Participant Information Sheet (PIS)

General Information

Study Title: The WUP's (Weight loss, Urogynaecology Symptoms, Psychological Changes) Study

Full Study Title: The Effects of Bariatric Surgery on Urinary Symptoms and the Pelvic Floor, and the Psychological Changes Associated with Weight Loss in Relation to Urogynaecology Symptoms: A Single service Prospective Observational Cohort Study

Sponsor Name: The University of Birmingham

Researchers: Mr Philip Toozs-Hobson (Chief Investigator) and Dr Chioma Chilaka (student)

We are running a study with your clinic team as part of a student study with the student directly engaging with you and collecting data. You have been invited to join this study as you are under the care of the weight loss services (bariatric team). We are looking at the connection between weight loss, bladder symptoms, and mental health and wellbeing, we are interested in investigating whether you have symptoms related to vaginal wall weakness (prolapse) or bladder problems. We are looking at how these symptoms change as a result of the treatment you will have under the care of the bariatric team. Joining this study does not in any way affect your treatment for your weight.

Joining the study is entirely up to you. Before you decided to join our study, we would like you to understand what it involves. We would like you to take some time to read the following information carefully and talk to others before making your decision. One of our team members is available to go through this information leaflet with you if you prefer. Thank you for taking time to read this leaflet and thank you for your time to discuss the study today.

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Part 1: Information about the Study

What is the study about?

You have been referred to the Bariatric services as you want to consider surgery as part of your choice to manage your weight. Having a raised body max index (BMI) can lead to multiple problems such as diabetes and heart disease. Some complications are not always spoken about, such as problems holding your bladder and vaginal wall weakness (prolapses). About one in three women in the UK have problems with holding their urine. Research has shown that lower urinary tract symptoms (LUTS) increase when you are overweight. Our study is to look at whether weight loss associated with bariatric surgery correct these symptoms in women who have problems with their bladder.

We also know weight can have an impact on mental health. We would like to follow your progress and assess your mental health and the impact weight loss has.

Our aim is to understand the changes that occur due to weight loss, and to look at new ways to help women with these problems and improve future care. The study is designed to walk with you along your weight loss journey. We are looking for about fifty women to take part. The study is voluntary, and it is your choice if you would like to take part.

Why have I been asked to take part?

Our study is looking at women over the age of 18 who qualify for NHS funded weight loss surgery in the West Midlands. You meet our criteria and so have been invited to be involved.

Do I need to take part?

No. It entirely voluntarily. Throughout the study we will check to ensure that you are still happy to continue, and you are free to withdraw at any point without a reason.

How does this study affect the care I receive with the weight loss team?

This study will not affect the treatment you will receive in any shape or form. You will continue to have all the routine care from the weight loss team as usual. If are still interested to take part in the study, please go to part 2 of this information sheet.

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By your side

Part 2: Your role in the study

What will happen to me if I take part?

If you decide to take part in the study, we will contact you before your weight loss operation and after your operation. We will contact you over three-monthly intervals for a total of eighteen months following your surgery.

There are two groups, and you can decided to be in either or both. The first is group A (the physical group), the second is group B (the psychological group).

For the **Group A,** the meetings will consist of:

- An electronic questionnaire which will ask you about your urinary symptoms, if any. You can fill this out in clinic or at home. The questionnaire will take about twenty minutes to complete, and you can skip any part that you feel doesn't apply to you or you are unhappy to answer. Some of the questions in the questionnaire will sensitive e.g urinary, bowel, vaginal and sexual activity questions.
- An **optional** physical vaginal examination to assess any present prolapse. The vaginal examination takes 1-2 minutes and will be with a nurse chaperone. It is optional but does help us connect the symptoms with the physical findings.

We will contact the **Group A** in 6 times, once before surgery and then every 3 months for eighteen months.

For examinations, we will aim to see you alongside your routine follow up in clinic. The examinations are optional and you can decide at each time whether or not you agree to have the examination. Just because you agree on one occasion this doesn't mean that you have to agree on every occasion.

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For the **Group B,** the meetings will consist of:

- Up to 60 minutes initially talking interview with premade questions. The interview can take place in clinical or virtually (or the phone).
- We will repeat the interview in clinic or virtually at:

  The pre-operative stage

  Six Months after your operation

  Twelve Months after your operation

It is likely that the follow up interviews will take less time and more likely to be about twenty to thirty minutes. Following the study, if anyone would like further help with their symptoms, they will be able to be seen by the gynaecology team for further help.

Will this affect the care I receive?

No. Your weight loss care is not affected in any way. You will still get all the routine follow up and care from your team. Deciding not to take part in this study will also not affect your care.

What type of information about me will be collected?

