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# Improving the long-term care of patients who have had bariatric surgery: PROMISE CARE study

**Submission date**
23/05/2023

**Recruitment status**
No longer recruiting

**Registration date**
23/06/2023

**Overall study status**
Completed

**Last Edited**
29/04/2024

**Condition category**
Surgery

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

## Plain English summary of protocol

Background and study aims
Scientific studies have shown the benefits of weight-loss surgery. However, people who have had weight-loss surgery can regain weight, struggle with excess skin and/or develop low vitamins and nutrients levels, which can have serious effects on health and wellbeing. Weight-loss surgery patients can have a complex mixture of physical and psychological health needs that require careful monitoring after surgery.
Guidance recommends that patients are reviewed by their surgical team for 2 years after surgery and then have yearly GP reviews. However, research suggests these yearly GP reviews are not happening. This is concerning as patients who do not receive follow-up have worse health outcomes. We know that GPs are not confident in caring for weight-loss surgery patients, and that patients want more support. We plan to develop and test a package of care to support weight-loss surgery patients, but before we can do this, we need to do some developmental work to inform this future study. It is not clear how or who would be best to give this long-term care, or how patients would prefer to receive it. There are also difficulties in deciding what this care should look like, including variation in existing weight management services, primary /secondary care capacity issues and variable patient needs.

The study aims to understand the issues relating to high quality long-term care following weight-loss surgery from the perspectives of patients, healthcare professionals and commissioners (NHS managers who pay for services). This will help us decide what should be included in the package of long-term care for weight-loss surgery patients.

Who can participate?
Healthcare professionals who work within an NHS or private adult specialist weight management or bariatric surgery service in the UK and patients who have had bariatric surgery.

What does the study involve?
Firstly, we will interview healthcare professionals as we currently do not have any detailed information on their views. Then we will hold three discussion events using “system mapping”, a process that allows us to gather information to produce a visual map (diagram) that shows all the issues related to delivering this care and what affects those issues, from the perspectives of patient stakeholders and professional groups.

After this we will meet with stakeholders again to discuss the “map” and agree what type and format of intervention or interventions to develop and test in a larger research study to see if it works.

What are the possible benefits and risks of participating?
It is unlikely that participation will have any direct benefit to you, although some people enjoy sharing their views and experiences in interviews or discussions. Your participation may improve the planning and delivery of healthcare for future patients who have had weight-loss surgery.

There are few, if any, risks or disadvantages to participating, other than the fact that your participation will take some of your time. The researchers will make sure participation is scheduled at a time that is convenient to the majority of participants and there will be regular breaks. Some people may find it distressing talking about their experiences of personal health, living with obesity and/or weight-loss surgery. Should you experience any distress during the interview/group discussion event, you will be offered the opportunity to take a break from or leave the interview/ discussion event without any consequence. The researcher will listen to you and if needed will provide you with details of local help services or offer to make contact with someone on your behalf.

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

When is the study starting and how long is it expected to run for?
November 2022 to March 2024

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

Who is the main contact?
Dr Helen Paretti, h.parretti@uea.ac.uk

### Study website
https://www.uea.ac.uk/web/groups-and-centres/projects/promise-care-study

## Contact information

### Type(s)
Principal Investigator

### Contact name
Dr Helen Parretti

### ORCID ID
http://orcid.org/0000-0002-7184-269X

### Contact details
Norwich Medical School
University of East Anglia
Norwich
United Kingdom
NR4 7TJ

+44 1603 591532
h.parretti@uea.ac.uk

# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number
320028

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
CPMS 55256, IRAS 320028

# Study information

### Scientific Title
Improving the long-term care of patients who have had bariatric surgery

### Acronym
PROMISE CARE

### Study objectives
The overall aim of this research is not to develop an intervention(s), but to gain an in-depth understanding of the issues around providing long-term post-bariatric surgery care to inform the subsequent development and testing of an intervention in a future study.

Several different study methods will be employed to address this aim.

Work Package 1:
To explore primary care healthcare professionals' views, experiences and behaviours around long term post-bariatric surgery care.

Work Package 2:
Illustrate different stakeholder perspectives of the current issues in post-bariatric surgery care.

Work Package 3:
Seek agreement from stakeholders on recommendations for future intervention(s).

