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Impact of digital information on managing symptoms and recovery after surgery for gullet or stomach cancer

Submission date
15/11/2023

Recruitment status
Recruiting

Registration date
19/01/2024

Overall study status
Ongoing

Last Edited
07/11/2025

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Around 13,500 people in England and Wales are diagnosed with oesophago-gastric (food pipe or stomach) cancer each year, of which around 5,000 (40%) have major surgery. Patients stay in hospital for around 1-2 weeks after surgery. Even when well enough to continue their recovery at home, patients may still experience surgery-related problems or feel unwell with symptoms such as pain or tiredness. There is growing evidence that electronic (online/web-based) reporting of symptoms can improve patients' wellbeing by providing patients with information about how best to manage symptoms. However, this has not been studied in patients undergoing surgery for cancer. This study aims to find out if patients recovering at home from surgery for food pipe or stomach cancer benefit from electronic (online/web-based) symptom management information.

Who can participate?
Patients aged 18 years and overrecovering at home from surgery for food pipe or stomach cancer

What does the study involve?
Participants will be randomly placed in one of two groups. Participants in the 'electronic information tool' group will be asked to report their symptoms using an electronic (online/web-based) tool while also receiving their usual care. The tool will provide information about self-care (e.g., self-management of symptoms by the patient) or, if reported symptoms are more serious, provide information to the patient to contact their healthcare team. Patients in the 'usual care' group will not use the electronic information tool to report their symptoms or receive symptom management information. All patients will complete questionnaires during the study, including before their surgery, when ready for discharge home and at several timepoints up to 4 weeks thereafter. The researchers will use the questionnaire answers to see if patients in the 'electronic information tool' group have a better recovery from surgery than those in the usual care group. They will also look at whether the electronic information tool is good value for money for the NHS.

What are the possible benefits and risks of participating?
There are no known benefits of taking part in the study, but it is hoped that the results from this study may benefit the NHS and improve the management of future patients. Some participants may find it beneficial to record their symptoms and/or answer questions about the symptoms they are experiencing, in terms of keeping track of their recovery as it improves, and being mindful of how they are feeling and the subsequent ability to manage their symptoms.
There are no known risks or disadvantages of taking part in the study. Participants in both study groups will receive usual care. A possible disadvantage to participants may be the time it takes to complete the study questionnaires, although the researchers have tried to keep these to a minimum. Some of the questions in the study questionnaires may cause participants to feel upset by acting as a reminder of the symptoms they are experiencing.

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

When is the study starting and how long is it expected to run for?
December 2022 to May 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
rose-study@bristol.ac.uk

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-online-tool-manage-symptoms-surgery-oesophageal-cancer-stomach-cancer-rose

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
298723

Protocol serial number
CPMS 59351, IRAS 298723

Study information

Scientific Title
Impact of feedback from Real-time, electronic symptom monitoring on post-discharge recOvery after Surgery for oEsophago-gastric cancer: a multi-centre randomised controlled trial: the ROSE study

Acronym
ROSE

Study objectives
The study is testing the hypothesis that tailored, digital symptom management information can improve patients' recovery after discharge from hospital following surgery for oesophageal (gullet/food pipe) or gastric (stomach) cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/12/2023, East of England - Cambridgeshire and Hertfordshire Research Ethics Committee (2 Redman Place, London, EC20 1JQ, UK; +44 (0)2071048096; cambsandherts.rec@hra.nhs.uk), ref: 23/EE/0254

Study design
Randomized; Interventional; Design type: Process of Care, Education or Self-Management, Management of Care

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Oesophago-gastric cancer

Interventions
The ROSE study is a multicentre parallel group Randomised Controlled Trial with an internal pilot phase. 206 participants will be randomised from approximately six NHS hospitals in England, in a 1:1 ratio to the intervention (ROSE electronic information tool) or control (no ROSE electronic information tool). This means that everyone who joins the study will be put into one of the two groups. The group that participants will be put into will be chosen at random by a computer so that the two groups are as similar as possible and can be compared fairly. This process is called randomisation. As mentioned in previous sections, evidence is lacking for using electronic symptom reporting and information tools in major cancer surgery, so a control group of participants who do not use the electronic information tool is necessary in order to compare the results of the intervention to usual care.

Participants in the control group will be required to complete the same set of health-related and resource-use questionnaires as those in the intervention arm (to collect the study outcome measures). They will do this by completing outcome questionnaires within the electronic system that hosts the ROSE electronic information tool, but they will not have access to the tool (intervention) component of the system.

