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Investigation into the impact of a physical activity health promotion pack on the wellbeing of people living with cancer

Submission date
25/07/2017

Recruitment status
No longer recruiting

Registration date
26/07/2017

Overall study status
Completed

Last Edited
21/06/2019

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The aim of this study is to understand the impact of health promotion information on the wellbeing of people living with cancer. This study will compare the provision of guidelines, and provision of a health promotion pack to support people living with cancer to change a lifestyle behaviour. This study will allow for a greater understanding of the needs of people living with cancer, and how health promotion information can be better designed, developed, and distributed in the future.

Who can participate?
Adults aged 18 and older who are living with cancer.

What does the study involve?
This is a two arm, waiting list control study with embedded process evaluation. Participants in the control arm are sent, in the mail, the physical activity guidelines for people living with cancer. Participants in the intervention arm will be sent, in the mail, a printed physical activity health promotion pack, and directed to online tools, as well as receiving four e-newsletters over 12 weeks. Data will be collected via online survey on physical activity, self efficacy and quality of life at baseline, and at 12 weeks follow up. The intervention group is followed up again at 24 weeks with the same measures collected. The control arm receives the intervention at 12 weeks and is followed up again at 24 weeks. Use of the physical activity health promotion pack is assessed as part of the online survey administered to the intervention group at 12 weeks. Participants from the intervention arm are split into two groups, those inactive before their cancer diagnosis, and those active before their cancer diagnosis. Initially five participants from each of these group are randomly allocated to take part in a phone interview to gain a deeper understanding of their interaction with, and views of, the physical activity health promotion pack. Additional interviews are conducted if new themes are still emerging following these initial phone interviews.

What are the possible benefits and risks of participating?
There are no direct benefits with participating. Participants may find answering questions

regarding their cancer distressing, and if so, they will be directed to the support that they need. Participants will be provided with additional information to consider before making any changes to their lifestyle, to ensure that it is right for them.

Where is the study run from?
University of Surrey (UK)

When is the study starting and how long is it expected to run for?
October 2016 to October 2018

Who is funding the study?
Investigator initiated and funded (UK)

Who is the main contact?
Justin Webb
justin.webb@surrey.ac.uk

Contact information

Type(s)
Public

Contact name
Mr Justin Webb

Contact details
University of Surrey
Guildford
United Kingdom
GU2 7XH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MoveMoreRCT

Study information

Scientific Title
A randomised waiting list control trial, with embedded process evaluation, to investigate the impact of a physical activity health promotion pack on the wellbeing of people living with cancer

Study objectives

Hypothesis:
A physical activity health promotion pack will improve physical activity levels in people living with cancer over provision of the physical activity guidelines.

Primary study aim:
The primary aim of this study is to test the effectiveness of a physical activity health promotion pack in moving people living with cancer categorised as 'inactive' or 'moderately active', to 'active'.

Secondary study aims:
1. Testing the impact of the physical activity health promotion pack on the quality of life of people living with and beyond cancer
2. Sub group analysis to understand for whom the physical activity health promotion pack positively impacts upon physical activity and quality of life, in the context of pre-diagnosis levels of physical activity, and self-efficacy
3. A process evaluation to further understand the mechanisms for change

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Surrey Ethics Committee, 15/03/2017, ref: UEC/2017/023/FHMS

Study design
This is a two arm, waiting list control study with embedded process evaluation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
People living with cancer

Interventions
Participants are randomised using simple randomisation (toss of a coin) to either the intervention or the control group.

Intervention arm: A printed physical activity health promotion pack sent in the mail, supported by an online forum with patients and cancer specialist physiotherapist, online video case studies, and four e-newsletters sent to participants email accounts over 12 weeks.

Control: The guidelines for physical activity, sent in the mail.

This is a two arm, waiting list control study with embedded process evaluation. Participants in the control arm are sent, in the mail, the physical activity guidelines for people living with cancer. Participants in the intervention arm are sent, in the mail, a printed physical activity health promotion pack, and directed to online tools, as well as receiving four e-newsletters over 12 weeks. Data is collected via online survey on physical activity, self efficacy and quality of life at baseline, and at 12 weeks follow up. The intervention group will be followed up again at 24 weeks with the same measures collected. The control arm will receive the intervention at 12 weeks and will be followed up again at 24 weeks.

Use of the physical activity health promotion pack will be assessed as part of the online survey administered to the intervention group at 12 weeks. Participants from the intervention arm will be split into two groups, those inactive before their cancer diagnosis, and those active before their cancer diagnosis. Initially five participants from each of these group will be randomly selected to take part in a phone interview to gain a deeper understanding of their interaction with, and views of, the physical activity health promotion pack. Additional interviews will be conducted if new themes are still emerging following these initial phone interviews.

Intervention Type
Behavioural

Primary outcome measure
Physical activity levels are measured using the Godin Leisure-Time Exercise Questionnaire at baseline, 12weeks, and 24 weeks.

Secondary outcome measures
1. Quality of life is measured using the FACT-G7 questionnaire at baseline, 12weeks, and 24 weeks
2. Self-efficacy is measured using a single-item measure based on a previous study (Kampshoff, van Mechelen, Schep, Nijziel and Witlox et al. (2016)) at baseline, 12weeks, and 24 weeks

Overall study start date
01/10/2016

Completion date
31/10/2018

Eligibility

Key inclusion criteria
1. People living with cancer
2. Aged 18 or over
3. Who can read English
4. Able to provide consent
5. Have an active e-mail account

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
164

Total final enrolment
104

Key exclusion criteria
1. Those less than eight weeks post-surgery
2. Those experiencing extreme fatigue, anaemia or severe balance and coordination problems
3. Those with cancer in your bones, or bone thinning
4. Those with a heart or lung condition
5. Those experiencing pain in their chest at rest, during daily activities or when becoming active
6. Those experiencing persistent pain in their muscles, bones or joints
7. Those with swelling or inflammation in the abdomen, groin, or lower extremity
8. Those who have been informed by a doctor to only do medically supervised physical activity

Date of first enrolment
20/03/2017

Date of final enrolment
01/03/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Surrey
388 Stag Hill
Guildford
United Kingdom
GU2 7XH

Sponsor information

Organisation
University of Surrey

Sponsor details
388 Stag Hill
Guildford
England
United Kingdom
GU2 7XH

Sponsor type
University/education

Website
www.surrey.ac.uk

ROR
https://ror.org/00ks66431

Funder(s)

Funder type
Not defined

Funder Name
University of Surrey

Funder Name
Macmillan Cancer Support

Alternative Name(s)
Macmillan, Society for the Prevention and Relief of Cancer, Cancer Relief Macmillan Fund, Macmillan Cancer Relief, MCS

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location

United Kingdom

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication of the protocol in the Journal of Medical Internet Research (JMIR). It is planned to publish the study results in a high-impact peer reviewed journal, with further dissemination at relevant conferences, such as the National Cancer Research Institute conference.

Intention to publish date
01/01/2019

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2019	21/06/2019	Yes	No