ISRCTN07465566 https://doi.org/10.1186/ISRCTN07465566

A pilot study to test the effects of physical activity consultations on the physical activity levels and other health outcomes of people living with colorectal cancer and their partners

Submission date
13/12/2010

Recruitment status
No longer recruiting

Registration date
17/02/2011

Overall study status
Completed

Last Edited
12/12/2017

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Miss Pamela Flynn

Contact details
Cancer Care Research Centre
School of Nursing, Midwifery and Health
Unit 1 Scion House
Innovation Park
University of Stirling
Stirling
United Kingdom
FK9 4LA
+44 (0)1786 849260
pamela.flynn@stir.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A pilot study of a randomised controlled trial to evaluate the effects of physical activity consultations on the physical activity levels and other health outcomes of people living with colorectal cancer and their partners

Study objectives
Evidence suggests that increased physical activity following diagnosis and treatment for colorectal cancer may reduce the risk of disease recurrence after 2.7 years and improve survival by up to 50%. Studies have also shown an association between increased physical activity and other health outcomes for people living with colorectal cancer, for example improved quality of life and improved mental well-being.

Partners may play a role in affecting physical activity behaviour change. The family can be a significant determinant of individual health behaviours. Shared familial environmental factors have been shown to partly account for similarities in physical activity levels amongst family members.

Research has also shown that spousal support is an important factor in smoking cessation, use of health services and weight reduction. Partners may be also a receptive target for physical activity behaviour change. Physical activity consultations may help to increase the physical activity levels and improve the health outcomes of the partners of people living with colorectal cancer as well as the patient.

Primary aim:
To evaluate the feasibility of conducting a randomised controlled trial of physical activity consultations with people living with colorectal cancer and their partners.

Research questions:
1. Is it possible to recruit patients who have completed all surgery and treatment for colorectal cancer in the last 24 months?
2. What would a likely response rate be for a future randomised controlled trial?
3. What are the demographic characteristics of those who are recruited to the study?
4. Can participants be retained in the study for the full 6 months?
5. Is it possible to conduct joint physical activity consultations with people living with colorectal cancer and their partners?
6. Are the outcome measures able to be used and acceptable for use with people living with colorectal cancer and their partners?
7. What would the effect size be for a future power calculation?

Secondary aim:
To evaluate the effects of physical activity consultations on physical activity levels, mental health, quality of life and body composition.

Research questions:
1. What is the effect of physical activity consultations on the physical activity levels of people living with colorectal cancer and their partners?
2. What is the effect of physical activity consultations on depression and anxiety?
3. What is the effect of physical activity consultations on quality of life?
4. What is the effect of physical activity consultations on body composition?
5. Do cancer and other health risk perceptions, intra-couple support and self-efficacy predict any changes in physical activity levels?

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland Research Ethics Committee 2, 02/08/2010, ref: 10/S0709/39

Study design
Single-centre prospective non-blinded randomised controlled pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Colorectal cancer

Interventions
The intervention for this study is joint physical activity consultations. Physical activity consultations involve face-to-face discussions and include, for example, assessment of current levels of physical activity, exploration of pros and cons of being active, exploration of physical activity options and the setting of realistic and achievable physical activity goals. The aim of the consultation is to develop an activity plan that is tailored to the participant's lifestyle, motivation and health status. The activity plan will be developed for the couple, although within this their physical activities may vary and they may choose to exercise independently of one another. Couples will be encouraged to become and remain regularly physically active in order to achieve health and fitness benefits, in other words to meet the physical activity recommendations for adults.

All couples who take part in the study will be randomly assigned to either Group 1 (Intervention: Physical activity consultations) or Group 2 (Control: Usual care).

Couples in the Intervention arm of the trial will receive a 1 - 2 hour face-to-face physical activity consultation after baseline measures and a consultation 3 months after the first consultation. Couples will also receive 2 contact telephone calls from the researcher following each consultation; one at 3 weeks and one at 7 weeks (4 in total throughout their participation in the study).

