PROMISE CARE STUDY

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

PARTICIPANT INFORMATION LEAFLET

(Healthcare Professional Interviews)

You are being invited to take part in a research study organised by researchers at the University of East Anglia in collaboration with the Universities of Bristol and Birmingham, Leeds Beckett University, Cavill Associates* (a company that provides research and consultancy services in public health) and University Hospitals Coventry and Warwickshire NHS Trust. Before deciding whether or not to take part, it is important for you to understand why the research is being carried out and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish, before deciding whether or not to take part. Thank you.

What is the purpose of the study?

The clinical benefits of bariatric surgery have been well-established in research studies. However, people who have had bariatric surgery can regain weight, struggle with excess skin and/or develop nutritional deficiencies, which can have serious effects on their health and wellbeing. Bariatric 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 at least 2 years after surgery and once discharged from the surgical team, have annual reviews as part of a shared care model of chronic disease management. However, research suggests that, in primary care, these annual reviews are not happening.

We ultimately plan to develop and test a package of care to improve the long-term care and support for patients who have had bariatric surgery, but before we can do this we need to do some research. It is not clear how or who would be best to give this long-term care, or how patients would prefer to receive it.

Overall, this study aims to understand how best to support patients in the long-term following bariatric surgery from the perspectives of patients, healthcare professionals and commissioners. This will help us decide what should be included in a future package of long-term care for patients who have had bariatric surgery. The first part of this study will involve interviews with healthcare professionals, like you, to explore their views and experiences of delivering long-term care for people who have had bariatric surgery.

Why have I been invited to participate?

You are being invited to consider participating in an interview because you are a healthcare professional with experience of managing patients after bariatric surgery in primary care (such as a GP or a practice nurse) or a healthcare professional working within a bariatric surgery team. We are aiming to include participants from a range of different professions and clinical settings from across the UK.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, the researcher will send you a consent form and ask you complete and return this before the interview to confirm that you are willing to take part. You can return the completed consent form by email, WhatsApp (sending a photo or scan of the completed consent form) or complete it online via a weblink, as you prefer. At the start of your interview we will ask you to verbally re-confirm this consent and that you agree to take part.

If I volunteer, will I be guaranteed to take part?

No. We need to make sure that we undertake interviews with a diverse range of participants and so we might not talk to everyone who agrees to participate.

What happens if I take part?

This research involves taking part in one interview which we expect to last up to an hour. If you decide to take part, the researcher will contact you (via email/telephone/text/WhatsApp) to arrange a suitable date and time for the interview. The interview will either be held remotely using a secure online platform or via telephone, according to your preference (we may also be able to offer an opportunity to hold the interview in person at the British Obesity and Metabolic Surgery Society Annual Meeting in June). The interview will be recorded either using an encrypted dictaphone or using the online platform software (audio recording only will be stored). Topics to be discussed in the interview will be informed by findings of previous research and expert opinion, including clinicians and people with direct experience of having had bariatric surgery. The findings from the interviews will contribute to later work packages (group discussion meetings) in PROMISE CARE which will develop a "system map" (this is like a mind map or spider diagram) summarising issues and factors influencing long-term care after bariatric surgery from the perspectives of patients, healthcare professionals and commissioners. If you agree, we would like to record the interview for research purposes. Interviews via online platform will be video/audio recorded, if video recorded just the audio data will be used for the research and you can choose not to have your camera on if you prefer. Interviews via telephone will be audio recorded using an encrypted dictaphone.

If you might be interested in also taking part in the later online group discussion meetings that will develop the system map and/or panel discussion meetings you can indicate your interest during the consent process. *(Note: this is optional and you can consent to just taking part in an interview. You can also say no at a later date for the group discussion meetings and/or panel meetings even if you say yes now).*

What are the possible benefits of taking part?

It is unlikely that participation will have any direct benefit to you, although some people enjoy sharing their views and experiences in interviews. Your participation may improve the planning and delivery of healthcare for future patients who have had bariatric surgery.

What are the possible disadvantages and risks of taking part?

There are few, if any, disadvantages to taking part in this study, other than the fact that the interview will take about an hour of your time. The researchers will make sure the interview is scheduled at a time that is convenient to you.

Will I be paid for taking part?

Reimbursement for the time that you spend taking part in the interview will be available on request.

What if I change my mind?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We will be able to destroy recordings and transcripts (written copies of the recordings) of your interview data if you request this within two weeks after the recordings were made, but we will not be able to remove your data thereafter, as we will have begun to analyse the data. If you decide you would like to withdraw you should contact the research team via email (promise.care@uea.ac.uk) or via telephone call/text/WhatsApp (07730 736717/07572 978084) to let them know.