All participants will receive standard post-operative clinical care. The study is unblinded because of the nature of the intervention, as participants will need to interact with the electronic information tool to provide their information. Randomisation will take place at the point of discharge from hospital to home and participants will be followed up for four weeks post-randomisation.

Participants will be required to do or undergo the following procedures:
Before surgery:
1. Read the ROSE study Patient Information Leaflet. This will be provided either at their face-to-face or virtual pre-surgery appointment, or potential participants will be invited to take part by post
2. Provide informed consent
3. Complete EuroQol- 5 Dimension-5 Level (EQ-5D-5L) and Functional Assessment of Cancer Therapy-Esophageal (FACT-E) or Functional Assessment of Cancer Therapy-Gastric (FACT-Ga) questionnaires (paper or electronic, in-hospital or at home)
At the point of hospital discharge:
1. Receive a demonstration of the electronic outcome measure (questionnaire) system
2. Complete QoR-40, EQ-5D-5L and FACT-E or FACT-Ga questionnaires (paper or electronic, in-hospital or at home)
3. Intervention group only - receive a demonstration of the electronic information tool by a

research nurse, involving the completion of the electronic information tool symptom questionnaire (electronic)

Post-discharge:
1. Week 1 (day 6), week 2 (day 14), week 3 (day 21), and week 4 (day 28) post-discharge – complete QoR-40 questionnaire (electronic).
2. Intervention group only – Week 1 (Days 3, 6), week 2 (day 14), week 3 (day 21), and week 4 (day 28) (or more frequently if patient wishes - i.e. if they experience new or a change in symptoms) post-discharge – complete electronic information tool symptom-report questionnaire (electronic).
3. Day 28 – additionally, complete EQ-5D-5L, healthcare resource use questionnaire, and FACT-E or FACT-Ga (electronic).
4. Day 28 – Telephone call with a Research Nurse to collect information on health resource use (also for safety reporting purposes).

Patients will receive email/SMS reminders to complete the post-discharge study questionnaires, which will be completed electronically/online to reduce patient and administrative burden. Participants will also be able to view their previously completed questionnaires in the ROSE electronic tool system.

Recruitment will take place over 24 months (including a 6-month pilot phase). Continuation into the main phase of the trial will only happen if certain milestones are achieved: (i) three sites have opened to recruitment and (ii) 20 participants have been recruited. If these targets are not met, a recovery plan will be proposed if: (i) 14-20 participants have been recruited after 6 months and (ii) a minimum of three sites have opened to recruitment. After 1 month of follow-up of the final participants, data cleaning, analysis and write-up will take approximately 6-7 months.

No interim analyses of the data (analyses before the study has collected all of the data) are planned.

Participants and/or clinical personnel will know which study group participants have been randomised (allocated) to (that is, they will not be "blinded" to the study group allocation). The trial will therefore be at risk of performance bias, meaning that there may be differences in a participant's care caused by knowing which study group a patient has been randomised to. To minimise performance bias caused by post-randomisation differences in hospital care, randomisation will occur as close to discharge as possible. Performance bias will also be minimised by defining the procedures that will take place in the intervention and control groups, standardising procedures for participant follow-up, and monitoring adherence to the study protocol.

Selection bias (a type of bias that is caused by the researcher selecting which participants go into the intervention or control groups) will be excluded by concealing the randomisation process (researchers will not be able to see or predict the next random allocation prior to randomisation).

Detection bias (caused by differences in how outcomes are measured in the intervention and control groups) will be minimised by using validated patient-reported outcome measures (validated questionnaires). These will be administered and reminders sent in the same way for all participants.

Attrition bias (bias caused by differences between the study groups in how and which participants are lost from the study) will be minimised by using established methods developed in the Bristol Trials Centre (BTC) to maximise the quality and completeness of the data (e.g., regular monitoring of data, detailed querying of data in-built into the study database, offering participants alternative methods for participating in study follow-up (e.g., postal, online or telephone). Any instances of non-adherence to the intervention (e.g., when participants do not complete the electronic information tool) will be documented and reviewed at study meetings and an action plan for maximising adherence drawn up as appropriate. Data will be analysed using an intention-to-treat approach (i.e. analysing data according to the participants' treatment allocation, irrespective of whether they followed the standard procedures in the intervention or control group, future management and events), and every effort will be made to include all randomised patients. Sensitivity to attrition bias (that is, the impact of losing participants from the study on the study findings) will be investigated in the statistical analysis, implementing appropriate imputations for missing data (that is, replacing the missing data) if appropriate. Follow-up for the primary outcome (the outcome that has been selected as the most important outcome for patients and clinicians) should be complete for all patients.

