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PARTICIPANT INFORMATION SHEET

Study Title: **BARI-LIFESTYLE Observational Study: Evaluation of changes in body composition, physical activity levels and quality of life in the first year following bariatric surgery.**

Study Number: **16/0232**

IRAS Project ID: **220368**

You are invited to take part in a research study looking at how body composition (the relative amounts of body fat, muscle and bone), physical activity levels and quality of life change in the first year following bariatric surgery. Before you decide if you would like to take part, it is important you understand why this research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others including your GP if you wish. Part one of this information sheet tells you the purpose of this study and what will happen to you if you take part. Part two gives you more detailed information about the way in which this research is conducted and our duty of care towards you throughout the study. Please feel free to ask us if there is anything that

is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

PART ONE

1. What is the purpose of this study?

The purpose of this research project is to study how body composition, physical activity levels and quality of life change in people who have undergone bariatric surgery. We want to gain knowledge on how weight loss after bariatric surgery affects the relative amounts of muscle and fat in your body, your bone density, physical fitness, diseases linked to obesity (e.g. diabetes, high blood pressure, high cholesterol level, sleep apnoea) and your quality of life. Gastric bypass and sleeve gastrectomy are the two most common bariatric procedures undertaken in the UK and worldwide. Thus, we will be studying people before and after both of these two operations. Information gained from this study may be compared with information from other studies to help us design better follow-up care in the future for people undergoing bariatric surgery.

2. Why have I been invited?

You have been invited because you are scheduled to undergo either gastric bypass or sleeve gastrectomy surgery.

3. Do I have to take part?

It is up to you to decide whether or not to take part and we will provide any further information to help you make your decision. You will be allowed to decide whether you would like to take part in this study within one week after being approached by us. If you wish to take part, you can contact any of our researchers. Their contact detail is provided on the first and last page of this information sheet. If after one week we do not hear anything from you, our research team will be in contact with you, provided that you give us your name and contact number and a verbal consent for us to contact you. If you decide to take part, you will be asked to sign two copies of consent form. Your participation will be on voluntary basis, and you will be free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

4. What will happen to me and what will I have to do if I take part?

If you agree to take part in the study, we will need you to attend on 4 occasions. These study visits will be timed to coincide with your normal follow-up appointments with the bariatric team at the hospital. Your visits will be once before surgery and then 3 times after surgery at approximately 3, 6 and 12 months post-surgery. You will be asked to eat nothing after 8 pm the night before each of the study visit and to drink only water. The first visit will take place approximately six weeks before your planned surgery and will last for approximately 2-4 hours. During this visit, the following will take place:

1. You will have your normal clinic visit assessments taken including measurement of your height, weight and usual blood tests.
2. To assess your physical fitness, we will ask you to:
    a. Walk at your normal pace along an even corridor for 6 minutes.

b. Sit on a chair, stand up and then sit back down. We will ask you to do this 5 times as quickly as you can.
c. Squeeze a handheld device for 3-5 seconds as hard as possible so that we can assess your hand-grip strength. You will be asked to do this 3 times with each hand.

3. Your body composition will be assessed using:
   a. A dual energy X-ray absorptiometry (DXA) scan. This is a quick and painless procedure that involves lying on your back on an X-ray table so an area of your body (body fat, muscle, and bone) can be scanned. DXA scan uses a very low level of X-ray radiation. This means it is safe for the technician doing the scan to stay in the room with you (in standard X-ray tests, the technician has to stay behind a protective screen).
   b. A bioelectrical impedance scan. This is a non-invasive and painless procedure that requires you to step on the pads of a scale. A very low level and safe electrical signal will measure your body fat and muscle.
4. You will be asked to complete 3 health-related quality of life questionnaires that will assess how your health impacts upon your physical, social, mental and emotional functioning.
5. To monitor your physical activity levels, you will be given:
   a. A Fitbit activity tracker. This is a watch-like device that you wear on your non-dominant hand (the hand that you do not write with). The device displays the time and also tells you how active you have been. This is for yours to keep and to help you become more active. You will be taught how to use this. This device links to a smartphone or a computer allowing you to monitor your activity levels over time. In order to use the Fitbit and tailor this to you personally, you will be required to enter your email address, height, weight and gender. Fitbit allows third-party access to these data and the data generated from the Fitbit. For further information regarding the safety of your data, you can refer to Fitbit Privacy Policy https://www.fitbit.com/uk/legal/privacy.
   b. An Actigraph activity tracker, a small device (dimension: 4.6 cm by 3.3 cm by 1.5 cm: weight 19 g), to wear on a belt around your waist, underneath your clothes, for one week. You will be asked to wear this continuously, removing this only to shower or take a bath. For the captured data to be valid, you have to wear the device for at least 10 hours daily. Whilst you are wearing the Actigraph, we will give you an activity diary to record your daily activities on an hourly basis and a food diary to record what you are eating. You will be given a stamped addressed envelope to post back the Actigraph and the diaries to us at the end of the week.

The same assessments will be repeated during your follow-up visits to see the Bariatric Team at approximately 3-month after surgery (2nd visit) and approximately 6-month (3rd visit) and 12-month (4th visit) after surgery. However, the DXA scan will only be repeated at your 12-month follow-up visit. Some of you will be invited to attend lifestyle interventions, such as counselling and exercise activities, during the study.