### Ethics approval required
Ethics approval required

### Ethics approval(s)
Approved 21/02/2023, North East - Newcastle and North Tyneside 1 Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 2071048255; newcastlenorthtyneside1.rec@hra.nhs.uk), ref: 23/NE/0039

## Study design
Qualitative interviews, system mapping and stakeholder panel discussion meetings

## Primary study design
Observational

## Secondary study design
Qualitative study

## Study setting(s)
GP practice, Hospital

## Study type(s)
Other

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

## Health condition(s) or problem(s) studied
Obesity - post-bariatric surgery follow-up care

## Interventions
Qualitative interviews, system mapping and stakeholder panel discussion meetings will be used to address the study objectives.

PARTICIPANTS
• Healthcare professionals who work within an NHS adult specialist weight management or bariatric surgery service in the UK (for at least 1 year) (e.g. obesity physician, bariatric surgeon, specialist dietitian, specialist nurse, specialist clinical psychologist, specialist physiotherapist /physical activity professional).
• Primary care health professionals (e.g. GP, practice nurse) working in the UK who have experience of seeing patients who have had bariatric surgery patients within NHS primary care.
• Patients who have had any type of bariatric surgery either NHS funded or privately funded, performed in the UK or abroad, are aged 18 years or over, living in the UK , have capacity to provide informed consent and sufficient competence in English to participate in workshops.
• Commissioners e.g. from Integrated Care Boards or national bodies who have experience of commissioning for adult weight management services/bariatric surgery.

RECRUITMENT SUMMARY
We will use multiple strategies in the recruitment of professional (healthcare professionals and commissioners) participants to ensure we recruit a sample that is diverse in terms of professional background, geographical location, clinical seniority, and experiences of managing patients post-bariatric surgery (including any clinical pathways).
Clinical research networks (CRNs) in the West Midlands and East of England have agreed to help with recruitment of GPs working in those areas. These areas will allow recruitment from a range of settings, enabling representation from participants working in services in urban, rural or coastal areas. In addition we will recruit via professional organisations (via their newsletters /emails to members, webpages and social media), professional networks, social media and snowballing.
Given the current pressure on NHS services and our wish to recruit a diversity of participants we

have decided to take an approach to sampling for the patient participants for the system mapping workshops and the stakeholder panel meetings, which will initially use social media, patient organisations, the study webpage and snowballing, so reducing our dependence on clinical gatekeepers for access. If this recruitment strategy is not successful, or if some targeted recruitment needed to ensure our sample is diverse in experience and key demographics, we will use Patient Identification Centres (PICs) at GP surgeries in the West Midlands and the East of England (supported by the CRNs in these areas). In addition, we may also use NHS bariatric surgery units as PIC sites to identify patients who have recently been, or are about to be discharged 2 years post-surgery, if required to aid recruitment.
An invitation letter will be sent with a participant information sheet and an expression of interest form to be returned to the research team if interested in taking part (via email/weblink /WhatsApp/post). We will use the expression of interest forms to support where possible, purposive sampling to facilitate a maximum variation sample. Participants who take part in the earlier studies will be potentially eligible to also participate in the later studies, but we will also undertake additional recruitment as needed to maintain diversity in the sample.

INFORMED CONSENT SUMMARY
Potential participants who contact the research team with an expression of interest form will be contacted by a researcher to check they have read and understood the participant information leaflet and if they have any questions about the study. If they wish to proceed they will be sent a consent form to complete and return to the research team.
Throughout this research we will offer multiple routes to communicate with the research team and receive and send forms - these will include completion of an online version via a weblink, email/WhatsApp (link or photo/scan of forms) or post as preferred by the potential participant. Consent will also include video recording of the interview/workshop/meeting (we will inform all potential participants that they can attend with their camera off, if preferred (only the audio data will be used for the research). If someone wishes to participate in a group workshop or meeting, but either is unable to attend or does not wish to be recorded they will not be able to take part (as this is a discussion group it is not possible to exclude a given individual from being recorded). The exception to this will be for
the patient system mapping workshops where we will offer an opportunity to contribute their views and experiences by completing and sending us a structured patient journey in an audio /video or written format.
For all interviews, workshops and meetings if a completed consent form for any participants has not been received prior to the workshop, the researcher will take verbal informed consent (for group workshops/meeting we will invite the participant to join a private breakout room with a researcher for this to be completed). This will be recorded separately to the rest of the interview /workshop/meeting. The researcher will read out each of the consent form statements, initial these (or not) depending on the participant's responses and sign a written consent form to confirm they have taken consent.
The consent forms for the earlier studies will include optional consent to be contacted regarding participation in later studies. Those who give consent to be contacted regarding this will have the option to decline participation if contacted about the later studies.

DATA COLLECTION AND ANALYSIS SUMMARY
All studies within this project will be held remotely to facilitate inclusion of participants across the UK (given the variation in bariatric surgery and weight management services across the UK), as well as for those who may have difficulty travelling due to agoraphobia, disability and/or work /caring responsibilities. We are aware that some people may find taking part in an online meeting to be challenging or intimidating. All patient participants in the studies will be offered support led by our PPIE co-I (with help from other members of the study team and PPIE support at UEA) related to attending the workshops and meetings. This includes being offered a meeting

pre-workshop/panel meetings to help them to be prepared for the meeting, a debrief meeting after the workshops/panel meetings and/or help with navigating the technology required to attend the meeting. We will offer costs for mobile data needed to attend the meeting if required and our PPI co-I and another patient and public involvement advisory group (PAG) member will also be present during all the meetings.

Work package 1
Semi-structured interviews with a purposive sample of primary care and specialist weight management service (WMS) healthcare professionals (HCPs) will be undertaken to investigate experiences and views on managing patients post bariatric surgery. The discussion guide and analysis will be theoretically informed by the Capability-Opportunity-Motivation-Behaviour model (COM-B) and the Theoretical Domains Framework (TDF), as this is an approach designed to elicit modifiable determinants of change (barriers and enablers), as well as potential processes for addressing these determinants (mechanisms of change). This will facilitate future translation into intervention strategies. We will seek to recruit up to 25 participants for these interviews. Results from the interviews will be synthesised and the overarching findings will be used to inform the system mapping workshops - see Work package 2.

Work package 2
Stakeholder system mapping workshops will be held with a) patients who have had bariatric surgery and then b) a wider group of stakeholders including HCPs, commissioners and patients. These will build on the issues and concepts identified in Work package 1 and explore them in more detail. The output of these workshops will be a comprehensive “system map” (a visual map like a mind map or spider diagram) of the issues in post-bariatric surgery care and factors influencing outcomes, that represents the perspectives of the different stakeholders. The map will be drafted in real time (allowing participants to input directly to the mapping process) and then refined based on thematic analysis of workshop transcripts. We will seek to recruit 20 participants to each of the three system mapping workshops (1 patients only workshop, 2 workshops with a range of stakeholders: patients, healthcare professionals and commissioners). We will aim for participants in the wider stakeholder system mapping workshops to attend both workshops and there will also be opportunities for participants from earlier studies to participate in the later studies throughout this project if they wish to do so.

Work package 3
Stakeholder (patients, HCPs and commissioners) panel discussion meetings will be held to to seek agreement from stakeholders on recommendations for a future intervention(s) including key design elements. These meetings will bring together the outputs from the earlier studies and use established methods (such as nominal group technique) to facilitate discussion and find agreement about what is important to include in a future intervention(s).

## Intervention Type
Other

## Primary outcome measure
1. An in-depth understanding of healthcare professionals’ perspectives and experiences of long-term post-bariatric surgery care measured using qualitative interviews informed by theoretical frameworks for understanding behaviour: COM-B and TDF, and using the Framework Method for analysis
2. A co-produced system map (with key stakeholders), which will facilitate a comprehensive understanding of the complex healthcare issue of long-term care after bariatric surgery, measured using online stakeholder workshops during which the system map is developed and

refined in real time, with some additional refinement after the workshops using thematic analysis of workshop transcripts
3. Identified and agreed priorities and key design elements for a future intervention to improve long-term care after bariatric surgery measured using panel meetings with key stakeholders, which will be informed by the earlier work packages

### Secondary outcome measures
There are no secondary outcome measures

### Overall study start date
01/11/2022

### Completion date
05/03/2024

## Eligibility

### Key inclusion criteria
Work package 1
1.1. Healthcare professionals who work within an NHS or private adult specialist weight management or bariatric surgery service in the UK (for at least 1 year) (e.g. obesity physician, bariatric surgeon, specialist registered dietitian, specialist nurse, specialist clinical psychologist, specialist physiotherapist/physical activity professional).
1.2. Primary care healthcare professionals (e.g. GP, practice nurse) working in the UK who have experience of seeing patients who have had bariatric surgery.

Work package 2
Patient stakeholder system mapping workshop
2.1. Patients who have had bariatric surgery either NHS funded or privately funded, performed in the UK or abroad.
2.2. Patients can have had any type of bariatric surgery procedure conducted for weight management (including those who have had revisional surgery).
2.3. Eligible patients need to be aged 18 years or over, living in the UK, have capacity to provide informed consent and sufficient competence in English to participate in workshops (screened during expression of interest/consent process).
2.4. Patients who do not have sufficient English to participate in workshops, but sufficient to give written informed consent will still be eligible to submit a “structured patient journey” written in another language, but will not be eligible to participate in the workshops. This opportunity will be stated in the patient information leaflet.

