Reducing patient delay in Acute Coronary Syndrome (RAPiD)

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Title

Reducing patient delay in Acute Coronary Syndrome (RAPiD): Research protocol for a web-based Randomised Controlled Trial examining the effect of a behaviour change intervention.

Running head

Reducing patient delay in Acute Coronary Syndrome (The RAPiD Trial)

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Authors' contributions
This paper was originally drafted by BF and PA and revised following review by MJ, BW, KS, SD, ST and ND.

Title

Reducing patient delay in Acute Coronary Syndrome (RAPiD): Research protocol for a web-based Randomised Controlled Trial examining the effect of a behaviour change intervention on participants' intentions to seek help.

Abstract

Aims

To evaluate the efficacy of a behaviour change technique-based intervention and compare two possible modes of delivery (text+visual and text-only) with usual care.

Background

Patient delay prevents many people from achieving optimal benefit of time-dependent treatments for Acute Coronary Syndrome. Reducing delay would reduce mortality and

morbidity, but interventions to change behaviour have had mixed results. Systematic inclusion of behaviour change techniques or a visual mode of delivery might improve the efficacy of interventions.

Design

A 3-arm web-based, parallel randomised controlled trial of a theory-based intervention.

Methods

The intervention comprises 12 behaviour change techniques systematically identified following systematic review and a consensus exercise undertaken with behaviour change experts. We aim to recruit n=177 participants who have experienced Acute Coronary Syndrome in the previous 6 months from a National Health Service Hospital. Consenting participants will be randomly allocated in equal numbers to one of three study groups: i) usual care ii) usual care plus text-only behaviour change technique-based intervention or iii) usual care plus text+visual behaviour change technique-based intervention. The primary outcome will be the change in intention to phone an ambulance immediately with symptoms of Acute Coronary Syndrome ≥15 minutes duration, assessed using two randomised series of 8 scenarios representing varied symptoms before and after delivery of the interventions or control condition (usual care). Funding granted January 2014.

Discussion

Positive results changing intentions would lead to a randomised controlled trial of the behaviour change intervention in clinical practice, assessing patient delay in the event of actual symptoms.

Trial registration: Registered at Clinicaltrials.gov: NCT02820103

Keywords: Acute Coronary Syndrome; ACS; delay; patient delay; behaviour; behaviour change; BCT; cardiac; nursing; intervention

Summary statement

Why this study is needed

- It is unclear what the essential 'active ingredients' of an intervention to reduce delay with symptoms of Acute Coronary Syndrome are.

- It is unclear whether Behaviour Change Technique-based interventions are more effective than usual care and whether a visual mode of delivery is more effective than text-only.

INTRODUCTION

Early access to advanced life support and treatment is critical to reducing mortality and morbidity in Acute Coronary Syndrome (ACS). However, the benefits of treatment are time-dependent with maximum benefit achieved when treatment is given within 2 hours of symptom onset (Boersma, 2006, Steg et al., 2012). However, delay to receipt of treatment remains common worldwide (Steg et al., 2012, Dracup et al., 2003) with reported average time-to-treatment ranging from 1 to over 7 hrs (Farquharson et al. *under review*). A very recent randomised controlled trial (RCT) conducted in Ireland (Mooney et al., 2014) reported median pre-hospital time of 7hrs 10 mins providing contemporary evidence that delay times remain well out-with the ideal.

Significant efforts by emergency and acute care services to facilitate rapid transport, diagnosis and treatment of patients with ACS have minimised door-treatment time recently (Schiele et al., 2010). The interval that contributes most to pre-hospital time has been identified as 'patient delay' i.e. the interval between onset of symptoms and seeking medical help ((GISSI), 1995) and this has remained largely unchanged (Schiele et al., 2010, Saczynski et al., 2008). Reducing patient delay could lead to substantial reductions in mortality but to date, interventions have had limited success.

Background

A substantial number of interventions to reduce patient delay in ACS, some large and comprehensive (e.g. REACT (Luepker et al., 2000)), have been evaluated (Mooney et al., 2012). These have included mass media (Luepker et al., 2000, Ho et al., 1989, Moses et al., 1991, Bett et al., 1993, Blohm et al., 1994), community (Luepker et al., 2000) and individual interventions (Mooney et al., 2014, Dracup et al., 2009). There is some evidence that interventions can change attitudes and improve knowledge (Buckley et al., 2007) but disappointingly most have been unsuccessful in changing behaviour (Kainth et al., 2004, Dracup et al., 2009). Recently, Mooney et al. (2014) reported more encouraging results from an RCT of a 40-min individualized educational intervention with 1-month follow-up by telephone. Median patient delay time was significantly lower amongst those who received the intervention compared with the control group (1.7 h vs. 7.1 h; $p \leq .001$). However, the intervention described appears almost identical to that described by Dracup et al. (2009) who conversely did not find a significant difference in delay time between those who received the

intervention and the control group. It therefore remains unclear what the essential 'active ingredients' are for an intervention to reduce patient delay with symptoms of ACS.