5. What are the possible disadvantages and risks in taking part?

A possible disadvantage of taking part is the inconvenience of spending more time than usual for the assessment to complete during your normal follow-up visit in the hospital. The DXA scan uses to assess your body fat, muscle, and bone will involve some exposure to X-ray radiation, but the amount you

receive is exceedingly small and isn't considered to be harmful. Only a trained health professional will perform this procedure for you.

6. What are the benefits of taking part?

There is no direct benefit to you from the study. However, it is hoped that information gained from this study will help us design better follow-up care for people undergoing bariatric surgery in the future.

7. What happens when the research study stops?

If the study is stopped for any reason, we will tell you why and arrange for your continuing care.

8. What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information concerning this is given in Part Two of this information sheet.

9. Will my taking part in the study be kept confidential?

Yes. We will follow the ethical and legal practice, and all information about you will be handled in confidence. The details are included in Part Two.

If the information in Part One has interested you and you are considering participation, please read the additional information in Part Two before making a decision.

PART TWO

10. What if relevant new information becomes available?

Sometimes during the research study, new information is found out about how to care for patients. If this happens, we will tell you about it and discuss with you whether you want to or should continue your participation in this study. If you decide not to carry on, we will make arrangements for your care to continue. If you decide to continue in the study, you will be asked to sign an updated consent form. Also, on receiving new information, we might consider it to be in your best interest to withdraw from the study. If so, we will explain the reasons and arrange for your care to continue.

11. What will happen if I do not want to carry on with the study?

You will be free to withdraw from the study at any time and without giving a reason. A decision to withdraw will not affect the standard of care you receive. If you withdraw from the study, we will destroy all your identifiable personal data. Unless you object, your data that is collected up to the point of your withdrawal will be retained and included in the study analysis.

12. What if there is a problem?

If you have any problems during the study, or would like to discuss the study, you can contact any of the research investigators. You can find their contact detail on the first and last page of this information sheet. You can also speak to the Patient Advice and Liaison Service (PALS), at University College London Hospital (they can be found on the ground floor of main building, or by phoning 020

3447 3042). When contacting them, please quote the study number that can be found on the first page of this information sheet. In the event of any adverse events occurring as a consequence of your participation in this study, you will be compensated through the University College London (UCL) insurance scheme.

13. Will my taking part in the study be kept confidential?

If you consent to take part in this study, the records obtained while you are in this study will remain strictly confidential at all times. All data will be collected and stored in accordance with the Data Protection Act 1998. You will be given a unique trial identification number at the start and used on your records instead of your name. The master list linking your name and the trial identification number will be kept in a secure location. This way, your personal identity and the information you provide in the study cannot be connected by anyone outside the study team. Only your initials, date of birth and trial identification number will be used for identification. Names will not be used in any of the study records or in any report or publication. All these personal data will be held in a secure location, and hard copies of information will be kept in locked cabinets, electronic copies of information will be kept in password-protected computers to which only members of the research team will have access. Your data will not be passed to anyone else outside the research team or the Sponsor (University College London) who is not involved in the study. It will be stored securely for 20 years (the length of time we need to keep research information for) then arrangement for confidential destruction will be made. All of the results of the study that are analysed and published will be fully anonymised so that neither you nor your individual results will be identified.

14. Will my GP be informed of my involvement?

With your permission, your GP will be notified that you are taking part in this study.

15. What will happen to the results of the research study?

The results of the study will be available after it finishes and will usually be published in a medical journal and presented at a scientific conference. The data will be anonymised and none of the participants involved in this study will be identified in any report or publication. The results or the publication of this study will be made available to you upon request.

16. Who is organising and funding the research?

This research study is being organised by the Centre for Obesity Research, University College London (UCL). The Chief Investigator is Professor Rachel L. Batterham (Consultant Obesity Physician, Diabetologist, and Endocrinologist) who has a vast experience in clinical research studies. This study is being sponsored by University College London (UCL) and is funded by the National Institute for Health Research (NIHR), the Sir Jules Thorn Charitable Trust and the Rosetrees Trust.

17. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by London-Dulwich Research Ethics Committee.

18. Contact for further information:

You are encouraged to ask any questions you wish, before, during or after your participation in this study. If you require any further information or any concerns while taking part in this study, please contact one of the following research investigators:

Professor Rachel L. Batterham : r.batterham@ucl.ac.uk
Dr Andrea Pucci : a.pucci@ucl.ac.uk
Ms Helen Kingett : h.kingett@nhs.net
Dr Jacqueline Doyle : jacqueline.doyle3@nhs.net
Dr Alisia Carnemolla : a.carnemolla@ucl.ac.uk
Mr Friedrich C. Jassil : friedrich.jassil.13@ucl.ac.uk

If you decide you would like to take part, then please read and sign two copies of the consent form. You will be given a copy of this information sheet and one original copy of the signed consent form to keep. You can have more time to think this over if you are at all unsure.

THANK YOU FOR TAKING THE TIME TO READ THIS INFORMATION SHEET AND TO CONSIDER THIS STUDY