Wider stakeholder system mapping workshop
2.5. Eligibility criteria for patients will be the same as for the patient stakeholder system mapping workshop (with the exception that patients submitting structured patient journeys will not be eligible for this work package).
2.6. Eligibility criteria for healthcare professionals will be the same as for Work package 1. Healthcare professional participants will be eligible whether or not they participated in Work package 1.
2.7. Commissioners e.g. from Integrated Care Boards (ICBs) or national bodies who have experience of commissioning for adult weight management services/bariatric surgery will be eligible to participate.

Work package 3
3.1. Eligibility criteria for the stakeholder panel discussion meeting will be the same as for patients and professional participants in Work package 2. Participants will be eligible whether or not they participated in the earlier work packages.

### Participant type(s)
Patient, Health professional, Other

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
47

### Total final enrolment
52

### Key exclusion criteria
Work package 1
1.1. Any participants who do not fulfil inclusion criteria will be excluded.

Work package 2
Patient stakeholder system mapping workshop
2.1. Any participants who do not fulfil inclusion criteria will be excluded. We will also exclude patients who have had bariatric surgery not for weight management, i.e. for gastric cancer, or had gastric balloons.

Wider stakeholder system mapping workshop
2.2. Any participants who do not fulfil inclusion criteria will be excluded.

Work package 3
3.1. Any participants who do not fulfil inclusion criteria will be excluded.

For all work packages, we will also exclude those who do not consent to video recording of the interview/workshop/panel meeting (for group workshops/meetings it is not possible to exclude one individual from the recording).

### Date of first enrolment
14/04/2023

### Date of final enrolment
26/02/2024

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**University Medical Centre**
University of East Anglia
Earlham Road
Norwich
United Kingdom
NR4 7TJ

## Sponsor information

### Organisation
University of East Anglia

### Sponsor details
Norwich Medical School
Norwich
England
United Kingdom
NR4 7TJ
-
researchsponsor@uea.ac.uk

### Sponsor type
University/education

### Website
https://www.uea.ac.uk/

### ROR
https://ror.org/026k5mg93

## Funder(s)

### Funder type
Government

### Funder Name

National Institute for Health and Care Research

### Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

## Results and Publications

### Publication and dissemination plan
We will submit academic paper(s) for publication in peer-reviewed journals such as Surgery for Obesity and Related Diseases and British Journal of General Practice. Presentations will be delivered at conferences concerned with obesity/bariatric surgery or healthcare services, such as UK Congress on Obesity and Society for Academic Primary Care meeting. Authorship of outputs arising from this study will follow the International Committee of Medical Journal Editors (ICMJE) guidelines. All study team members will be invited to be named as co-authors on publications, given their contributions to designing the study.

In addition to publishing in relevant clinical journals and presenting at clinical conferences, an accessible lay summary will be developed with PPI contributors, and disseminated to the wider patient population through social media, study webpages and patient groups (i.e. Obesity UK, European Coalition for People Living with Obesity (ECPO) and Global Obesity Patient Alliance). In addition, PPIE contributors will aim to produce short “talking heads” videos at key points of the project, which will be included on the project webpage.

### Intention to publish date
30/04/2025

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Helen Parretti, h.parretti@uea.ac.uk once the main findings of the study have been accepted for publication.

When the study is complete, all anonymised study data will be preserved for ten years in accordance with the University of East Anglia Code of Practice. The research team will consider external requests to gain access to anonymised data, to be securely shared under the auspices of the chief investigator (and always in accordance with the Data Protection Act of 2018 and the EU General Data Protection Regulation 2016/679). All requestors wishing to obtain study data will be asked to provide a brief research proposal including the objectives and timelines of the candidate project, intellectual property rights, and expectations for publications and citations. These details will form the basis of a Data Sharing Agreement between the University of East

Anglia and the requestor, to clearly establish the responsibilities of each party. It is expected that requestors will, as a minimum, acknowledge the original research team and NIHR funding, and will consider co-authorship of any subsequent publications, if appropriate. Permission for anonymised data to be shared for the purpose of future academic research will be sought from all participants via the informed consent form.

## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| HRA research summary | | | 26/07/2023 | No | No |