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BOUNCED: are cancer patients diagnosed with partial bowel obstruction able to follow a 4 stage diet and does it reduce symptoms and improve quality of life?

Submission date
25/01/2021

Recruitment status
No longer recruiting

Registration date
15/02/2021

Overall study status
Completed

Last Edited
15/11/2024

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Bowel obstruction is a common complication in patients with ovarian, peritoneal and bowel cancer due to a mass or spread of disease, causing narrowing to the gut, as these cancers can grow on the bowel surface. Certain foods may lead to symptoms such as pain, bloating, feeling full, feeling sick, vomiting and difficulty passing a bowel motion. There is limited evidence to establish the best diet to follow when someone is diagnosed with the risk of bowel obstruction and is experiencing symptoms after eating and drinking.

The Dietitians at the Royal Surrey have developed a 4 stage bowel obstruction diet which they have been using with patients for 3 years. The 4 stages are clear fluids, all thin liquids, low fibre soft smooth diet, low fibre soft sloppy diet. Depending on the severity of symptoms and the risk of a blockage, patients are asked to follow a certain stage of the diet. They are advised to move up and down the stages as symptoms improve or get worse.

This feasibility study aims to investigate if the diet can be used and is effective in clinical practice. The objectives are to see if this diet is easy to follow, can reduce symptoms of bowel obstruction, can improve quality of life, and reduce admissions to hospital because of bowel blockages.

Who can participate?
Patients who have had a CT scan and have been shown to be at risk of bowel obstruction with a partial blockage due to colorectal, ovarian, or peritoneal cancer, and are experiencing symptoms as a result.

What does the study involve?
After signing a consent form the dietitian will explain how the 4 stage diet works and which stage of the diet each participant starts from. They will also explain what to do if symptoms get worse or better and how to move to a different stage of the diet.

During the study, participants will be asked to complete a simple diet diary every day, as well as 3 other questionnaires. These will ask about symptoms and aspects that may affect their quality of life and will need to be completed at the start and the end of the trial. On the last day of the trial, they will also be asked to answer 4 questions about how easy or difficult they found the diet to follow.

Involvement in the study will last for 4 weeks (28 days). The dietitian will review participants weekly during the study. This will either be in person at the cancer centre or at home by telephone or video call.

What are the possible benefits and risks of participating?
The benefits of taking part in the study are not yet known, but it is hoped that the results will help patients in the future. The 4 stage bowel obstruction diet has not been shown to cause harm and is a safe form of nutrition. Participants may develop symptoms from their cancer that are not necessarily related to the diet and will receive help with these. It is not anticipated that following the 4 stage diet will prevent routine cancer care from going ahead.

Where is the study run from?
St Luke's Cancer Centre in Guildford (UK) and the Royal Surrey Hospital in Guildford, Surrey (UK)

When is the study starting and how long is it expected to run for?
From February 2019 to November 2022

Who is funding the study?
GUTS Fighting Bowel Cancer (UK)

Who is the main contact?
Lindsey Allan, lindseyallan@nhs.net

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
272626

Protocol serial number
CPMS 48020, IRAS 272626

Study information

Scientific Title
Managing oral diet following a diagnosis of sub-acute bowel obstruction: a feasibility study exploring the efficacy of a 4 stage Bowel ObstrUctioN CancEr Diet and quality of life in cancer patients (BOUNCED)

Acronym
BOUNCED

Study objectives
To determine whether a 4 stage bowel obstruction diet as a means of managing oral intake in patients symptomatic with malignant sub-acute bowel obstruction (SBO) is deliverable and effective in clinical practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/02/2021, West Midlands - Solihull Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham NG1 6FS; +44 (0)207 1048310; solihull.rec@hra.nhs.uk), REC ref: 21/WM/0006

Study design
Mixed methods single-arm non-randomized feasibility study

Primary study design
Interventional

Study type(s)
Quality of life, Treatment

Health condition(s) or problem(s) studied
Bowel obstruction as a result of colorectal or ovarian cancer

Interventions
At baseline, participants will be provided with a participant information sheet and assessed for eligibility. After signing a consent form the participants will also be weighed and asked about personal details, medical history, cancer history, and any concomitant medications or treatment being used. The dietitian will explain to participants how the 4 stage diet works and which stage of the diet each participant starts from. They will also explain what to do if symptoms get worse

or better and how to move to a different stage of the diet. Participants will be asked to follow the 4 stage diet for 4 weeks (28 days).