What if something goes wrong?

This study carries a very low risk of causing physical or psychological harm. If you wish to complain, or have concerns about any aspect of the way you have been approached or treated during the course of this study, please contact Dr Helen Parretti (h.parretti@uea.ac.uk, chief investigator) or researchsponsor@uea.ac.uk.

Will my taking part in this study be kept confidential?

All information from the interview will be treated in confidence. However, in certain circumstances, such as any disclosures which may indicate harm to yourself or others, we may have to breach this confidentiality. This would be discussed with you beforehand wherever possible.

How will my information be used?

We will need to use information from you for this research project. People will use this information to do the research, or to check your records to make sure that the research is being done properly. We will keep all information about you safe and secure.

This will include some personal information for example, your name and contact details (used to contact you about taking part in the study). All electronic personal information will be stored on a University of East Anglia secure server. Any personal information on paper will be stored in a locked filing cabinet within a locked office. This information will only be accessible to the chief investigator and other members of the research team. It will be stored separately from the rest of your study information.

To do this research we will also need to use information from you from the audio/video recording of the interview you take part in. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a unique code number/identifier instead.

The audio data from the interview recording will be transcribed (e.g. a written record of the interview produced) by a University of East Anglia employee or a University of East Anglia approved transcribing service who has signed

a "Personal Data Processing Agreement" with the University. We will do our best to de-identify the transcripts so that neither you nor other individuals can be recognised. Interview recordings will be stored on a University of East Anglia's (UEA) secure server, which will only be accessed by the research team. Any paper copies of the transcripts will be stored securely in a locked filing cabinet at the University of East Anglia. Once we have finished the study, we will keep some of the data so we can check the results (see next two sections). We will write our reports in a way that no-one can work out that you took part in the study.

What will happen to the results of the research study?

The results of this study will be reported in scientific journals. Summaries of the findings may be prepared for patients and the public and presented at scientific conferences and meetings. Results may also be used for teaching and training purposes. We may use direct quotes from the interviews when we report the findings, but any quotes will be de-identified (e.g. avoiding use of names/places). In the interest of making the best use of publicly funded research, we may use transcripts of interviews in our work looking at similar issues over the next 10 years.

What will happen to my data?

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. We will hold electronic recordings and transcripts of your data on a University of East Anglia (UEA) secure server. Recordings will be kept up to 12 months after the PROMISE CARE study has ended and de-identified data, including transcripts will be kept for 10 years. All personal data (e.g. contact details) will be destroyed within 12 months of the end of the PROMISE CARE study.

In addition, we will ask for your permission to make any transcripts relating to your data "Controlled Access". This means that transcripts will be stored in a secure online database indefinitely for potential analysis by other researchers. These individuals will need to submit an application to do this, which will be assessed by the chief investigator and PROMISE CARE research team. Data will not be released unless the research team approves this. Any data released will be anonymised, so that you/others will not be identifiable. This is optional and you can still take part in this study and not consent to your data being used for future studies.

The University of East Anglia is the data controller for this study and the lead contact is David Bridge, Data Protection Officer. You can find out more about how we use your information by sending an email to dataprotection@uea.ac.uk. For information on how we use your data from online forms, who it may be shared with, your rights, and who to contact if you have any questions or concerns, see https://www.uea.ac.uk/web/about/university-information/statutory-and-legal/data-protection/data-protection-for-webforms.

Who is organizing and funding the research?

The study is funded by the National Institute for Health Research (NIHR 204217) and sponsored by the University of East Anglia.

Who has reviewed the study?

All research that involves NHS patients or staff is reviewed by an independent Research Ethics Committee (REC) to protect your safety, rights, wellbeing, and dignity. The study was approved on 21/2/2023 by the North East – Newcastle & North Tyneside 1 Research Ethics Committee (reference: 23/NE/0039).

What happens next?

Before you decide whether to take part, we would be happy to answer any question about the study. Please contact Dr Helen Parretti (chief investigator) or Dr Ross Watkins (contact details below).

If you decide you want to take part, please return the expression of interest questionnaire or contact Dr Helen Parretti or Dr Ross Watkins (see below contact details).

Dr. Helen Parretti: h.parretti@uea.ac.uk 07572 978084

Dr Ross Watkins: promise.care@uea.ac.uk 07730 736717

Thank you for reading this information sheet.
Please keep a copy of this information.

* Cavill Associates (https://www.cavill.net/) have a contract in place with the University of East Anglia and will be contractually obliged to adhere to the requirements of the protocol and study sponsor.