HS&DR 12/5001/09 The use of cardiac rehabilitation services to aid the recovery of patients with bowel cancer: a pilot randomised controlled trial (RCT) with embedded feasibility study

Cardiac Rehabilitation in Bowel Cancer (CRIB)

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BACKGROUND

Colorectal cancer (CRC) is the fourth most common cancer in the United Kingdom and there are approximately 244,000 CRC survivors. Higher levels of post-diagnosis physical activity are associated with improved CRC outcomes, both survival and quality of life. Yet, CRC survivors are not meeting the recommended physical activity levels associated with health benefits. A barrier to physical activity interventions becoming standard NHS cancer care occurs because there are difficulties around implementation. Thus, when designing this study, particular attention was paid to this issue. This study is novel in that it aims to test an existing, evidence- and theory-based cardiac rehabilitation service for a different patient group, that is, people with CRC. There were four main reasons why cardiac rehabilitation was chosen:

1. Physical activity is the cornerstone of cardiac rehabilitation,

2. Cardiac rehabilitation is evidence-based and informed by theories of behaviour change,

3. Cardiac rehabilitation clinicians have the expertise to provide relevant rehabilitation, including monitored physical activity, to a wide variety of patients such as those with a CRC diagnosis,

4. Cardiac Rehabilitation is widely available throughout the UK.

OBJECTIVES

The aims of the CRIB (Cardiac Rehabilitation In Bowel cancer) study were to assess whether cardiac rehabilitation is a feasible and acceptable model of rehabilitation to aid the recovery of CRC survivors (i.e., examine intervention implementation potential) and to test the feasibility and acceptability of the protocol design (i.e., examine methodological standard). The study is not designed to measure the effect of cardiac rehabilitation on health outcomes. Thus, the overall purpose of the study was to assess whether it is appropriate to progress to an effectiveness trial and, if so, to optimise the design and conduct of any such trial.

METHODS

We undertook a phased programme of work comprising intervention testing and feasibility work in one site (Phase I) and a pilot randomised controlled trial (RCT) in three sites (Phase II). The estimated sample size was 12 and 66 CRC patients in Phases I and II, respectively. Phase II was supplemented with an economic evaluation to consider resource use of providing the intervention compared with usual care. There was also a qualitative study that aimed to explore the views and experiences of all CRC participants, 6 cardiac patients and 12 clinicians involved in the study.

In both Phases, people with CRC were recruited from hospitals and considered for inclusion if they were 18 years old and over, diagnosed with primary CRC and in the recovery period post-surgery. People with CRC were excluded if they had advanced disease, failed clinical/risk assessment for rehabilitation and deemed unsafe to participate in exercise classes, had severe cognitive impairment, or were unable to communicate in English, as this is the language used in delivering cardiac rehabilitation.

The intervention was referral of people with CRC to cardiac rehabilitation, which comprised approximately 12 exercises classes and cardiac-specific education sessions over 12 weeks, depending on site. Cardiac rehabilitation physiotherapists and other cardiac rehabilitation clinicians received training in cancer and exercise.

The primary outcomes were the difference in measures of physical activity and sedentary behaviour between the intervention and usual care (control) group measured by accelerometer at 12 weeks' post-randomisation. The secondary outcomes were self-reported measures of quality of life, anxiety, depression, and fatigue. In this study we assessed the feasibility and acceptability of data collection instruments for these proposed outcomes.

Interviews were carried out with people with CRC recruited to the study and cancer and cardiac clinicians. In addition, focus groups with people with coronary heart disease (CHD) attending cardiac rehabilitation were conducted and analysed using thematic analysis.

PHASE I

Results

Participants

Three CRC patients, 3 CRC nurse specialists and the cardiac rehabilitation senior physiotherapist in Site 1 were interviewed during Phase I. A focus group involving 12 cardiac rehabilitation clinicians (8 physiotherapists/assistants, 4 nurses) in Site 2 was also conducted.

Feasibility and acceptability of trial components

The feasibility and acceptability of trial components were tested in one site with the following results:

There were 34 new CRC patient admissions and the 24 (70%) eligible patients were given study information. Ten (42%) eligible patients were willing to participate in the study (mean age 71 years, 6 males, 8 open surgery/2 laparoscopic surgery, 5 receiving adjuvant therapy, 4 with a stoma). Four (17%) patients signed a consent form and were entered into the study and 6 withdrew due to ill-health (n=3), travel problems (n=2) or could not subsequently be contacted (n=1). Three patients remained in the study. One adverse event was reported, which was not related to the study.

The characteristics of 10 eligible participants willing to participate and 7 eligible participants who declined to participate were compared. The age range and CRC diagnosis in each group were similar. There were proportionately more men and more people who had open surgery in the willingness to participate group.

Participants did not report difficulties wearing an accelerometer. All questionnaires were completed and there were no missing data. Participants found sections of the questionnaires repetitive, in particular questions about quality of life. They also found some questions not relevant, for example, questions about being physically active at work when most participants had retired.

Nurses did not report difficulties applying exclusion criteria and found that it was feasible and acceptable to approach patients on the surgical ward about the study. Perceived barriers to participation were:

- Travel distance from cardiac rehabilitation facility
- Returning to work and therefore unable to attend cardiac rehabilitation
- Feeling fit and well and therefore perceiving cardiac rehabilitation as unnecessary
- Having on-going treatment and not feeling well enough to attend cardiac rehabilitation
- Poor recovery from surgery

Feasibility and acceptability of the intervention

The average number of days between a patient indicating willingness to participate in the study and starting cardiac rehabilitation was 70 days. Participants were expected to attend

10 consecutive cardiac rehabilitation exercise classes; the four participants attended 10, 6, 5 and 0 classes, respectively.

Themes from the interviews and focus groups were: referral pathways to cardiac rehabilitation, importance of exercise for patients with CRC, cancer and cardiac patients exercising together, and cardiac rehabilitation education sessions.

Before any CRC patients were recruited, all clinicians (6 CRC nurses, 10 cardiac rehabilitation physiotherapists and 4 cardiac rehabilitation nurses) in all three sites who were involved in recruitment or delivering the intervention attended a one-day cancer and exercise training event. A cancer and exercise specialist delivered the training face-to-face in two sites and by video conferencing in one site. Fourteen evaluation forms were returned. All scaled questions marked highly with a score of 4 or 5; with 5 being the maximum score.

Conclusions

The feasibility and acceptability of trial components and the intervention were only tested on one site over a short period of six months, including a very small number of patients and clinicians. A decision was reached among the research team, funder and advisory group to proceed to Phase II with the following main modifications to trial procedures and the intervention:

Trial procedures

- Approach CRC patients about the study on the surgical ward
- Remove duplication of questions and include a physical activity questionnaire relevant for this age group
- Include people with metastatic disease

Intervention

- Refer CRC patients to cardiac rehabilitation only when they feel ready to begin exercise classes
- Include on the referral form information about co-morbidities, treatments, date of surgery, relevant previous medical history
- Modify the intervention so that CRC nurses provide cancer-specific education sessions and lifestyle advice to CRC patients to supplement the cardiac rehabilitation education sessions.

PHASE II

Results

Randomised controlled trial

The screening rate was 79%. One hundred and ninety-eight people were admitted to hospital for CRC surgery and, of these, a CRC nurse assessed 156 for eligibility. The eligibility rate was 67%. Out of the 198 people admitted for surgery, 133 met eligibility criteria. The main reason for excluding a patient was poor mobility. The consent rate was 31%. Forty-one out of 133 eligible patients gave written consent. The most common reason given by patients for non-participation was poor recovery from surgery, co-morbidity or receiving adjuvant therapy. The randomisation rate was 100%. No adverse events were reported. The retention rate was 93%. Three out of 41 participants formally left the study (2 control and 1 intervention).

There were no significant differences in age, gender and type of surgery (colon or rectal) between consenting and non-consenting eligible patients but people with metastatic disease, having open surgery, and a stoma, were more likely not to participate. However, there was recruitment bias; though eligible, most participants were already meeting the recommended level for moderate-to-vigorous physical activity (i.e., 30 minutes a day).

The completion rate for self-report questionnaires at baseline, follow-up 1 and follow-up 2 was 97.5% (20 intervention, 20 control), 75.6% (15 intervention, 16 control) and 61% (12 intervention and 13 control), respectively. The completion rate for accelerometers at baseline, follow-up 1 and follow-up 2 was 68% (14 intervention and 14 control), 56% (11 intervention 12 control) and 34% (6 intervention and 8 control), respectively. There was a total of 65 accelerometer device datasets across all 3 time-points. Twenty out of 65 (31%) accelerometer device datasets were removed from analysis because data were invalid. The main reason for missing accelerometer data was not wearing the device (35%).

Thirteen out of 21 participants (62%) completed the cardiac rehabilitation programme. Three participants started cardiac rehabilitation but could not complete all cardiac rehabilitation classes and five did not begin cardiac rehabilitation (38%).