During the study, participants will be asked to complete a simple diet diary every day. Participants will also be asked to complete 2 questionnaires both at the start and end of the study. These will ask about symptoms and aspects that may affect quality of life. On the last day of the trial, participants will also be weighed and asked to answer a 4 stage ease of use questionnaire about how easy or difficult they found the diet to follow.

The dietitian will review participants weekly during the study either in person at the cancer center or at home by telephone or video call. This review will include a review of any adverse events, concomitant medications or treatment, diet diary, stages of the diet participants have followed during the preceding 7 days since their last review, and details of any oral nutritional supplements used (to include the name and how many taken each day).

Intervention Type
Behavioural

Primary outcome(s)
1. Acceptability of a 4 stage diet to patients measured using the ease of use questionnaire at 4 weeks
2. Symptoms of sub-acute bowel obstruction (abdominal pain, feeling bloated, feeling full-up quickly, nausea, or vomiting) measured using the Memorial Symptom Assessment Scale questionnaire (MSAS) at baseline and 4 weeks. The MSAS has been adapted to include the key additional symptom of early satiety that can be experienced by patients with sub-acute bowel obstruction and will be graded on a scale of 0 (not at all) to 4 (very much).

Key secondary outcome(s))
1. A&E attendances or hospital admissions due to bowel obstruction will be measured from hospital records between 3 months prior to the study and baseline, and between baseline and 4 weeks
2. Health-related Quality of Life measured using the European Organization for Research and Treatment of Cancer Quality of Life questionnaire (QLQ-C30) at baseline and 4 weeks
3. Weight measured in kilograms and as a percentage indicating percentage weight change from start to end of the trial at baseline and 4 weeks

Completion date
02/11/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 14/12/2022:
1. Aged ≥18 years
2. Able to tolerate the oral diet
3. Diagnosis of colorectal cancer with a primary tumour in situ, locally advanced disease or peritoneal spread causing clinical symptoms of bowel obstruction OR diagnosis of gynaecological cancer with spread to the peritoneum causing clinical symptoms of bowel obstruction
4. Bowel obstruction considered inoperable at the time of consent
5. Presenting with any of the following clinical symptoms of sub-acute bowel obstruction:

5.1. Abdominal pain
5.2. Bloating after eating
5.3. Early satiety
5.4. Nausea
5.5. Vomiting
6. Capacity to give informed consent

Previous inclusion criteria:
1. Aged ≥18 years
2. Able to tolerate the oral diet
3. Confirmed diagnosis of sub-acute bowel obstruction due to underlying malignancy including those with colorectal or gynaecological cancers with a primary or secondary tumour in situ and those undergoing cancer treatment or supportive care
4. Patients diagnosed with advanced inoperable cancers of colorectal or gynaecological origin
5. Presenting in outpatient clinics or admitted from A&E with a minimum of 2 symptoms of the following subacute bowel obstruction:
5.1. Abdominal pain
5.2. Bloating after eating
5.3. Early satiety
5.4. Nausea
5.5. Vomiting
6. Capacity to give informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
30

Key exclusion criteria
1. No symptoms of bowel obstruction
2. Have not already been given the advice to follow the 4 stage bowel obstruction diet
3. Unable to read and communicate in the English language

Date of first enrolment
02/03/2021

Date of final enrolment
05/10/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Surrey County Hospital NHS Foundation Trust
Egerton Road
Guildford
United Kingdom
GU2 7XX

Sponsor information

Organisation
Royal Surrey County Hospital NHS Foundation Trust

ROR
https://ror.org/050bd8661

Funder(s)

Funder type
Government

Funder Name
Guts UK Charity

Alternative Name(s)
Guts UK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Lindsey Allan, lindseyallan@nhs.net

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/11/2024	15/11/2024	Yes	No
Basic results		14/11/2024	15/11/2024	No	No
HRA research summary			28/06/2023	No	No