be a trouble shooting section'.	Available to participant

Additional file 3: Selected Stakeholder Expert panel feedback with resulting action

PATHway feature	Description of Expert Feedback	Illustrative Quote	Recommendation/how it is addressed within PATHway system.
General PATHway system	Will participants have the technological skill to use PATHway	'my concern would be...a lot of the older people are not good at IT and that would be the one thing that I would be apprehensive about'.	Report detailing interest from Buys et al. (2016).
	Could be issues seeing the avatar if the screen is too small	'If somebody is watching that on a laptop some of the movements seem to be quite small...is there any scope for connecting to a TV?'	Providing HDMI cables not possible within project budget.

	Combat lack of services outside urban areas	'when they are finished cardiac rehab they would love to have something else to follow on, so this would be very good, that we would have that for them'	Consider future dissemination and implementation plans outside of the city.
	Lack of GP input in the system thus far.	'I was struck by the absence of the role of the GP so far in it, and that may be quite deliberate, sometimes I think GPs can be barriers to this kind of stuff'	GP's were included in the individual interviews [reported separately].
	Theory mapping -> BCW Policy categories are not addressed.	'I recognise the process you have gone through and I think it is very good, I just wonder why you don't have policy categories?'	Policy categories added.
Exercise library	Exercises need to be age friendly.	'exercises need to be age-tailored, very definitely, what happens if you see something like that [high leg extension] is you turn it off and say this isn't for me-I can't do that'	Exercises reviewed for appropriateness.
Accuracy of exercises	Teaching points on how to perform exercises need to be included	'It keeps on commenting on my accuracy and telling me I'm not accurate but it doesn't tell me why or what I need to do differently to be more accurate?'	Reduce accuracy level; unable to build in teaching points during ExerClass, however Practice Individual exercise function available which has teaching points.
Pre-screening questions	Keep 'Did you take your medication today?' question.	'There was a very nice question there 'did you take your tablets today' and that is crucial in rehab...people die because of not taking tablets'.	Keep the medication adherence question as part of screening. Medication adherence also is an available health behaviour change goal that can activate daily reminders.
Familiarisation phase	Induction and support is key to the introduction of the system to participants.	'People are actually capable of doing a lot, depending on the induction, and that brings us back to where the induction is going to take place. Cardiac rehab in the hospitals and in the hospital setting is under severe pressure'	Familiarisation phase will be implemented. Training manuals provided. Staffing provided.
Exercise prescription	Who prescribes the exercises? Would have an issue if this was just done by the computer. Human	Noted during presentation; not recorded	Clinician and participant input into exercise prescription to be reviewed at each testing stage. Exercise preferences can also be tailored by the participant.

	choice is very important factor, so that the exercises can be altered.		
Zensor-during Health and fitness assessment	Could be ideal for some but not all. Concern over who is going to analyses the ECGs.	Noted during presentation; not recorded	Zensor readings available to health professionals on clinical interface.
Health behaviour change Goal Selection	In CR, exercise has been the basis from which the other lifestyle components have been modelled. These lifestyle components are just as important as the exercise.	Noted during presentation; not recorded	Need to emphasise goal setting among all health behaviours.
MyHealthyLifestyle	Need to consider depression and sexual activity/sexual functioning in the PATHway system.	Noted during presentation; not recorded	Module to be created in relation to sexual activity and functioning. Stress management component to be extended to ensure mental health and well-being elements are catered for.
Leader board	Wouldn't encourage competition	'we wouldn't encourage competition...because I have a totally different competition to someone else and we wouldn't encourage our patients to compete'.	Leader board removed.
On-screen text	Language is too formal in the system	'Some of the language seemed...a little bit formal...it should be designed to be something that you can relate to very easily and very quickly'	All on-screen text reviewed.
Health behaviour change notifications	Important to have prompts and cues	'If you are encouraging people to re-engage, you know those people who fall off, the nudging process, the notification process, whatever that is [important]'	Encourage participants to keep notifications turned on in preferences.
Exercise consultation	Need face-to-face meetings.	'I would be urging you to think about placing it within the context of, finding a parallel face-to-face solution as well, that it is linked with.'	Baseline consultation on how to use the PATHway system implemented within the familiarisation phase.
Social interaction	Peer support- seen as vital for continued participant engagement.	'I'm not sure how much reliance you can place on those community links...how much reliance can you put on peer support to achieve the results you want, I am not	Encourage the use of the multi-player class and calendar functions when planning in exercise consultation.

		sure people will end up with a very large peer support group 6months down the line'.	
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Additional File 4



Template for Intervention Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist

Information to include when describing an intervention and the location of the information

Item number	Item
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BRIEF NAME

1. Provide the name or a phrase that describes the intervention.

PATHway: Technology-enabled behaviour change as a pathway towards the better self-management of cardiovascular disease (CVD).

WHY

2. Describe any rationale, theory, or goal of the elements essential to the intervention.

The PATHway intervention was developed using the Behaviour Change Wheel and SCT approach. It aims to increase levels of active energy expenditure in individuals with CVD following hospital based cardiac rehabilitation (CR). Additionally, Secondary outcomes include cardiopulmonary endurance capacity, muscle strength, body composition, cardiovascular risk factors, peripheral endothelial vascular function, patient satisfaction, health related quality of live (HRQoL), wellbeing, mediators of behaviour change and safety.

