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Study to assess the delivery of a lifestyle intervention for colorectal cancer patients undergoing potentially curative treatment

Submission date 03/04/2014	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 20/05/2014	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 29/03/2019	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-study-looking-at-giving-lifestyle-advice-to-people-having-treatment-for-bowel-cancer-treatwell

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
TreatWELL study protocol V2 13.12.13

Study information

Scientific Title
TreatWELL - A feasibility study to assess the delivery of a lifestyle intervention for colorectal cancer patients undergoing potentially curative treatment

Acronym
TreatWELL

Study objectives
That it is feasible to deliver a lifestyle intervention (smoking cessation, increased physical activity, alcohol reduction and a healthy diet) to patients undergoing potentially curative treatment, initiated at diagnosis of colorectal (bowel) cancer throughout the pre-surgery, post-surgery and recovery period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of Scotland Research Ethics Service,17/12/2013, ref.13/ES/0153

Study design
Non-randomised feasibility trial to inform the feasibility of undertaking a future randomised controlled trial

Primary study design
Interventional

Secondary study design
Non 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

Bowel cancer / Diagnosis of Bowel Cancer / Lifestyle intervention

Interventions
Three 1-hour counselling sessions with a lifestyle counsellor. These will take place during three phases of the study; phase-1 pre-surgery, phase-2 surgical recovery and phase-3 post-surgery / adjuvant therapy recovery. The counselling sessions will be tailored to phase and include advice and support on smoking cessation, increased physical activity, alcohol reduction and a healthy diet and body weight. The face-to-face sessions are designed to be interactive and will include a 10 minute walk and talk session. Fortnightly telephone calls will also be made to the participants and the intervention will be supported with written materials. Behavioural techniques include goal setting, action planning (implementation intentions), coping planning and self-monitoring.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Uptake of intervention programme (recruitment levels, time from diagnosis to intervention). This will be monitored through accurate recording of the screening and recruitment of patients diagnosed with colorectal cancer over a 5 month period.
2. Delivery of the intervention (Can the programme be implemented in the NHS setting? What is the length of time in each phase? Fidelity to protocol). This will be monitored by accurate recording of length of time each participant spends in each phase of the study and by acceptability interviews at the end of phases 2 and 3 with study staff and participants.
3. Patient responses and evaluation measures (To what extent can patients achieve their goals? Can evaluation measures be undertaken successfully? Retention rate). Goal setting and goal achievement will be addressed and recorded at each contact between the lifestyle counsellors and participants (either face to face contact or telephone contact will be made every two weeks). The research nurse will take note of any evaluation measures that are not undertaken and the reason why. Retention rate will be assessed by keeping accurate records of how long each participant spends in the study and whether any participants withdraw from the study before the end.
4. Patients' views (acceptability of programme, what factors do patients think influence adherence?) This will be monitored using exit questionnaires and acceptability interviews at the end of phases 2 and 3 of the study.
5. Intervention costs. Everything that is spent during the study will be carefully recorded and analysed.

Primary outcome measures will be measured at baseline and at the end of each phase of the study (phase-1 pre-surgery, phase-2 surgical recovery and phase-3 post-surgery / adjuvant therapy recovery).

Secondary outcome measures
1. Self-reported smoking, self-reported alcohol intake, physical activity (Scottish physical activity questionnaire and 6 minute walk test)
2. Dietary measures (DINE questionnaire)
3. Physiological measures (height, weight, waist circumference, skin fold thickness)

4. Fatigue (questionnaire)
5. Bowel function (questionnaire)
6. Quality of life (questionnaire)

Secondary outcome measures will be measured at baseline and at the end of each phase of the study (phase-1 pre-surgery, phase-2 surgical recovery and phase-3 post-surgery / adjuvant therapy recovery).

Overall study start date
01/12/2013

Completion date
30/06/2015

Eligibility

Key inclusion criteria
1. Adults (18 years and over)
2. Capable of giving informed consent
3. With stage I to III colorectal cancer
4. Eligible for potentially curative treatment (must be fit for major surgery)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
35

Key exclusion criteria
1. Severe cognitive impairment
2. Not fit for major surgery

Date of first enrolment
01/04/2014

Date of final enrolment
31/10/2014

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre
Centre for Research into Cancer Prevention and Screening
Dundee
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Sponsor information

Organisation
Tayside Medical Science Centre (UK)

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Sponsor type
Research organisation

ROR
https://ror.org/000ywep40

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office (UK), Ref. CZH/4/939

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Publication is currently in prep for BMJ open – submission by end of september. The work has been presented at UKSBM conference.

Intention to publish date
30/09/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Annie Anderson a.s.anderson@dundee.ac.uk all data collected (including qualitative), available now.

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
Participant information sheet	version V3	18/12/2013	11/08/2017	No	Yes
Protocol file	version V1	14/11/2013	11/08/2017	No	No
Results article	results	06/06/2018		Yes	No
HRA research summary			28/06/2023	No	No