We will collect information on your:

- Age, ethnicity, weight and medical background.
- Initials
- NHS number
- Name
- contact details
- Blood sample results from your team (no new samples will be taken)

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 also collect your answers to questions from a symptom's questionnaire and from your interview. If you choose to have the vaginal examination, we will record the findings from this assessment. The data will be stored securely on NHS facilities in locked rooms. The audio recordings will be recorded on an encrypted Dictaphone or on MS team. The interview will be transcribed by the student researcher and professional transcribers, if necessary, who will sign a confidentiality clause. The recordings will be deleted immediately after transcription. Your data will be kept for

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three months after the study ends to analyse the results after which point the recordings will be deleted.

What are the advantages of taking part in the study?

If you choose to take part in the study, you will have an extra team walking with you along your weight loss journey. You can discuss any bladder or prolapse problems that you have not had the opportunity to understand, and treatment options should this be appropriate. Some participants find it is helpful to take part in the interview as it is an opportunity to talk about how you feel about your weight loss journey and about other things that may be on your mind. If any symptoms are identified during the research and you need further help, your GP can be informed at your request, and if appropriate you can be referred to the gynaecology team. Taking part will give you an opportunity to learn more about medical conditions that affect the bladder and the support of the vaginal walls. Though there is no direct benefit for participants, you will be helping to better our knowledge and understanding in this area.

What are the disadvantages of taking part in the study?

Being part of this study will take up a small amount of your time. You will be asked some questions about urinary symptoms which you may find personal. You can skip any questions that you do not want to answer. If you choose to have a vaginal examination, a small number of women may find it uncomfortable.

What happens now if I decide to participate?

If you decide to participate you will be asked to come back to read, sign and date the consent form. By signing it you acknowledge that you have understood the aims of the research, and what you are being asked to do.

What happens if I change my mind during the study?

You are free to withdraw your participation at any time, without providing a reason.

Will my participation in the study be kept confidential?

Yes, absolutely, this very important to us we would only share information with your General Practitioner (GP) if you specifically asked us to do so. We will keep your details anonymous, , none of your personal information such as your name will be seen by anyone outside of the

research team. We will write to your GP to let them know that you took part providing we have your consent to, but no other details are shared unless you specifically as us to. If there are disclosures made that may put you or others in harms way, we will have to escalate is appropriately.

What if there is a problem or complaint?

We do not anticipate there to be any problems in taking part in this study. Participants will be given the option to give feedback with the researcher and to talk through any issues raised during this research. There are contact details also at the end of this information leaflet.

If you have any concerns or complaints about the study, you can speak to any member of the team for more answers. If you prefer to speak to someone independent of the research team about your complaint, then you can contact the University of Birmingham Research Governance team on: researchgovernance@contacts.bham.ac.uk.

If you remain unhappy and wish to complain formally then you can do this through the National Health Service Complaints Procedure, details of which can be obtained at www.nhs.uk or by phoning 0845 601 3012.

PALs: Customer Relations - PALS service. Birmingham and Solihull Mental Health NHS Foundation Trust. Trust Headquarters. Unit 1, B1. 50 Summer Hill Road, Birmingham B1 3RB. https://www.uhb.nhs.uk/pals-contact.htm.

We do not anticipate any harm to come to you during this study. If you are harmed because of taking part research project, there are no special compensation arrangements.

What do I do now?

Once you have read this information sheet and all questions have been answered to your satisfaction, we will ask you if you still want to participate in the study. If so, we will ask you sign a consent form and arrange a date and time of when we will conduct the interview.

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By your side

Part 3: After the Study

What will happen to the results of the research study?

The results of the study will be analysed and published in medical journals. We will be able to send a copy of the results and publications to you.

Who is sponsoring the research?

The University of Birmingham.

Who is organising and funding the study?

The study has been organised by Mr Philip Toozs-Hobson, Dr Chioma Chilaka, Dr Helen Egan. The study is not funded and is part of Dr Chilaka's MD degree.

Who will review the study?

All research in the National Health Service is looked at by an independent group of people, called a Research Ethics Committee to help protect the individuals involved. This study has been reviewed and given favourable opinion by Liverpool Central Research Ethics Committee.

How will we use information about you?

We will use this information to conduct the study and to check records to make sure that the study is being conducted properly. Your data will have a code number so that none of your personal information is identifiable. We will keep all information about you safe and secure. Once we have finished the study, we will keep the data for 3 months so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

Your anonymised data will be kept for future research. Your anonymised data will not leave the UK.

What are your choices about how your information is used?

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 need to manage your records in specific ways for the research to be reliable. This means that we will not be able to let you see or change the data we hold about you until the study is complete.

Where can you find out more about how your information is used?

You can find out more about how we use your information by visiting the website: www.hra.nhs.uk/information-about-patients/. You can ask one of the research team or ringing us on **0121 472 1377** – ask for Mr Toozs-Hobson's secretary on extension **5422**.

What happens if I have more questions?

If you do not understand something in this leaflet or if you have further questions, you may ask the researcher now. Or you can contact the researcher via email on: Chioma.chilaka@nhs.net. You can ring us on **0121 472 1377** and ask for Mr Toozs-Hobson's secretary on extension **5422.** You can also contact the University of Birmingham: researchgovernance@contacts.bham.ac.uk.

Thank you for your time.

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