ISRCTN62859294 https://doi.org/10.1186/ISRCTN62859294

The feasibility of performing a walking programme in patients with rectal cancer undergoing chemo-radiotherapy (the REx trial)

Submission date 21/01/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/03/2014	**Overall study status** Completed	
Last Edited 25/10/2022	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-walking-programme-chemoradiotherapy-rectal-cancer-rex

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
The REx Trial GN130N328

Study information

Scientific Title
A pilot study of the feasibility and patient-related outcomes of performing a walking intervention in patients undergoing treatment for rectal cancer (the REx trial)

Study objectives
It is hypothesised that improving exercise capacity pre-operatively (pre-habilitation) by performing an individualised walking intervention will be feasible and lead to improvement in peri-operative psychological and physical health.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland Research Ethics Service (WoSRES), 22/04/2014, ref: 14/WS/0079

Study design
Randomised controlled trial

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 to request a patient information sheet

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

Interventions
The patients randomized to the walking group will have a consultation with the Project Co-ordinator (PC) where the walking intervention, including the use of the pedometer, will be explained with stepping count targets described. Pedometers have been used successfully by this research team and have been shown to be a motivational tool, which will increase walking in the short term and sustain walking over 12 months. The walking programme will consist of 15-17 weeks of intervention with the first 6 weeks consisting of graduated bi-weekly goals.
The aim will be that walking behaviour is either maintained over the remaining weeks or

increased according to the individual. The goal is for the participants to increase their average daily step count by 3000 accumulated above their baseline value: based on the assumption that an adult walking at a moderate pace produces 100 steps/minute, an increase of 3000 steps on 5 days of the week would correspond to approximately 150 minutes of moderate physical activity over the course of the week, which is the recommended physical activity level for older adults in Scotland.

Control group: No walking intervention

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. To assess the feasibility of performing a walking intervention in patients with rectal cancer undergoing pre-operative chemo-radiotherapy.
2. How many patients can be recruited per month on average and what proportion of eligible patients are willing to be recruited?
3. Are patients willing to be randomised?
4. What is the initial retention and adherence levels that can be achieved for the programme in both interventional and control groups?
5. How many patients drop out of such a study and for what reasons?
6. Are patients able to carry out the intervention as planned and can it be successfully implemented?
7. How acceptable are the intervention, the delivery of, the duration of, the intensity of and the exit strategy to the participants?
8. What are the indicative cost implications of intervention delivery?

To assess primary and secondary outcomes, Tests 1 and 2 will be performed at two time points: pre-chemo-radiotherapy and post-chemo-radiotherapy/pre-surgery (referred to as Test 1 and Test 2, respectively). These tests include: feasibility measurements; body mass index, hip and waist circumference; sit-to-stand test, 6-minute walking test; sedentary time, active time, average steps walked per day. Psychological and quality of life will also be assessed at Tests 1 and 2 by: Becks Depression Inventory (BDI-II), FACT-C, PANAS, EORTC-QLQ C30. Peri-operative outcomes will be recorded during the patient's in-hospital stay post-surgery and for up to 30 days after surgery (length of hospital stay, length of level 2 stay, complications, time to medical discharge, mortality).

Secondary outcome measures
1. Does pre-habilitation increase the number of steps walked per day?
2. Does pre-habilitation lead to improved recovery after surgery (in terms of time to step down from critical care; incidence of morbidity and time to discharge from hospital)?
3. Does pre-habilitation increase the average time spent per day in physical activity?
4. Does pre-habilitation decrease the average time spent per day in sedentary behaviour?
5. Does pre-habilitation lead to reduced fatigue and improved psychological and quality of life parameters?

Overall study start date
01/06/2014

Completion date
01/06/2016

Eligibility

Key inclusion criteria
1. Any patient over 18 years of age
2. Independently mobile
3. Has been diagnosed with rectal cancer
4. Planned first line of treatment is chemotherapy and radiotherapy followed by curative surgery (timing at discretion of surgeon, but expected between 10-12 weeks post-CRX)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Chemotherapy and radiotherapy not first-line treatment
2. Patient has had previous malignancies
3. Significant co-morbidity where inclusion into this trial would put the patients health at risk
4. Patient has any mental, physical or psychological impairment that prevents them from giving signed informed consent
5. Patient is already achieving their recommended activity level per week where participation in a walking programme would mean he/she would be exercising at a lower level than normal

Date of first enrolment
01/06/2014

Date of final enrolment
01/06/2016

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Royal Alexandra Hospital
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Sponsor information

Organisation
NHS Greater Glasgow and Clyde (UK)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office (UK), ref.: CZH/4/984

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

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
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	feasibility results	01/05/2019	21/01/2019	Yes	No
Plain English results			20/02/2020	No	Yes
Results article	muscle mass results	01/09/2020	22/06/2020	Yes	No
HRA research summary			28/06/2023	No	No