Qualitative study

The qualitative study included 38 participants (22 patients with CRC, 8 patients with cardiovascular disease, 2 CRC nurses, 6 cardiac rehabilitation clinicians). Key themes and sub-themes shown in parenthesis were: benefits for people with CRC attending cardiac rehabilitation (delivered by health experts, benefits of physical activity, confidence, motivation, peer support, social skills), barriers for people with CRC attending cardiac rehabilitation (travel and distance, recovery from treatments, stoma), generic versus disease-specific rehabilitation, key concerns about including people with cancer in cardiac rehabilitation (capability of clinicians, capacity of cardiac rehabilitation), and barriers to involvement in a study about cardiac rehabilitation (randomisation, study information, participant burden) (CRC participants only).

Economic evaluation

Response rates for the health service resource use questionnaire and a questionnaire to measure quality-adjusted life year were high. Key resources used to deliver cardiac rehabilitation were staff time, equipment and room hire. Two sites provided historical data that related to all cardiac rehabilitation costs, which were £375 and £437, respectively. One site provided an estimated cost per patient for hiring a physiotherapy assistant to accommodate an additional 24 CRC patients into the cardiac rehabilitation service, which was £198.71. NHS resource use was similar between CRC patients allocated to the cardiac rehabilitation intervention and the usual care groups. Costs incurred by CRC patients allocated to the cardiac rehabilitation intervention group specifically related to attending the cardiac rehabilitation intervention (for example, travel, clothing) were relatively small (£50).

LIMITATIONS

This feasibility and pilot work, conducted in only 3 sites, highlights a range of trial design limitations including sub-optimal eligibility, consent and completion rates, missing data and recruitment bias. It also highlights limitations of cardiac rehabilitation for patients with cancer including capacity, costs and capability issues. To make a full multi-centre trial feasible we recommend an internal pilot with clear stop-proceed rules, induction training for staff, and participant incentives. We also recommend an embedded process evaluation so that each site's contextual factors impacting cardiac rehabilitation for patients with cancer are illuminated.

CONCLUSIONS

Implications for healthcare

The main novel finding is that cardiac rehabilitation for cancer and cardiac patients together is feasible and acceptable, thereby challenging disease-specific rehabilitation models.

This study suggests that cardiac rehabilitation is an acceptable and feasible rehabilitation service for people with CRC and their clinical care teams but the capacity of cardiac rehabilitation to accommodate additional patients with cancer and the capability of cardiac rehabilitation clinicians to provide cancer-specific psychosocial support are key concerns. Before UK-wide implementation, it is critical to address these concerns and then to find out if this model of rehabilitation has a health benefit. A major strength of this feasibility and pilot study however, is that we evaluated an already widely available existing rehabilitation service: cardiac rehabilitation. The aim of this study was not to attempt to change and adapt cardiac rehabilitation, but to find out if it is feasible and acceptable to refer people with CRC to this current service as it is currently configured. We were successful in achieving this aim.

IMPLICATIONS FOR FUTURE RESEARCH

Research priorities

In order to maximise the success of any future effectiveness trial, research priorities include addressing CRC patient barriers to attending cardiac rehabilitation and consenting to the study (for example, travel, poor recovery), gaps in cardiac rehabilitation provision for cancer patients such as cancer-specific psychosocial support, recruitment bias, missing accelerometer data, retention of control group participants, and marginal costs related to expanding cardiac rehabilitation provision to other patients groups.

To address concerns about capacity, we recommend that additional resources be given to cardiac rehabilitation (if required) so that they can take more patients. To address concerns about the competence of cardiac rehabilitation clinicians to address cancer-specific issues, we recommend that the cancer team address cancer-specific needs and that cardiac rehabilitation attend to generic concerns of patients. To address travel barriers to attending cardiac rehabilitation outreach services should be offered. To address recruitment bias, induction training to cancer clinicians about cardiac rehabilitation so that they only refer and offer the service to patients who need it most i.e. those currently not meeting the recommended guidelines for physical activity, should be provided. This training will also point out the ability of cardiac rehabilitation to support people who for instance, have a disability or are immobile, thereby encouraging referral of patients to the service who are frail etc. To improve up-take of the service, we recommend ensuring that patients are part of decision-making about the start date for attending cardiac rehabilitation. This is so that those who wish to begin at the end of all active treatment can still participate. To improve completion rates, especially participants allocated to the control arm, we recommend providing incentives to remain in the study such as monetary incentives and regular reminders. To reduce missing accelerometer data, we recommend training researchers so

that they communicate the importance of these data and how to wear the device to participants.

Next steps

A major strength and advantage of pragmatic trials is the testing of already existing services in real-world settings. It is very different to an explanatory trial where the intervention is tightly controlled and managed by the investigating team. A future multi-centre effectiveness trial should incorporate the recommended protocol modifications and include an internal pilot trial with clear 'stop-go' rules that are formally reviewed before proceeding to the full-scale trial.

Study registration

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