WHAT

3. Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).

The PATHway intervention includes:

- (1) Technology components: a portable PC including PATHway software, Microsoft Kinect® camera, Microsoft Band 2 heart rate monitor, Blood pressure device, Zensor 3-lead ECG device)
Development of the PATHway content described in current paper.
- (2) Familiarisation phase: Four familiarisation classes conducted with user (checklist available in Additional File 2)
- (3) Support materials: User Manual, How to videos, FAQ guide.

Further details are provided in the PATHway RCT protocol paper.

4. Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.

The PATHway intervention consists of the potential delivery of 22 BCTs to participants. The PATHway intervention will support participants to better self-manage CVD and lifestyle behaviours. A portable PC including PATHway software will be provided to participants and familiarisation classes will be provided.

WHO PROVIDED

5. For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.

Criteria for the PATHway team member:

1. Be trained in the use of the PATHway system.
2. Have experience with dealing with patients with cardiovascular disease particularly around maintenance of recommended levels of physical activity.
3. Be able to advise on acceptability or feasibility issues with the intervention and study protocol.

HOW

6. Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.

The PATHway intervention is a technology-enabled intervention and will be delivered remotely, following four face-to-face familiarisation classes.

WHERE

7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	The PATHway familiarisation classes will be delivered at cardiac rehabilitation hospital centres. The PATHway system will be installed within the participants homes from the first familiarisation class.
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WHEN and HOW MUCH

8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	As an eHealth intervention, PATHway is available to participants when desired from the point of familiarisation, as the content is readily accessible via technology in their own home at any point. Following four 1-hour familiarisation classes, participants should be confident to use any of the PATHway functions as desired.
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TAILORING

9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	N/A (intervention not yet delivered).
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MODIFICATIONS

10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	N/A (intervention not yet delivered).
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HOW WELL

11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Fidelity of intervention delivery will be assessed using usage statistics and de-brief interviews. Further details are provided in the PATHway RCT protocol paper.
12.†	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	N/A (intervention not yet delivered).

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use ‘?’ if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement**. When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

Additional file 5: PATHway consultation script

PATHway consultation

When: to be conducted at baseline testing with intervention group only

Note: RCT questionnaires need to be completed prior to the PATHway consultation.

Time spent: approx. 15 minutes

Semi-structured script:

1. Greetings and introduction
2. Discuss participant's previous physical activity history
3. Review PATHway Exercise Prescription with participant
4. I can see from your questionnaires that you currently do X minutes per week currently, and our recommendation is Y minutes per week.
 - a. Do you think this exercise prescription is feasible for you?
5. How do you think PATHway can help you to meet this exercise prescription?
 - a. Brainstorm and list pros of Using PATHway to help you meet exercise prescription
6. Can you think of any barriers Barriers to using PATHway to help you meet PA goals
 - a. Brainstorm and list barriers. We will also raise PATHway specific barriers e.g. no internet connection, MSB2 does not work, but also some PATHway exercise barriers e.g. I cannot get the exercise class exercises to match what I like.
7. How do you think you can try and overcome these barriers?
 - a. Developing self-efficacy strategies here (i.e., collaboratively discuss solutions [participant lead] or options to enhance self-efficacy around facing identified barriers).
8. So how do you feel after discussing the pros and cons- are you content with your prescription or do you feel you need to revise the goals?
 - a. Confirm goals with participant
9. As you know it can be difficult to remain active long term, so now I want us to consider putting plans in place for times where there are unavoidable lapses but also for when you are finding it difficult to maintain your exercise prescription.
 - a. It's important to remember that a lapse does not have to mean a relapse to sedentary behaviour
 - b. identify possible high risk situations and coping strategies.
10. Finish up, thank you etc.

Additional file 6: Sample health behaviour change notifications and associated BCTs.

Health behavior change notification	Behaviour change techniques
1) Well done! You've completed X minutes of physical activity this week. Think about adding in an Exerclass or Exergame into your week to keep active!	3.1 Social support (unspecified), 3.2 social support (practical), 4.1 instruction on how to perform the behaviour, 10.4 Social reward
2) Great work this week! So far you've completed X Exerclasses, X Exergames, and X minutes of physical activity. You're doing great and one step closer to your weekly goal!	3.1 Social support (unspecified), 2.2 feedback on behaviour, 10.4 Social reward
3) You're doing great this week with your physical activity! Try adding an Exerclass or Exergame to keep going this week.	3.1 Social support (unspecified), 3.2 social support (practical), 4.1 instruction on how to perform the behaviour, 10.4 Social reward
4) You've nearly reached your physical activity goal of X minutes for the week! Keep up the great work you've only two more days.	3.1 Social support (unspecified), 2.2 feedback on behaviour, 10.4 Social reward
5) You have X minutes left of your weekly goal of X minutes of physical activity left! You can reach your goal this week, keep up the good work!	2.2 feedback on behaviour, 3.1 Social support (unspecified), 10.4 Social reward, 15.1 verbal persuasion about capability

Additional file 7: Selected screenshots of PATHway

Example of the prototype good habits visualisation interface:



Example of the prototype ExerClass:



Example of the prototype Exergame:

