Behavioural intervention to increase physical activity among patients with coronary heart disease: Protocol for a randomised controlled trial

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A B S T R A C T

Background: Although physical activity has significant health benefits in the treatment of patients with coronary heart disease, patients often do not follow prescribed physical activity recommendations. Behavioural strategies have been shown to be efficacious in increasing physical activity among those patients with coronary heart disease who are attending structured cardiac rehabilitation programmes. Research has also shown that tailoring consultation according to patients' needs and sending motivational reminders are successful ways of motivating patients to be physically active. However, there is a lack of evidence for the efficacy of behavioural interventions based on individualised consultation in promoting physical activity among those patients with coronary heart disease who are not attending structured physical activity programmes.

Objective: This paper outlines the study protocol for a trial which is currently underway, to examine the effect of a behavioural change intervention delivered through individualised consultation calls and motivational reminder text messages on the level of physical activity among patients with coronary heart disease.

Setting: Two large hospitals in Jordan.

Participants: Eligible patients aged between 18 and 70 years, who are clinically stable, are able to perform physical activity and who have access to a mobile telephone have been randomly allocated to control or intervention group.

Design and methods: Two-group randomised controlled trial. Behavioural intervention will be compared with usual care in increasing physical activity levels among patients with coronary heart disease. The control group (n = 85) will receive advice from their doctors about physical activity as they would in usual practice. The intervention group (n = 71) will receive the same advice, but will also receive behavioural change intervention (goal-setting, feed-back, self-monitoring) that will be delivered over a period of six months. Intervention will be delivered through individually tailored face-to-face and telephone consultations, supported by motivational SMS text messages to encourage and

remind patients to attain these goals. The participants and the researcher delivering the intervention are not blinded to group assignment.
Results: Recruitment started in February 2012 and preliminary findings are expected in November 2012.
Conclusion: It is hypothesised that behavioural intervention delivered through tailored individualised consultation supported by motivational SMS text message reminders will help CHD patients to increase their level of PA.
Trial registration: The study is registered as a clinical trial at ISRCTN register (ISRCTN48570595).

What is already known about the topic?

- Globally, physical activity among those patients with coronary heart disease who are not attending cardiac rehabilitation programmes is low; effective interventions are required to motivate patients to perform and maintain physical activity.
- Tailored interventions and motivational programs that aim to change behaviour according to patients' needs are known to increase physical activity; yet few interventions have demonstrated their efficacy in well-designed, controlled trials.

What this paper adds

- This paper outlines the protocol and methodology of a randomised controlled trial to examine the efficacy of tailored behavioural intervention in increasing physical activity levels among patients with coronary heart disease.
- To our knowledge this is the first study to implement a multi-component behavioural intervention through individualised consultation and motivational messaging among those patients with coronary heart disease who are not attending structured physical activity programmes.

Background

Physical activity (PA) exists as an important health behaviour for the treatment and prevention of coronary heart disease (CHD) (Balady et al., 2007; Shiroma and Lee, 2010). However, physical inactivity is common among people with CHD (Lear et al., 2003), and most patients who would benefit from participating in PA are not referred to exercise training programmes (Thomas, 2007; Wenger, 2008). Patients with CHD who are not attending structured cardiac rehabilitation programmes (CRPs) may benefit from unstructured interventions to improve their physiological and psychological health. It has previously been documented that home-based CRPs consisting of PA education and self-monitoring can improve systolic blood pressure, mortality and quality of life (Jolly et al., 2006).

In Jordan, which is located in the Middle East, there are no structured PA programmes available to CHD patients. The proportion of CHD patients in Jordan who are sedentary is high, and even greater than that observed in the US. In Jordan, for example, it has been documented that 48% of patients who are not attending CRPs fail to meet PA recommendations (Alsaleh and Alhasan, 2006), compared with 45% in the US (Reid et al., 2006). Therefore, there is a need to develop interventions to increase PA levels among those Jordanian CHD patients

who are not attending structured PA programmes. Physical activity interventions must seek to motivate patients to engage in PA regularly. In addition, there is a need to enhance health care providers' access to those physically inactive patients who are not attending rehabilitation or PA programmes, and this may be achieved through telecommunication, including telephone consultation and mobile phone text messaging.

Behavioural strategies have been influential in increasing PA among CHD patients; such strategies aim to modify individuals' behaviours and their life style choices through goal-setting, feed-back and self-monitoring (Conn et al., 2008; Ferrier et al., 2011). However, few studies have demonstrated the effectiveness of behavioural interventions among those CHD patients who are not attending structured CRPs and PA programmes. Whilst a recent review identified nine trials that have indicated the efficacy of behavioural interventions (goal-setting, self-monitoring, PA prescription) in increasing PA among CHD patients not attending CRPs, these studies were limited scope and provided patients with just one or two face-to-face meetings or consultations. Previous work has been further limited by a lack of ongoing support and follow-up (<12 weeks) provided to patients and also by methodological weaknesses including small sample sizes and poorly described interventions.

One intervention delivery method that has shown efficacy in motivating patients to increase their PA level is the provision of consultation and this is used to encourage individuals to be regularly physically active by applying a client-centred, one-to-one counselling approach (Hughes and Mutrie, 2006). Tailored individualised consultation with patients based on assessment of PA levels, PA types and addressing barriers to being active may be used to motivate patients to develop specific goals according to their needs. To date, the majority of behavioural interventions delivered among CHD patients have not provided individually tailored consultation and have failed to provide patients with on-going support (Furber et al., 2010; Oliveira et al., 2008).

Furthermore, enhancing patients' motivation to initiate and maintain PA is very important in increasing CHD patients' participation in PA programmes. Telephone support and motivational SMS text message reminders have been identified as effective methods of engaging both healthy people, and chronically diseased populations, in PA (Furber et al., 2010; Stolic et al., 2010). However, no previous interventions incorporated these methods for the delivery and support of behavioural interventions designed for motivating CHD patients to be physically active.

Thus, there is a need to develop behavioural intervention that: (a) is able to encourage patients to increase PA by providing them with strategies that motivate them to develop individualised plans including goal-setting and self-monitoring and to receive feed-back; (b) focuses on developing patients' specific needs by providing individualised consultation; (c) is delivered through methods that offer continuous support and follow-up, (e.g. via telephone support and motivational text messages; (d) includes a representative sample size and (e) provides a detailed description of intervention components. This trial will inform the international guidelines about the usefulness of such intervention with those CHD patients who are not attending structured PA programmes in increasing their levels of PA.

The primary aim of this study is to examine the effect of a multi-component behavioural intervention (including goal-setting, self-monitoring, and feed-back) in increasing self-reported PA levels among Jordanian patients with CHD. The secondary aims will be to assess the effectiveness of the behavioural intervention in reducing blood pressure (BP) and body mass index (BMI), and improving quality of life (QOL) and self-efficacy for physical activity. In addition, the study will examine PA correlates among CHD patients including socio-demographic characteristics (e.g. age, gender, income, living status) and health status factors. Patients' perceptions and experiences of the intervention will be investigated post-intervention by a semi-structured questionnaire.

Methods

2.1. Study hypothesis

The main hypothesis of this study is that delivering multi-component behavioural intervention (through individualised goal-setting, self-monitoring, feed-back, follow up and motivational reminders) will improve self-reported PA level.

2.2. Study design and study population

This study is a simple multicentre parallel group randomised controlled trial. The study design is consistent with the guidelines of Consolidated Standards of Reporting Trials (CONSORT) (Schulz et al., 2010). Participants have been recruited between February and April 2012 and the intervention is currently being delivered. The expected completion date for the trial is October 2012. Participants enrolled in this study meet the following eligibility criteria: clinically stable and able to perform PA according to their physician; aged between 18 and 70 years; have access to and ability to use a mobile phone. Those patients who have comorbidities or unstable major health problems which prevent them from participating in PA are excluded from the study. Informed consent was gained from all the participants. The study has been approved by the University of Nottingham Medical School Ethics Committee, and also the Institutional Review Boards at the two participating hospitals (King Abdullah University Hospital and Jordan University Hospital) in Jordan.

2.3. Randomisation and blinding

Group allocation was concealed to the point of randomisation. Randomisation was then conducted using sequentially numbered opaque, sealed envelopes by a researcher who was not involved in the intervention delivery; the researcher who enrolled the participants also assigned them randomly to one of two groups (control and intervention group) and provided the intervention. Baseline data was collected prior to randomisation. Once random allocation had taken place, blinding of participants and researcher was not possible since both are naturally aware of the group allocation due to the level of interaction required for those in the intervention group.

2.4. Power calculation

Based on a previous study, to detect a difference in mean change of PA amount (30 min per week) on the International Physical Activity Questionnaire (IPAQ)

between the control and intervention groups with standard deviation of 60 min (Ferrier et al., 2011) we calculated a total required sample size of 156 participants (both control and intervention groups) with a two-sided 5% significance level and a power of 80%. A 15% attrition rate is expected based on the findings of previous studies (Hansen et al., 2006; Luszczynska, 2006).

3. Data collection and measurement instruments

3.1. Demographic data

Data was collected from control and intervention groups at baseline, prior to randomisation (Time One) between February and April 2012. Follow-up data will be collected six months after baseline data collection (Time Two) between August and October 2012. Demographic data were collected using a socio-demographic and health characteristics questionnaire (including age, gender, income, marital status, living status (where and with whom), educational level, job role, physical health, smoking, medical diagnosis, co-morbidities).

3.2. Primary outcome

The primary outcome is PA level measured by using IPAQ. IPAQ defines walking to include any form of walking from place to place which equals 3.3 metabolic equivalents (METs). Moderate PA is defined as that which needs moderate physical effort and causing some shortness of breath. This equals four METs. (IPAQ can be accessed at http://www.ipaq.ki.se/ipaq.htm). In this trial, participants will be classified as physically active if they meet the recommended PA guidelines of 30 min of moderate intensity activity on at least five days per week (or a total of 150 min per week), or if they engage in a combination of walking and moderate-intensity activities achieving a minimum of at least 600 MET-minutes/week.

3.3. Secondary outcomes

The secondary outcomes include BP, BMI, self-efficacy for PA and QOL. Self-efficacy for PA is assessed using the Exercise Self Efficacy Scale (ESES) (Resnick and Jenkins, 2000). The scale will identify the extent of participants' confidence in performing the required level of PA (regular moderate PA of 30 min on five days per week) by rating their level of confidence for being active in specific situations. QOL is measured by the Mac-New Heart Disease Health-Related Quality of Life Questionnaire which is a self-administered questionnaire designed to evaluate the QOL aspects of physical, emotional and social functioning affected by CHD (Valenti et al., 1996). In addition, patients' perceptions about those aspects of the intervention which meet with success or failure and any barriers to PA which they may face, will be assessed after the intervention by use of a semi-structured survey.

4. Procedure

The control group will receive their usual standard of care and treatment which includes general advice from their physicians about the benefits of PA and methods of being more active. The intervention group will receive advice from their physicians as usual, plus the intervention which consists of tailored behavioural change strategies (for being physically active) delivered over a six month period. This includes a single face-to-face individualised consultation with

the researcher, conducted after collecting baseline data at the patients' home or in the hospital clinic, six telephone call consultations (one call each month) supplemented by 18 motivational SMS text messages reminders (comprised of one message each week for the first three months, followed by one message every two weeks for the final three months. The tailored consultation aims to help participants to integrate moderate PA into their daily routine, for example, performing brisk walking of 30 min daily for a minimum of five days per week and doing muscle strength activities such as shoulder shrug and bent knee push, from 8 to 11 repetitions per set, up to two times per week, as prescribed by international recommendations (Balady et al., 2007; Metkus et al., 2010). Participants are encouraged to develop their PA programme over time. For example, they are advised to take a brisk walk for a duration of 10 min for five days per week, and are instructed to increase the length of PA over time up to 30 min for five days per week (Metkus et al., 2010). The consultation is individually tailored based on the current PA level and needs of every patient. The intervention is guided by Social Cognitive Theory and Self-Efficacy Theory via mediators of health behaviours that are enhanced by giving patients information about the benefits of PA, discussing individual barriers to physical activity and how these might be addressed, and by improving patients' self-efficacy for PA.

5. Intervention

5.1. Individualised consultation

Behavioural strategies are being delivered to patients through individualised consultation in which participants are encouraged to set personal goals and implement self-monitoring in addition to providing them with feedback.
The goals are both short-term (one month), for example 'I will go for a brisk walk five times weekly for 30 min', and longer term (six months), for example 'I will go to work by walking instead of going by car for the next six months'. Self-monitoring includes teaching patients to document their engagement with PA in a diary, including the type and amount of PA they take part in; they are encouraged to revisit this diary and check their PA level at the end of each week. Feedback on progress and discussion of personal goals and diary notes are discussed with the patients through the telephone consultation calls.

5.2. SMS text messages

Periodic 'reminder' text messages are sent to the participants at pre-determined time intervals. These consist of general motivational statements reminding them of their commitment to be more active, encouraging them to achieve their personal goals and helping them to overcome the barriers of PA.

6. Statistical analysis

The data will be analysed by using SPSS statistical software (SPSS, Inc., release 15.0). Analysis will include means and standard deviation for continuous variables and frequencies and percentages to describe categorical variables. Primary outcome measures and secondary measures will be compared between the two groups using independent t-test and chi square. Multivariate analysis will be used to adjust for differences in baseline characteristics and scores. The P-value of <0.05 will be considered as statistically significant. Missing data will

be treated by using pre-specified analysis such as multiple imputation and maximum likelihood methods.

Conflict of interest

None.

Funding

None – this research is being conducted as part of a doctoral study.

Ethical approval

The study has been approved by the University of Nottingham Medical School Ethics Committee, and also the Institutional Review Boards at the two participating hospitals (King Abdullah University Hospital and Jordan University Hospital) in Jordan.

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