Limitations in how behavioural interventions are described in the literature hamper systematic review and replicability (Michie et al., 2009, Davidson et al., 2003). The development and refinement of a taxonomy of Behaviour Change Techniques (BCTTv1) (Michie et al., 2013) has defined 93 BCTs and created a common language for reporting the active content of interventions. BCTTv1 (Michie et al., 2013), comprises an extensive hierarchical classification of clearly labelled, well-defined BCTs with expert consensus that they are proposed, active components of behaviour change interventions. BCTs are distinct (non-overlapping and non-redundant), precise and can therefore be used reliably to describe and replicate interventions.

There is evidence to suggest that embedding evidence-based BCTs (Webb et al., 2010) in interventions can lead to more successful behaviour change. In lung cancer, another condition with time-sensitive medical treatments (Smith et al., 2013, Smith et al., 2012), an intervention based on psychological theory using BCTs has been effective in reducing the time before consulting with symptoms. Thus we intend to develop and test a theory-based intervention with systematically embedded BCTs. The intervention draws on three psychological theories that explain the determinants of patient delay: Leventhal's Commonsense Model of Self-Regulation (1984), the Theory of Planned Behaviour (Ajzen, 1991) and Social Cognitive Theory (Bandura, 1998). According to these theories, patient behaviour in response to symptoms is influenced by their beliefs about the symptoms (i.e. identity/label of the condition, expected timeline, likely cause, consequences and potential for cure or control of symptoms), beliefs about urgent help seeking behaviour (i.e. attitude, perceived social

pressure/norm and perception of control over the behaviour) and beliefs about the ability to perform the behaviour (i.e. self-efficacy). Combining these three theories, we propose that an intervention that a) alters illness representations relating to symptoms of ACS, b) results in more positive attitudes, subjective norm and perceived behavioural control regarding seeking prompt medical help for ACS symptoms and c) enhances self-efficacy in seeking medical help for ACS symptoms immediately will result in people intending to seek help sooner.

In earlier work undertaken as part of the Reducing ACS Patient Delay (RAPiD) study, we systematically developed the intervention using pre-specified, empirical methods (Systematic Review (SR) and consensus study) in parallel to identify potentially useful BCTs. The SR of previous interventions to reduce delay (Farquharson et al., 2014) (Farquharson et al. *under review*) was intended to identify BCTs associated with effective interventions. However, the included studies were too heterogenous to combine statistically and similar BCTs were used in both effective and ineffective interventions and so conclusions about effective BCTs could not be drawn. In parallel with the review, the consensus study (modified Delphi) was conducted with n=12 behaviour change experts. In Round 1 the experts were asked to judge which of the 93 BCTs in the taxonomy might be used to address the three proposed theoretical elements of the intervention and to identify which should be included in an 'ideal' intervention. In Round 2, the results of Round 1 were fed back to the experts and they were then asked to rate each of the 93 BCTs in the BCTTv1 as either 'necessary', 'desirable' and 'probably unnecessary'. Those judged as 'necessary' by the majority of experts were included in the intervention. Twelve BCTs (see Box 1) were identified to be included in the intervention.

The accessibility (Steele et al., 2007), reach (Williams and Cameron, 2009) and effectiveness (Williams and Cameron, 2009) of interventions may also be influenced by the mode of delivery (e.g. visual, text, audio etc.) but there is a lack of evidence on the optimal format (Dombrowski et al. *in press*). It has been suggested that visual images are important in influencing people's responses to health information (Williams and Cameron, 2009), perhaps because they are emotionally evocative, memorable and more concrete than abstract (Leventhal et al., 1984), verbal (or text-only) messages (Paivio et al., 1994). Thus we will create two versions of the intervention (i.e. '*text+visual'* and *'text-only' BCT-based interventions*) and compare both modes to a control condition (usual care information) to examine which is more effective.

In line with Medical Research Council and later guidance (Craig et al., 2008, Eldridge et al., 2016) we first require to examine whether the developed interventions are acceptable and change the targeted behavioural determinants (cognitions) in the manner expected. Thus this protocol describes an Intervention Modelling Experiment (IME) (Bonetti et al., 2005) to test whether the interventions affect proximal predictors of behaviour, in this case 'intentions' about seeking help with symptoms and whether the targeted psychological constructs mediate effects on intention. This study is an RCT of an intervention which uses simulated symptom scenarios to measure changes in intention to phone an ambulance with people who have experienced a recent ACS event.

Patients who have experienced a prior ACS event were chosen as they are at high risk of recurrence (Anderson et al., 2013) and therefore a very important group in which to ensure prompt help-seeking. However, it is also recognised that encouraging people to seek prompt help with symptoms has the potential to increase numbers of unnecessary admissions, thereby exposing patients to risk and incurring additional cost and burden to the NHS. The trial

therefore also tests whether the intervention increases intentions to phone an ambulance for non-serious symptoms such as a sore toe or discomfort passing urine (i.e. checks for unintended consequences). The ultimate goal is to undertake a full scale RCT to test the effectiveness of the developed intervention on changing people's actual behaviour with symptoms of ACS.

THE STUDY

Aims

1. To test the effectiveness of the theory-based interventions (text+visual and text-only BCT-based interventions) against usual care in changing patients' intentions to phone ambulance immediately with symptoms of ACS ≥ 15 minutes duration.
2. To determine the more effective mode of delivery by comparing the text+visual BCT-based intervention and text-only BCT-based intervention, with the usual care group.
3. To investigate any unintended consequences of the intervention on intentions to phone an ambulance for non-life-threatening symptoms.

Research questions

RQ1 How effective are the developed interventions in increasing participants' intentions to phone ambulance immediately with ACS symptoms ≥ 15 mins duration?

a) Is the BCT-based intervention effective in changing intentions to phone an ambulance immediately with ACS symptoms ≥ 15 mins duration? [comparison of (i) usual care (control) *with* (ii) usual care plus BCT-based intervention (combined text-only and text+visual)]

b) Is the text+visual more effective in producing change in intentions than the text-only? [comparison of usual care plus text-only BCT-based intervention and usual care plus text+visual BCT-based intervention]

c) Are the BCT-based interventions (text-only and text+visual) effective in changing the targeted cognitions (i.e. illness representations, attitudes, perceived social norm, perceived behavioural control, self-efficacy) associated with intentions to phone ambulance immediately with ACS symptoms?

d) Are changes in intentions mediated by changes in the targeted cognitions?

RQ2 Do the developed interventions have undesired effects on participants' intentions to phone ambulance immediately for symptoms that are not life-threatening (toe discomfort or dysuria) of ≥15 mins duration?

e) Do the interventions change intentions to phone ambulance immediately for non-life-threatening symptoms? [comparison of (i) usual care (control) *with* (ii) usual care plus BCT-based intervention (combined text-only and text+visual)]

a) Do (i) text-only or (ii) text+visual differ in their effects on intentions for non-life-threatening symptoms (toe discomfort or dysuria)? [comparison of usual care plus text-only BCT-based intervention and usual care plus text+visual BCT-based intervention]

b) Do the interventions change the targeted cognitions (i.e. illness representations, attitudes, perceived social norm, perceived behavioural control, self-efficacy) associated with intentions to phone ambulance immediately for non-life threatening symptoms (toe discomfort or dysuria)

c) Are changes in intentions for non-life threatening symptoms mediated by changes in targeted cognitions?

Methods

Design

An IME conducted as a parallel 3-arm randomised controlled trial. The study will be web-based, conducted via a bespoke web-based solution shown to enable effective delivery and evaluation of behaviour change interventions (Treweek et al., 2014).

In the same online IME session and following data collection of baseline measures, participants (n=177) will be randomly allocated to one of three trial arms (n=59 each arm): i) usual care (information from leaflets used in usual care presented on screen) ii) usual care plus text-only BCT-based intervention or iii) usual care plus text+visual BCT-based intervention. Trial arm allocation will be concealed from all research team members except one (CJ) who will not be involved in data analysis. A randomly selected set of eight scenarios representing varied symptoms (described in more detail below) will be used to assess baseline intention to phone ambulance immediately with symptoms of ACS ≥15 minutes. We will then deliver the intervention or control conditions and use another, different, set of eight randomly selected scenarios to reassess intention to immediately phone an ambulance.

Setting & participants

The population of interest are people who have recently experienced ACS (within the previous six months). Potential participants will be identified via 2 routes – 1) from a specified NHS Board in Scotland (details of study site can be obtained from South East Scotland Research Ethics Committee 01) and 2) via the Scottish Health Research Register

(http://www.registerforshare.org), a register of people (includes over 120,000 individuals Sept 2016) interested in participating in health research and who agree to allow SHARE to use the coded data in their various NHS computer records to check whether they might be suitable for health research studies.

Inclusion criteria

Adults, aged > 18 years, who have experienced ACS within the previous six months

Exclusion criteria

Anyone still admitted to hospital

People who have experienced ACS within the previous two weeks.

Sample size

Using the dependent variable of behavioural intention we will seek to detect an effect size of d=0.66 (95% CI 0.51 to 0.82), identified in a meta-analysis of trials as measuring a 'medium to large' effect on change in intention and behaviour (Webb and Sheeran, 2006), which in turn led to a small to medium change in behaviour itself. We will seek to recruit 59 participants per group (177 total) to have 90% power of detecting an effect size of d=0.66 at a significance level of 0.025.

Recruitment procedures

Recruitment via NHS site

People admitted to the NHS site with confirmed ACS will be identified from hospital records by the local cardiac rehabilitation team and will access three linked databases which contain all the relevant information on in-patients: 1. The cardiac rehabilitation service database

(name, a unique Community Health Index identifier, age, gender, postcode, month of admission, diagnosis, clinical intervention and rehabilitation status). 2. NHS Multi-Disciplinary Information System database (date of event and discharge). 3. NHS Patient Administration System database (patient addresses). The rehabilitation team will search these databases for patients who have experienced an ACS event within the previous six months, but not in the last two weeks. Vital status checks will also be made to ensure patients are still alive and are not currently admitted to hospital for any reason.

A look-up table of patient identifiable information and demographics linked to the unique participant codes will be maintained by the cardiac rehabilitation team only and will not be shared with the research team at the recruitment stage. Once identified, a separate anonymised register of all eligible patients will be created to be accessed by the research team. This will contain a unique identifying code allocated to each eligible patient along with their basic demographic details including age, gender, clinical diagnosis, partial post code and date of event, but no personally identifiable information. This will enable the research team to assess the proportion recruited from those eligible to participate and other reasons for attrition as per CONSORT flow chart for trials (Schulz et al., 2010). Selection bias, i.e. whether the consenting and non-consenting participants differ in important ways will also be assessed by researchers using the key socio demographic and clinical variables. An invitation letter (Appendix 1) prepared by the research team along with the Participant Information Sheet (Appendix 2) will be posted by the cardiac rehabilitation service to all eligible patients. Following a second vital status check, a reminder letter will be posted by the cardiac rehabilitation team two weeks after the original letter to those who have not yet taken part.

Recruitment via SHARE

The SHARE office will identify and approach SHARE registrants who meet the study eligibility criteria (i.e. adults who have experienced ACS in previous 6 months) with a brief description of the proposed study. On receiving an affirmative response from the potential volunteers, their details will be provided to the research team. A letter of invitation along with the Participant Information Sheet will then be posted to the potential volunteers by the research team. A reminder letter will be sent two weeks after the original letter to those who have not yet taken part. Assessment of whether those recruited via the NHS site and SHARE differ in relation to sociodemographic and clinical factors will also be undertaken.

Consent procedure

The invitation letter and Participant Information Sheet sent to potential participants will contain a unique participant code and details of where they can access and take part in the web-based study. Potential participants will be asked to visit the study web-link to confirm consent and take part in the study. They can do this from anywhere they choose and from a range of devices. Those who do not wish to participate will not access the web-link.

Randomisation

Following informed consent, baseline demographic data will be collected before participants are randomly allocated to one of the three study groups. Allocation will be concealed from participants until they receive the intervention. The randomisation will be managed by the web-based study software. To ensure balance across the three groups a random permuted blocks approach will be adopted with seed value recorded. Participants will be randomised to the next available block through the study website.

Intervention

Control Condition (Usual care)

Participants in the control group will receive information that is currently used routinely in the NHS site to inform patients with ACS what to do if they experience symptoms after discharge. The information is provided in the form of two leaflets, labelled 'Using GTN' and a BHF leaflet (see Appendix 3). It explains the symptoms of angina and heart attack and advises what to do in the event of experiencing these symptoms. This information leaflet will be presented in written text format on screen. The usual care information will also be coded for the presence of any BCTs by the two independent BCT coders so that the presence of BCTs in the control condition can be reported for use in future systematic reviews.

Usual care plus Text+Visual BCT-based intervention (Intervention group 1)

Participants in the visual intervention group will receive usual care specified above plus a specifically developed Text+Visual BCT-based intervention, comprising the 12 BCTs identified from the SR and expert consensus study described earlier (see Box 1). The intervention was developed as follows: A draft plan for the intervention was developed by the research team, specifying the key messages, the BCTs and how these might be represented visually. This was shared with an animation team (CR, KD, TP) and professional script-writer (MG) who worked in collaboration to try to develop an engaging narrative and appealing visual style to deliver the BCTs. In an iterative process, this was reviewed and revised in response to feedback from the research team and two separate consultative user groups: one comprising clinicians involved in the care of people with ACS (1 cardiologist, 1 GP and 2 cardiac rehabilitation nurses) and one comprising people with experience of symptoms of ACS and their relatives (n=21). An animated video, just under 8 minutes in length was developed and is hosted online in the IME. The animation contains 9 of the 12

BCTs and tells the 'delay stories' of 3 different characters. It was not possible to deliver all of the 12 BCTs comprehensively in the relatively passive media of the animation as some techniques require active participation from participants (e.g. action planning). Thus n=7 BCTs (1.2 Problem solving; 1.4 Action planning; 5.2 Salience of consequences; 7.1 Prompts/cues; 9.3 Comparative imagining of future outcomes; 15.2 Mental rehearsal of successful performance) are also delivered via short web-based exercises which follow the animation.

Usual care plus text-only BCT-based intervention (Intervention group 2)

Participants in the text-only BCT-based intervention group will receive the usual care specified above plus a text-only BCT-based intervention. This was developed in the same way as the text+visual BCT-based intervention but does not include the visual elements (i.e. animation). Instead, the voiceover from the animated film is displayed in text on screen and narrated in audio. The BCTs which require active engagement are delivered via identical web-based exercises as the text+visual BCT-based intervention.

Checks to test BCTs are reliably present within the interventions

All but one of the BCTs were identified as being reliably present within the intervention by 2 behaviour-change experts, external to the project and blind to the BCTs intended for inclusion (see Appendix 4 for methods for this reliability check and details of how the BCT not identified by experts was modified).

Measures

Self-report questionnaire

Participants will be asked to complete a 30-item questionnaire (Appendix 5) assessing the following:

Socio-demographic information

The following socio-demographic information will be collected - age, ethnic origin, employment status, educational level, marital status and living arrangements. This information will be collected after the participants have consented, but before they are randomised and presented with any scenarios.

Primary outcome measures

Intention: Informed by the Theory of Planned Behaviour (Ajzen, 1991), participants' intentions to phone an ambulance immediately will be assessed in response to each scenario using a single Likert-type item ('*For these symptoms, after this amount of time, I would phone an ambulance immediately'*) scored 1=strongly disagree to 7=strongly agree.

Secondary outcome measures

Illness and symptom perceptions: Participants' illness representations in relation to symptoms presented in each scenario will be assessed using the Brief Illness Perception Questionnaire (B-IPQ) (Broadbent et al., 2006). The questionnaire consists of 9 items assessing the five components that make up a person's perception of their illness – identity (beliefs about the illness label and symptoms), cause (beliefs about factors responsible for causing illness), timeline (beliefs and expectations about the course of illness), consequences (beliefs and expectations about the impact of illness) and cure-control (beliefs about the

efficacy of treatment or coping behaviours). The questionnaire has good test-retest reliability, has been validated among people with Myocardial Infarction (MI) and has been shown able to distinguish between different illnesses (Broadbent et al., 2006).

Cognitive determinants of intention: Informed by the Theory of Planned Behaviour (Ajzen, 1991), the questionnaire will include – three items assessing attitude toward phoning an ambulance immediately using semantic differential scales (e.g. Useless-Useful) scored 1 to 7; three subjective norm items (e.g. people who are important to me think I should phone ambulance immediately in this situation) scored 1=Strongly disagree to 7=Strongly agree; and three perceived behavioural control items (e.g. Phoning an ambulance immediately in this situation is beyond my control) scored 1=Strongly disagree to 7=Strongly agree.

Self-efficacy: Informed by the Social Cognitive Model (Bandura, 1998), people's generic self-efficacy to call an ambulance immediately will be assessed once before and once after the intervention. Participants will be asked to rate how certain they are that they could phone an ambulance immediately in nine different situations which vary in how difficult it would be to phone an ambulance (e.g. if you were out with friends). Responses will be elicited on a scale ranging from 0=not at all certain to 100=highly certain.

Materials used to assess primary and secondary outcomes

Behavioural Intention and Cognitive mediators (Symptom Scenarios)

The study will use scenarios representing varied symptoms before and after the intervention to elicit participants' intentions and cognitions about seeking help. To ensure the scenarios reliably present the intended life-threatening and non-life threatening symptoms, all the scenarios will be independently coded for presence or absence of trigger symptoms by at least

two clinicians from the study's key user group. Scenarios will only be used where both coders agree the trigger is present or absent. To avoid response bias and memory effects, a *range* of symptom scenarios will be used and presented in a random order before and after the intervention so that we can evaluate whether participant intentions and cognitions have changed in the specific context desired.

A pool of 32 symptom scenarios will be created by the research team, (comprising health psychologists, behavioural scientists and cardiac clinicians), by varying the following four variables: –location of discomfort (chest, arm, toe, passing urine), duration of symptoms (>15min, <15min), number of symptoms (single or multiple) and severity of symptoms (mild or severe). These will include 8 'trigger scenarios', where it would be appropriate to call an ambulance (chest or arm discomfort lasting ≥15 minutes, either mild or severe, in isolation or with other symptoms) and 24 'non-trigger scenarios'. Figure 1 shows the possible scenarios for 'discomfort in chest'; similar will follow for arm, toe and passing urine. The pool of 32 scenarios are presented in Appendix 6.

Data collected automatically by the web-platform

The bespoke web-platform will record the following measures:

i) The amount of time spent by participants on the web pages containing the usual care information and the text-only or text+visual BCT-based interventions. This is a likely indication of whether or not participants viewed the presented information and may help explain the findings of the study in terms of timed engagement with the information/intervention (Danaher and Seeley, 2009).

ii) Participants' reaction time when responding to the behavioural intention question on reading each scenario. This measure of promptness/delay in responding could be considered a proxy for the difficulty of the decision and will further enhance our understanding of whether this is affected by the intervention.

Study procedure (Figure 2)

Participants will be asked to open the study web-page by typing in the address provided in the participant information sheet. Alternatively, participants can contact the research team to request the web link via email. The first page will summarise key information about the study and lead to a consent form followed by an introduction page which will provide instructions on completing the task. Participants will be asked to provide baseline socio-demographic information. The study task will involve three phases: before, intervention, after, to be completed within a single study session. We estimate this will take approximately 50-60 minutes per participant.

Before the Intervention

Participants will be first asked to complete the generic self-efficacy questions in relation to phoning an ambulance immediately. Using the software, all participants will then be presented on-screen with a randomly selected series of 8 scenarios (3 trigger scenarios and 5 non-trigger). Following each scenario, they will be asked about their intention to phone an ambulance immediately in response to those symptoms and to complete the following theory-based measures of their cognitions about those symptoms: illness representations in relation to symptoms, attitudes to seeking help immediately, perceived social norm and perceived behavioural control.

The software will randomly allocate participants to one of three study groups: i) usual care (control) ii) usual care plus text-only BCT-based intervention iii) usual care plus text+visual

BCT-based intervention. Allocation will be concealed from participants until they receive the intervention.

Intervention

In the intervention phase, participants are randomised to receive the text-only BCT-based intervention, text+visual BCT-based intervention, or the usual care information only, according to their group allocation.

After the intervention

After participants have seen the relevant intervention appropriate to their randomised group, they will be presented with a randomly selected series of different 8 scenarios to that presented at baseline (3 trigger and 5 non-trigger). Following each scenario, they will be asked about their intention to call an ambulance immediately in response to those symptoms and to complete the measures of cognitions about those symptoms (questionnaire in Appendix 5). To maximise collection of the primary outcome data (i.e. intention) during the post-intervention phase, participants' intentions will be elicited first following each scenario. Following completion of the post-intervention task, participants will be asked to complete the generic self-efficacy questions in relation to phoning an ambulance immediately. At the end of the task, participants will be thanked for taking part.

Data analysis

Two sets of 'total scores' will be calculated for primary and secondary outcomes for both pre- and post- intervention phases. One set will contain the total score for trigger scenarios, derived by taking the mean of scores in response to the three scenarios containing the necessary triggers of an emergency ambulance response. The other set containing the total scores for non-trigger scenarios, derived by taking the mean scores in response to the five

scenarios containing non-trigger symptoms. Descriptive statistics will be used to summarise the primary and secondary outcome measures pre and post-intervention and change in scores.

To assess the effect of intervention on the primary outcome variable intention to seek help immediately, we will compare the three study groups using Analysis of Covariance (ANCOVA) using the baseline level of intention as a covariate. However, this analysis plan will change according to whether the data have skewed distributions and whether non-parametric approaches are more appropriate. It is not possible to specify in advance exactly which approaches will be taken. Planned comparisons will be performed between i) usual care and text-only BCT-based intervention ii) usual care and text+visual BCT-based intervention iii) text-only and text+visual BCT-based interventions. Similar analyses will be performed to test the effect of interventions on the targeted cognitions. Mediation analyses will be performed using methods outlined by Hayes et al. (2009) to assess if the changes in intentions were mediated by changes in the targeted cognitions. Similar analyses will be conducted to assess the undesired effect of the intervention on intention to seek help immediately in response to the non-trigger scenarios.

All analysis will be by intention-to-treat. Any missing outcome data will be dealt with using the approach outlined as best practice by White et al. (2011). This involves comparing those who do and do not complete the study on psychological or demographic characteristics to assess if the data are missing in a systematic or random manner. The data will be assumed to be missing at random if no significant differences were found between those who do and do not complete the study. In this case, appropriate imputation procedures will be applied (preserving the groups as randomly allocated), followed by sensitivity analyses taking into account all randomised participants. All data will be reported in line with CONSORT guidance for statistical reporting of trial data (Schulz et al., 2010) and a CONSORT style flow chart will be provided (http://www.consort-statement.org/). A data monitoring

committee has not been convened as a) there is low risk of harm and b) because participants are in control of when they take part it would be difficult for a committee to intervene in the progress of the trial.

Ethical considerations

Ethical approval

Ethical approval has been provided by the South East Scotland Research Ethics Committee 01, Ref 15/SS/0155 who may audit the trial at any point. Caldicott approval has been obtained the participating hospital. It is not anticipated that any changes to the protocol will be required but if the need does arise, amendments will be detailed at clincialtrials.gov.uk and re-approved by South East Scotland Research Ethics Committee 01.

Informed consent

In recognition of individuals' rights to voluntarily participate in research and to freely consent or decline for their information to be used, full informed consent of all participants will be sought (see Appendix 7 for more detail of procedures and of the risk, burdens and benefits to participants).

Data protection, Security and Confidentiality

All participants will be given a unique code and all data will be attributed to individual participants using this code. Personally identifiable information will only be obtained and used by the research team at the follow-up phase (3 months after intervention) to collect data on participants' actual presentations to health services. To enable collection of the presentation data, the research team require access to participants' names, addresses, GP

practice and unique health record (Community Health Index; CHI) numbers. These data will be requested from the cardiac rehabilitation team for all who participate in the IME and provide consent for the research team to do this.

Identifiable participant data (name and address) will be accessible only to clinical staff and members of the research team directly involved in data collection and management. Identifiable participant information will be stored separately from the participant codes look-up table. Data management, back-up and data analysis will be conducted by members of the research team at their employing University institution. All data will be stored electronically and will only be accessible to the research team with a secure password. Data will be kept securely according to current Data Protection guidelines.

Validity and reliability

The study was subject to rigorous peer review prior to being awarded funding by the Chief Scientist Office. In line with best practice, the protocol is being published ahead of data collection. Both the trial and the intervention are described in accordance with current recommendations (the SPIRIT statement (Chan et al., 2013) and TIDieR template (Hoffmann et al., 2014)).

Discussion

Participants will be offered the opportunity to receive results from the trial and a 'lay summary' of the final report will be made publicly available by the funder (Chief Scientist Office). Results will be submitted for publication in an international, peer-reviewed journal and presented at conferences attended by clinicians and researchers.

Limitations

The approach outlined has several strengths but inevitably some limitations. We acknowledge that what people say they will do in response to hypothetical situations may not translate into the desired behaviour in the event of real-life experience of symptoms. It is important to make clear that changing behaviour without altering intentions to perform that behaviour is highly unlikely (Orbell and Sheeran, 1998) and therefore the successful creation of intentions is a necessary first step. The methods we propose should allow us to secure this crucial first step, a step recommended for evaluating complex interventions (Craig et al., 2008) and importantly, will provide information on mediating processes. We will therefore then be in a strong position to extend our testing to a trial with a behavioural primary outcome measure.

Author Contributions:

All authors have agreed on the final version and meet at least one of the following criteria (recommended by the ICMJE*):

1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;

2) drafting the article or revising it critically for important intellectual content.

* http://www.icmje.org/recommendations/

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Box 1. BCTs identified by consensus (with BCTTv1 number and label)

1.2	Problem solving
1.4	Action planning
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
5.2	Salience of health consequences
7.1	Prompts/cues
9.1	Credible source
9.2	Pro's & Con's
9.3	Comparative imagining of future outcomes
15.2	Mental rehearsal of successful performance

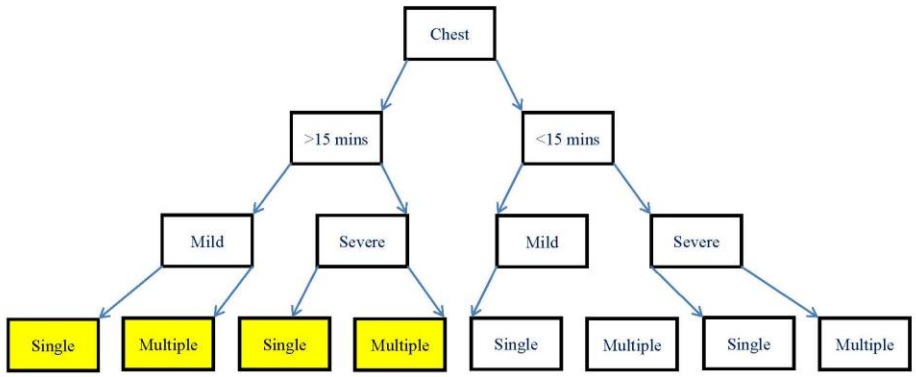
Table 1: Presence of BCTs. Results of expert coding (Intended BCTs highlighted in yellow)

		TEXT-ONLY		TEXT + VISUAL	
		Rater 1	Rater 2	Rater 1	Rater 2
1.1	Goal setting (behavior)	0	0	0	0
1.2	Problem solving	1	1	1	1
1.3	Goal setting (outcome)	0	0	0	0
1.4	Action planning	1	1	1	1
1.5	Review behavior goal(s)	0	0	0	0
1.6	Discrepancy between current behavior and goal	0	0	0	0
1.7	Review outcome goal(s)	0	0	0	0
1.8	Behavioral contract	0	0	0	0
1.9	Commitment	0	0	0	0
2.1	Monitoring of behavior by others without feedback	0	0	0	0
2.2	Feedback on behavior	0	0	0	0
2.3	Self-monitoring of behavior	0	0	0	0
2.4	Self-monitoring of outcome(s) of behavior	0	0	0	0
2.5	Monitoring outcome(s) of behavior by others w/o feedback	0	0	0	0
2.6	Biofeedback	0	0	0	0
2.7	Feedback on outcome(s) of behavior	0	0	0	0
3.1	Social support (unspecified)	0	0	0	0
3.2	Social support (practical)	1	1	1	1
3.3	Social support (emotional)	1	1	1	1
4.1	Instruction on how to perform a behavior	0	1	0	1
4.2	Information about antecedents	1	0	0	0
4.3	Re-attribution	0	0	0	0

4.4	Behavioral experiments	0	0	0	0
5.1	Information about health consequences	1	1	1	1
5.2	Salience of consequences	1	1	1	1
5.3	Information about social and environmental consequences	1	1	1	1
5.4	Monitoring of emotional consequences	0	0	0	0
5.5	Anticipated regret	0	0	0	0
5.6	Information about emotional consequences	0	0	1	1
6.1	Demonstration of the behavior	0	1	1	1
6.2	Social comparison	0	1	0	1
6.3	Information about others' approval	1	0	1	0
7.1	Prompts/cues	1	0	1	0
7.2	Cue signalling reward	0	0	0	0
7.3	Reduce prompts/cues	0	0	0	0
7.4	Remove access to the reward	0	0	0	0
7.5	Remove aversive stimulus	0	0	0	0
7.6	Satiation	0	0	0	0
7.7	Exposure	0	0	0	0
7.8	Associative learning	0	0	0	0
8.1	Behavioral practice/ rehearsal	1	0	1	0
8.2	Behavior substitution	0	0	0	0
8.3	Habit formation	0	0	0	0
8.4	Habit reversal	0	0	0	0
8.5	Overcorrection	0	0	0	0
8.6	Generalisation of a target behavior	0	0	0	0
8.7	Graded tasks	0	0	0	1
9.1	Credible source	1	1	1	1
9.2	Pros and cons	1	1	1	1
9.3	Comparative imagining of future outcomes	1	1	1	1
10.1	Material incentive (behavior)	0	0	0	0
10.2	Material reward (behavior)	0	0	0	0
10.3	Non-specific reward	0	0	0	0
10.4	Social reward	0	0	0	0
10.5	Social incentive	0	0	0	0
10.6	Non-specific incentive	0	0	0	0
10.7	Self-incentive	0	0	0	0
10.8	Incentive (outcome)	0	0	0	0
10.9	Self-reward	0	0	0	0
10.1	Reward (outcome)	0	0	0	0
10.1	Future punishment	0	0	0	0
11.1	Pharmacological support	0	0	0	0
11.2	Reduce negative emotions b	0	0	0	0
11.3	Conserving mental resources	0	0	0	0
11.4	Paradoxical instructions	0	0	0	0
12.1	Restructuring the physical environment	0	0	0	0
12.2	Restructuring the social environment	0	0	0	0

12.3	Avoidance/reducing exposure to cues for the behavior	0	0	0	0
12.4	Distraction	0	0	0	0
12.5	Adding objects to the environment	0	0	0	0
12.6	Body changes	0	0	0	0
13.1	Identification of self as role model	0	0	0	0
13.2	Framing/reframing	0	0	1	0
13.3	Incompatible beliefs	0	0	0	0
13.4	Valued self-identity	0	0	0	0
13.5	Identity associated with changed behavior	0	0	0	0
14.1	Behavior cost	0	0	0	0
14.2	Punishment	0	0	0	0
14.3	Remove reward	0	0	0	0
14.4	Reward approximation	0	0	0	0
14.5	Rewarding completion	0	0	0	0
14.6	Situation-specific reward	0	0	0	0
14.7	Reward incompatible behavior	0	0	0	0
14.8	Reward alternative behavior	0	0	0	0
14.9	Reduce reward frequency	0	0	0	0
14.1	Remove punishment	0	0	0	0
15.1	Verbal persuasion about capability	0	0	0	1
15.2	Mental rehearsal of successful performance	0	0	0	0
15.3	Focus on past success	0	0	0	0
15.4	Self-talk	0	0	0	0
16.1	Imaginary punishment	0	0	0	0
16.2	Imaginary reward	0	0	0	0
16.3	Vicarious consequences	0	0	0	0

Figure 1 Possible symptom scenarios for discomfort in chest. Shaded boxes indicate Trigger scenarios



Flowchart of study