ISRCTN42072606 https://doi.org/10.1186/ISRCTN42072606

CanWalk: a walking intervention for people with recurrent or metastatic cancer

Submission date	Recruitment status	[_] Prospectively registered
24/03/2014	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/04/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/06/2019	Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-walking-programme-for-people-who-have-cancer-that-has-come-back-or-spread-canwalk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A study to assess the acceptability and feasibility of a walking intervention for people with recurrent or metastatic cancer

Acronym
CanWalk

Study objectives
Research question: are community-based walking programmes feasible and effective in enhancing physical and psychological outcomes in people with recurrent or metastatic cancer?

Secondary research questions: the study will refine the walking intervention and ensure a full randomised controlled trial is appropriate and feasible.

Objectives:
1. Refine a brief intervention to encourage the uptake of the walking intervention
2. Investigate the acceptability to participants of:
2.1. The walking intervention
2.2. The study materials
2.3. Being randomised to intervention or control
2.4. The selected outcome measures
2.5. Using pedometers to assess adherence
3. Estimate the following factors needed to design the main study:
3.1. Number of eligible participants
3.2. Recruitment rate
3.4. Retention rate
3.5. Response rates to initial and follow-up questionnaires
3.6. Utility of objective and subjective methods to assess adherence to the walking intervention
4. Generate evidence to be used to estimate sample size for a future randomised controlled trial

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Lancaster, HRA NRES Centre - Manchester, 06/12/2013, ref: 13 /NW/0860

Study design
Feasibility study with exploratory multicentre randomised trial and qualitative interviewing

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Recurrent or metastatic cancer

Interventions
The intervention comprises a brief (10-minute) telephone or face-to-face session, based on NICE public health guidance on physical activity (NICE, 2013). It will discuss the importance and benefits of physical activity, and promote goal setting, action planning and self-monitoring as a means to increase physical activity. Study materials will also be provided in print and online formats to reinforce the intervention. Information on local Walking For Health (WfH) groups will be provided, including details of the WfH co-ordinator in the participant's local area. The intervention will be delivered by the researcher trained in motivational interviewing, which is a patient-centred, counselling-style approach that builds on an individual's motivation to change behaviour. The intervention sessions will, with consent, be audio-recorded and a random selection rated to ensure fidelity to the intervention manual.

Participants will be randomised 1:1 between the intervention (n=30) and standard care (n=30) using minimisation. Participants in the intervention group will be asked to participate in at least one WfH group activity per week and undertake walking on alternate days over 3 months, either independently or with WfH groups. The control group will be asked to continue their activities as usual during the study.

Participants will complete questionnaires at baseline (T0), 6 (T1), 12 (T2) and 24 (T3) weeks. Before posting out the follow-up questionnaires, the research team will contact the clinician responsible for the participant's care to check their current health status.

To collect data on physical activity levels, half of the participants in the intervention and control groups will be randomly allocated pedometers and will wear them for 7 days at the time of each assessment. Those patients randomly selected will be asked to collect baseline pedometer data once the research team has received a signed consent form. Patients will be asked to fill in a simple sheet recording how many steps they took each day over the 7-day period.

Semi-structured telephone interviews will be conducted with 10 participants (five per study group) to assess the acceptability of the intervention and evaluation methods. At the end of the intervention a maximum of 10 stakeholders (WfH Co-ordinators/walk leaders, Clinical Nurse Specialists, Oncologists, etc.) will be interviewed to determine the acceptability and feasibility of the walking intervention from a professional perspective.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

The feasibility and acceptability of a walking intervention that combines a motivational element with a pre-existing and nationally available walking programme

Secondary outcome measures
Participants will complete the following questionnaires at baseline (T0), 6 (T1), 12 (T2) and 24 (T3) weeks:
1. Quality of Life (Functional Assessment of Cancer Therapy scale- General; EuroQol)
2. Physical activity level (Scottish Physical Activity Questionnaire; General Practice Physical Activity Questionnaire)
3. Fatigue (Brief Fatigue Inventory)
4. Distress (depression anxiety stress scales)
5. Exercise self-efficacy (Spinal Cord Injury, to measure exercise self-efficacy)

At baseline and 24 weeks participants performance status will also be assessed (Eastern Cooperative Oncology Group) and the strength of their motivation to change behaviour using a brief ruler (100 mm visual analogue scale)

Overall study start date
01/02/2014

Completion date
01/02/2015

Eligibility

Key inclusion criteria
1. 16 years of age or older
2. Diagnosed with metastatic or recurrent cancer in the previous 6 months
3. Able to walk for a minimum of 30 minutes unaided

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Bone metastases that the clinician in charge of the patient's care considers a contra-indication to participating in the walking intervention
2. Unable to speak and understand English

Date of first enrolment
01/04/2014

Date of final enrolment
30/11/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Florence Nightingale School of Nursing and Midwifery
London
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Sponsor information

Organisation
King's College London (UK)

Sponsor details
c/o Keith Brennan
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SE1 1UL

Sponsor type
University/education

Website
http://www.kcl.ac.uk

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
Dimbleby Cancer Care (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results				No	Yes
Protocol article	protocol	01/12/2015		Yes	No
Results article	results	15/02/2017		Yes	No
HRA research summary			28/06/2023	No	No