Reporting bias (the selective reporting of only some of the outcomes measured in the study) will be minimised by having pre-specified outcomes and pre-specified statistical analysis and health economic analysis plans. Potential participants will be identified from hospital multidisciplinary healthcare team (MDT) meetings and/or pre-operative assessment clinic lists, screened for potential eligibility, and those patients who are potentially eligible will be invited to participate. All potential participants will be provided with a Participant Information Leaflet (PIL) describing the study either in person at their pre-operative outpatient appointment or by post/email. If the patient decides to take part, a member of the local hospital research team will confirm their eligibility and obtain written informed consent before surgery. A sample size (a total number of participants needed for the study to answer the research question) of 206 patients (103 per group) will provide 90% power to detect an effect of the intervention, allowing for up to 16% loss to follow-up (that is, allowing for up to 16% of participants to drop out of the study).

The researchers have worked extensively with patient and public contributors throughout the pilot study preceding this RCT, during the funding application and in the set-up of this project. This includes, but is not limited to, an online survey, engaging with existing patient support groups in online and in-person meetings and setting up a specific Patient Advisory Group (PAG) for the ROSE study. This engagement work has helped inform the recruitment strategy (in terms of how and when patients are approached for participation in the study) and enabled us to ensure that technical issues around IT systems were resolved in a way that places patients at the centre of the process.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Quality of recovery from surgery measured using the Quality of Recovery questionnaire (QoR-40) over 4 weeks post-randomisation (approximately 4 weeks post-discharge)

Key secondary outcome(s))

1. Economic impact from the NHS perspective of the electronic information tool compared with usual care within 4 weeks post-hospital discharge
2. Disease-specific symptoms and wellbeing/quality-of-life measured using Functional Assessment of Cancer Therapy
Esophageal/Gastric (FACT-E/Ga) questionnaires and general health status (EQ-5D-5L questionnaires) at 4 weeks post-discharge
3. Clinical events (including complications, readmission/reintervention, healthcare contacts) recorded within 4 weeks post-discharge
4. Healthcare resource use recorded within 4 weeks post-discharge

Completion date
30/05/2026

Eligibility

Key inclusion criteria
1. Adults aged >=18 years
2. Referred by the hospital multidisciplinary healthcare team for elective oesophagectomy (oesophageal resection) or total/subtotal gastrectomy (gastric resection) for oesophago-gastric cancer

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Planned discharge NOT back to their home
2. No access to a personal email account
3. No access to a computer/mobile device or internet at their usual place of residence
4. Unwilling to use electronic information tool/electronic questionnaire system or participate in research
5. Unable to provide written informed consent
6. Insufficient understanding of English to complete questionnaires
7. Participating in other research that would interfere with participation in this study

Date of first enrolment
29/05/2025

Date of final enrolment
28/05/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
University Hospitals Bristol and Weston NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
United Kingdom
BS1 3NU

Sponsor information

Organisation
University Hospitals Bristol and Weston NHS Foundation Trust

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR201483

Results and Publications

Individual participant data (IPD) sharing plan
Data will not be made available for sharing until after publication of the main results of the study. Thereafter, anonymised individual patient data may be made available for secondary research, conditional on assurance from the secondary researcher that the proposed use of the data is compliant with the MRC Policy on Data Sharing regarding scientific quality, ethical requirements, and value for money. A minimum requirement with respect to scientific quality will be a publicly available pre-specified protocol describing the purpose, methods, and analysis of the secondary research, e.g., a protocol for a Cochrane systematic review.

Anonymous research data will be stored securely and kept for future analysis at the University of Bristol's Research Data Storage Facility (RDSF). Requests for access to data must be via a written confidentiality and data-sharing agreement available from the RDSF website which will be confirmed by the CI (or appointed nominee). The data sharing agreement should cover limitations of use, transfer to third parties, data storage and acknowledgements. The person applying for the use of the data will be scrutinised for appropriate eligibility by members of the research team. Patient identifiers will not be passed on to any third party.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes