

The use of cardiac rehabilitation services to aid the recovery of patients with bowel cancer: a pilot randomised controlled trial with embedded feasibility study

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Scientific summary

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Scientific summary

Background

Colorectal cancer (CRC) is the fourth most common cancer in the UK, and there are approximately 244,000 CRC survivors. Higher levels of post-diagnosis physical activity are associated with improved CRC outcomes, in terms of both survival and quality of life. However, 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, namely 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 Cardiac Rehabilitation In Bowel cancer study were to assess whether or not 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 was not designed to measure the effect of cardiac rehabilitation on health outcomes. Thus, the overall purpose of the study was to assess whether or not it is appropriate to progress to an effectiveness trial and, if so, to optimise the design and conduct of any such trial.

Design

We undertook a phased programme of work comprising intervention testing and feasibility work (phase 1) and a pilot randomised controlled trial (phase 2), which 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, six cardiac patients and 12 clinicians involved in the study.

The intervention was the referral of people with CRC to cardiac rehabilitation, which comprised approximately 12 exercises classes and cardiac-specific education sessions over 12 weeks, depending on the 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) groups, measured by an 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 with cancer and cardiac clinicians. In addition, focus groups with people with coronary heart disease attending cardiac rehabilitation were conducted and analysed using thematic analysis.

Setting

The setting was CRC hospital wards and cardiac rehabilitation facilities. Phase 1 was conducted in one site and phase 2 (a pilot randomised controlled trial) was conducted in three sites.

Participants

In both phases, people with CRC were recruited from hospitals and considered for inclusion if they were aged ≥ 18 years, diagnosed with primary CRC and in the recovery period post surgery. People with CRC were excluded if they had advanced disease, had failed clinical/risk assessment for rehabilitation and were 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 estimated sample size was 12 and 66 CRC patients in phases 1 and 2, respectively.

Phase 1

Results

Participants

During phase 1, three CRC patients, three CRC nurse specialists and the cardiac rehabilitation senior physiotherapist in site 1 were interviewed. In addition, a focus group was conducted in site 2, involving 12 cardiac rehabilitation clinicians (eight physiotherapists/assistants and four nurses).

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 was 71 years, six were male, eight had undergone open surgery/two had undergone laparoscopic surgery, five were receiving adjuvant therapy, four had a stoma). Four (17%) patients signed a consent form and were entered into the study, and six withdrew owing to ill health ($n = 3$) or travel problems ($n = 2$), or because they 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 seven 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 undergone 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 the questions about quality of life. They also found some questions not relevant; for example, there were questions about being physically active at work, but most of the 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 ongoing 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 his or her willingness to participate in the study and starting cardiac rehabilitation was 70. Participants were expected to attend 10 consecutive cardiac rehabilitation exercise classes; the four participants attended 10, 6, 5 and 0 classes, respectively, thereby bringing a total of three participants remaining in the study.

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 (six CRC nurses, 10 cardiac rehabilitation physiotherapists and four cardiac rehabilitation nurses) in all three sites who were involved in recruitment or delivering the intervention attended a 1-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 6 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 2 with the following main modifications to the 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 to 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 comorbidities, treatments, date of surgery and 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 2

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%. Of the 198 people admitted for surgery, 133 met the 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, comorbidity 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 (two control and one 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 or who had a stoma were more likely not to participate. However, there was recruitment bias; although eligible, most participants were already meeting the recommended level for moderate to vigorous physical activity (i.e. 30 minutes per day).

The completion rate for self-report questionnaires at baseline, follow-up 1 and follow-up 2 was 97.5% (20 intervention and 20 control), 75.6% (15 intervention and 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 and 12 control) and 34% (six intervention and eight control), respectively. There was a total of 65 accelerometer device data sets across all three time points. Twenty out of 65 (31%) accelerometer device data sets were removed from analysis because data were invalid. The main reason for missing accelerometer data was a participant 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 of the classes and five (38%) did not begin cardiac rehabilitation.

Qualitative study

The qualitative study comprised 38 participants (22 patients with CRC, eight patients with cardiovascular disease, two CRC nurses and six cardiac rehabilitation clinicians). Key themes (subthemes shown in parentheses) 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 were high for the health service resource use questionnaire and a questionnaire to measure quality-adjusted life-years. The 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; this cost 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 (e.g. travel and clothing) were relatively small (approximately £50).

Limitations

This feasibility and pilot work, conducted in only three sites, highlights a range of trial design limitations, including suboptimal 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 multicentre 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 health care

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, namely 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

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 (e.g. travel or 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 patient 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 should be provided to cancer clinicians about cardiac rehabilitation, so that they refer and offer the service only to patients who need it most, that is, those currently not meeting the recommended guidelines for physical activity. 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 the referral of patients to the service who are frail, etc. To improve uptake of the service, we recommend ensuring that patients are part of the decision-making process about the start date for attending cardiac rehabilitation. This is so that those who wish to begin rehabilitation at the end of all active treatment can still participate. To improve completion rates, especially for 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 to participants the importance of these data and how to wear the device.

Next steps

A major strength and advantage of a pragmatic trial is the testing of already existing services in real-world settings. A pragmatic trial is very different from an explanatory trial, in which the intervention is tightly controlled and managed by the investigating team. A future multicentre 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.

Trial registration

This trial is registered as ISRCTN63510637.

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