Couples in the control arm of the trial will receive usual care. This involves a follow up appointment at the hospital clinic for the participant living with colorectal cancer to detect any evidence of cancer recurrence. Couples in the Usual Care arm will not receive advice on physical activity.

At baseline, 3 months and 6 months, outcome data will be collected from couples in the intervention and control arms of the trial.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Feasibility will be measured by calculating the following rates:
1. Recruitment rate (number of participants randomised/number of eligible participants)
2. Completion rate (number of participants completing baseline and 6 month intervention assessments/number of participants randomised)
3. Adherence rate (number of physical activity consultations and telephone calls conducted /number of physical activity consultations and telephone calls scheduled)

Secondary outcome measures
1. Change in physical activity will be measured from baseline to 3 and 6 months follow-up in individuals living with colorectal cancer and their partner. Physical activity will be assessed for 7 consecutive days at each time-point using the Actigraph GT1M-Plus accelerometer (Actigraph LLC, Pensacola, Florida). Monitors will be attached to adjustable elastic belts and worn over the right hip under clothing during all waking hours. The raw accelerometry output (accelerometer count per minute [cpm], averaged over the monitoring period) will be used as a measure of total physical activity and will also be used to quantify the amount of monitored time spent in sedentary behaviour and moderate and vigorous physical activity using validated cut off points. Physical activity will also be assessed subjectively using the long (self-report) version of the International Physical Activity Questionnaire (IPAQ) to ascertain the types of activities participants engaged in as this information is not provided by the accelerometers. This questionnaire measures time spent in moderate and vigorous activity across four domains (work, transport, housework/gardening and leisure time) and time spent sitting in the previous 7 days.
2. Mental well-being will be measured at baseline, 3 and 6 months using the Hospital Anxiety and Depression (HADS) Scale (0 = Not at all, 4 = Most of the time). This is a brief, self-report questionnaire used to measure state anxiety and depression over the past week.
3. Quality of life in people living with colorectal cancer will be measured at baseline, 3 and 6 months using the Functional Assessment of Cancer Therapy C General (FACT-G) questionnaire. The latest version 4 is formulated into separate subscales: physical, emotional, social/family and

functional well-being. The Functional Assessment of Cancer Therapy C Colorectal (FACT-C), which includes additional concerns for colorectal cancer patients, will also be used. Both scales questions are scored 0 = Not at all to 4 = Very much. Quality of life in partners will be measured by the WHOQOL-Bref instrument. The short form WHOQOL-Bref contains 26 items that have been extracted from the WHOQOL-100. It measures the following broad domains: physical health, psychological health, social relationships, and environment.
4. Body composition (i.e. fat and lean mass) will be measured at baseline, 3 and 6 months using a portable foot-to-foot bioelectrical impedance monitor (Tanita TBF-300 MA Body Composition Analyser, Harlow Printing Ltd, Tyne and Wear)
5. Predictors of change in physical activity: psychosocial constructs will be measured to test their predictive role for change in physical activity from baseline to 3 months and 6 months follow up in individuals living with colorectal cancer and their partners -
5.1. Perceptions of cancer risk in partners will be measured by a scale developed by Schwartz and colleague (Schwartz et al., 1995). The instrument has three items and uses a Likert scale ranging from 'much lower' to 'much higher' to generate a composite score.
5.2. Fear of cancer recurrence in individuals living with colorectal cancer will be measured using the Fear of Cancer Recurrence Inventory (Simard and Savard, 2009). The instrument has 42 items and uses a Likert scale to generate a composite score.
5.3. Key components of the revised theory of planner behaviour will be measured in individuals living with colorectal cancer and their partner using the following scales. Intention to exercise will be assessed on the mean of 2 items each measured on 7 point scales. Attitude will be assessed using the mean of 4 semantic differential scales, all scored -3 to +3 with higher scores indicating more positive attitudes towards exercising. Subjective norm will be assessed as the mean of 2 items, scored -3 to +3 with higher scores indicating stronger norms to exercise. Perceived behavourial control will be assessed as the mean of 3 items (scored 1 to 7), with higher scores indicating more control over exercising; past behaviour is well recognised as a strong predictor of future behaviour. This will be assessed as the mean of 2 items (scored 1 to 7), with higher scores indicating greater previous exercise; anticipated regret will be assessed by 2 items tapping inactivity regret that is anticipated regret about not exercising in the future, scored -3 to +3. The contributions of these predictor variables of attitude, subjective norm, perceived behavioural control etc in explaining the observed variance in, a) intention to exercise, and b) actual exercise behaviour 12 weeks and 6 months later will then be measured.
5.4. The quality of the relationship between the individual living with cancer and their partner will be measured to test if it affects adherence to the physical activity intervention or moderates any of the intervention effects. The validated relationship quality measures from the English Longitudinal Study of Ageing (Marmot et al., 2003) will be used, which assesses social support and is concerned with the quality of the respondent's social relationship with individual living with colorectal cancer or partner respectively. Specifically, respondents are asked about the presence of positive support from their partner (how much they understand the way the respondent feels about things, how much they can be relied on if the respondent has a serious problem and how much the respondent can open up to them to talk about worries); and about negative relations with each other (how much others criticise the respondent, how much they let the respondent down and how much they get on the respondent's nerves). Positive and negative support items are scored as 1 = not at all and 4 = a lot, such that higher numbers indicate more of each type of support. Three questions on the receipt of social support for physical activity in the previous week will also be included to assess whether the intervention changes received social support.

Overall study start date
20/01/2011

Completion date
20/10/2011

Eligibility

Key inclusion criteria
Individual living with colorectal cancer:
1. Initial diagnosis Dukes stage A-C2 colorectal cancer with no current evidence of metastatic disease
2. Aged 18 years or older, either sex
3. Have completed surgery in the last 24 months
4. Not currently undergoing surgery or adjuvant chemotherapy and/or radiation therapy for cancer
5. Has a partner
6. Not currently meeting national physical activity guidelines (of 30 minutes moderate-intensity activity five times per week)
7. Able to communicate in English

Partner:
1. Partner of individual living with colorectal cancer included in the study
2. Aged 18 years or older
3. Not currently undergoing surgery or adjuvant chemotherapy and/or radiation therapy for cancer
4. Able to communicate in English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30 couples (60 participants in total)

Key exclusion criteria
Individual living with colorectal cancer:
1. Initial diagnosis Dukes stage D
2. Evidence of metastatic disease
3. Suffers from unstable cardiac or respiratory disease (due to inappropriateness of physical activity intervention)
4. Partner is unwilling to participate in study
5. Currently undergoing surgery or adjuvant chemotherapy and/or radiation therapy for cancer
6. Currently achieving national physical activity guidelines
7. Unable to communicate in English

Partner:
1. Currently undergoing surgery or adjuvant chemotherapy and/or radiation therapy for cancer
2. Suffers from unstable cardiac or respiratory disease (due to inappropriateness of physical activity intervention)
3. Unable to communicate in English

Date of first enrolment
20/01/2011

Date of final enrolment
20/10/2011

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Cancer Care Research Centre
Stirling
United Kingdom
FK9 4LA

Sponsor information

Organisation
University of Stirling (UK)

Sponsor details
c/o Carol Johnstone
Research and Enterprise
3B1 Cottrell Building
Stirling
Scotland
United Kingdom
FK9 4LA
+44 (0)1786 466690
carol.johnstone@stir.ac.uk

Sponsor type
University/education

Website

http://www.stir.ac.uk/

ROR
https://ror.org/045wgfr59

Funder(s)

Funder type
University/education

Funder Name
University of Stirling (UK)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration