Cover Page

Study Title: The WUP's (Weight loss, Urogynaecology Symptoms and 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 Number: RG_21-138 (ERN_21-1174)

Sponsor Name: The University of Birmingham

IRAS ID: 313427

Chief Investigator: Mr Toozs-Hobson

Version: Version 3.0

General information

Protocol title: The WUP's (Weight loss, Urogynaecology Symptoms and Psychological Changes) Study Protocol

Name and address of the sponsor: The University of Birmingham, Edgbaston, Birmingham, B15 2TT, United Kingdom

Investigators:

- **Lead investigator**: Mr Toozs-Hobson, Birmingham Women's and Children's NHS Foundation Trust, Mindelsohn Way, Birmingham B15 2TG
- **Student Researcher**: Dr Chioma Chilaka, Birmingham Women's and Children's NHS Foundation Trust, Mindelsohn Way, Birmingham B15 2TG
- **Supervisor**: Dr Helen Egan, Birmingham City University, 15 Bartholomew Row, Birmingham B5 5JU
- **Statistician**: James Hodson, Research Development and Innovation, Second Floor, Institute of Translational Medicine, Heritage Building, Queen Elizabeth Hospital, University Hospitals Birmingham NHS Foundation Trust, Birmingham, B15 2TH

Organisations involved:

- Birmingham Women's and Children's NHS Foundation Trust, Mindelsohn Way, Birmingham B15 2TG
- Birmingham City University, 15 Bartholomew Row, Birmingham B5 5JU
- Birmingham Heartlands Hospital, Bordesley Green E, Birmingham B9 5SS

Content

Research protocol:

Abbreviations

BMI - Body mass index

BWH - Birmingham Women's Hospital

COVID-19 Coronavirus -19

ePAQ - Electronic personal health questionnaires

GCP - Good Clinical Practice

LUTS - Lower urinary tract symptoms

MDT - Multidisciplinary Team meeting

NHS - National Health Service

NICE - The National Institute for Health and Care Excellence

POP-Q - Pelvic Organ Prolapse Quantification System

Research Protocol

Project Summary

This study will observe participants as they undertake their bariatric journey with the bariatric team. We will assess their urinary symptoms with a questionnaire before their operation and at intervals following their procedure. They will be offered an **optional** vaginal examination also to see if their symptoms correlate with the vaginal examination findings and assess the changes with weight loss. We will conduct semi-structured interviews on a portion of the participants prior to surgery and after. We will **not** be carrying out any surgical interventions ourselves.

PICO Model	Summary
Participant	Adult, female participants already with the bariatric services awaiting bariatric surgery.
Intervention	The participants will undergo bariatric surgery as part of their routine care **by the bariatric services**. We will not conduct surgery ourselves. The interventions involved in the study are questionnaires, interviews and a vaginal examination (optional for the participants).
Comparison	Symptomatic difference between participants before and after having the bariatric surgery . The tools of assessment will be: 1. electronic Personal Health Questionnaires (ePAQ questionnaire) 2. An optional vaginal examination 3. Psychological interview 4. Blood test results available as part of their routine care
Outcomes	1. Change in ePAQ questionnaire assessments 2. Change in vaginal assessment. 3. Qualitative data from the interviews 4. Biochemical changes as weight loss occurs

The project will span eighteen months with three and six monthly intervals for assessments.

Rationale and Background Information

The rate of obesity is ever-increasing, and its impact is far-reaching. Pelvic floor dysfunction is usually confined to the realms of urogynaecology, yet the implications on the quality of life of an individual can be quite severe. It is already recognised that lower urinary tract symptoms (LUTS) increase with obesity. It is estimated that 28.7% of adults in England are obese and a further 35.6% are overweight but not obese (House of Commons Library 2019). It is well established that there is correlation between being overweight or obese and urinary incontinence symptoms(Purwar, Cartwright et al. 2019). A further study estimated that in the UK the prevalence of urinary incontinence in women is 34% (NICE). With growing obesity in the UK, it is inevitable that there will be a growing number of women suffering from urinary incontinence.

Since the revision of the use of mesh implants in urogynaecology surgery in 2018, there has been a shake up in the way urinary incontinence, (especially stress incontinence) is managed. This has led us to think in a broader sense about the way in which we approach the condition of incontinence. Immerging reviews have shown some promising signs of the use of bariatric surgery to improve the symptoms of urinary incontinence. It is an area that is under researched and an area of significance for practice, despite the knowledge of poorer outcomes in urogynaecology surgery (Bach, Hill et al. 2019). Often as doctors, the patient is seen in a clinical manner, however the psychological affiliation between obesity and weight management is well documented. As Gynaecologists, we do not properly understand obesity and the metabolic syndrome which occurs as a result of obesity. It is so relevant; that it is recommended in two of the NICE guidelines on the management of Obesity in Adults (NICE). To help treat incontinence most effectively in women in the future will take a combined approach of tacking obesity and is of paramount importance given the evidenced psychological components of obesity and of morbid obesity. We speculate that there is a role that mental resilience plays on the severity of symptoms (Israfil-Bayli, Lowe et al. 2015).

Obesity has two effect; firstly the direct "physical" effect, but secondly and increasingly recognised, the metabolic effects characterised in "metabolic syndrome" and may help explain why the impact of obesity varies between individuals. The situation is further complicated by the psychological effects firstly associated with developing obesity and secondly the impact of treatment and weight loss. We will also do a systematic review of the literature to look at what is already known about psychological impact of weight loss and effects on their quality of life on LUTS.

With the above in mind, we are interested to have data on the impact of weight loss to better inform women as to the importance of weight loss and it effects on pelvic organ prolapse and female urinary incontinence. Often, a purely surgical approach to conditions does not treat the underlying issues such

as metabolic syndrome as a driver for urgency, and hardly breaches any psychological origin. Our research seeks to gain a better insight into the extent of the role bariatric surgery plays on the pelvic floor regarding patient symptoms and psychological changes. This project is a Prospective Observational Cohort study, following participants undergoing bariatric surgery. We look to assess their urinary symptoms and pelvic floor dysfunction at baseline and at intervals as participants lose weight. The principal tool will be the electronic Personal Health Questionnaires (ePAQ questionnaire), a self-administered electronic smart pelvic floor questionnaire which is validated for use in Urogynaecology. It is widely used within Urogynaecology within the NHS. We will compare the treatment cohort to a group not undergoing surgery.

We will follow the participants up at three, six, nine, twelve and eighteen months following their surgery. Statical analysis will be non-parametric using chi squared. Women who consent will also have a pelvic examination to assess objective changes in any prolapse. In depth qualitative interviews will be conducted to understand how underlying psychological drivers change with particular emphasis on LUTS and based around the responses to the ePAQ questionnaire.

Our results will form a scientific basis informing as to the benefits of treating metabolic syndrome and weight loss and inform as to the role of bariatric surgery as a treatment option for urinary symptoms and pelvic prolapse management. The results will inform on decision making relating to treatment of LUTS in obese women and also help women understand the components of their condition.

This study will also help to assess the psychological impact of bariatric surgery to patients' symptoms and help-seeking behaviours. The project could also help to inform the development of tool kits to identify patients who are at more risk of psychological distress problems post-surgery. The project will give us an opportunity to work across disciplines such as Heartlands Bariatric service and psychological services.

This project is the latest in the series of our research programme looking at the relationship between obesity and LUTS. We know that there is limited evidence in the form of randomised controlled trials (RCTs) to conclusively answer our research questions. To implement change and influence national guidance, there need to be more substantial data to better direct future research. This project will be a steppingstone to build a series of experiments with solid research foundation that can be used to guide national changes. It will also allow the early development of long-term data akin to the BSUG website to help aid and facility future learning and studies.

Study goals and objectives

The main goal of our study is to see if there is a correlation between weight loss and Uro-gynaecological symptoms. We aim to achieve these goals by answering the following research questions:

Research Questions

1. ***Is there a correlation between weight loss and urinary symptoms?***
    a. If so, to what measurable extent?
    b. If so, is there a correlation with the amount of weight lost?
    c. If so, is there a correlation with the months that have passed following surgery?
2. ***Is there a correlation between weight loss and vaginal prolapse symptoms?***
    a. If so, to what measurable extent?
    b. If so, is there a correlation with the amount of weight lost?
    c. If so, is there a change in the POP-Q assessment?
3. ***Is there a correlation between weight loss and self-worth and help seeking behaviours?***
    a. Is there a discrepancy of self-worth between the control group and the treatment group?
    b. Does a sense of self-worth relating to obesity have an impact on participants seeking help for urinary and pelvic floor symptoms?

The main research questions seek to assess the changes weight loss has on the pelvic floor. 'Bariatric Surgery' incorporates a range of procedure that seeks to help morbidly obese participants to lose weight, as well as improve their metabolic status. The participants seen in bariatric clinics compose of an already established cohort of participants that will be monitored alongside their routine follow up as they lose weight. Using this established service will allow us to follow participants and assess the changes along their weight loss journey.

A lot of other health factors are affected by obesity, one such factor is the mental health of patients. Low self-esteem and self-worth are often factors patients suffer from (NHS and British Psychological Society). This study will also look at the effect of self-esteem in this cohort of participants and see if it affects how they respond to their care and how they seek help.

Our goal is to see if there is an objective correlation with weight loss, urinary symptoms, extent of prolapse and psychology. It will help to broaden our approach on managing urogynaecology symptoms and help direct us for the future.

Study design

	Summary
Participant	Adult, female participants already on the bariatric services awaiting bariatric surgery.
Intervention	This is a study administering questionnaires and interviews with patients and optional vaginal assessment of those who agree to this. Results of blood tests taken as part of standard of care will also be collected.
Comparison	Symptomatic difference inparticipants pre and post bariatric surgery . The tools of assessment will be: 1. electronic Personal Health Questionnaires (ePAQ questionnaire) and optional vaginal assessments. 2. Psychological interview
Outcomes	1. Change in ePAQ questionnaire assessments 2. Change in vaginal assessment. 3. Qualitative data from the interviews 4. Blood test results from the Bariatric team monitoring metabolic syndrome
Participant Numbers	Qualitative branch: 50 Quantitative branch: 20 – discussed with physiology professor at Birmingham City Hospital for advice
Location of recruitment	Heartland Hospital, Birmingham Women's Hospital
Follow up Intervals	3, 6, 9, 12 and 18 months
Tools of assessment	1. Electronic Personal Health Questionnaires (ePAQ questionnaire) and optional vaginal assessments. 2. Vaginal assessment using the Pelvic Organ Prolapse Quantification (POP-Q) System 3. Interview with questions designed by **Dr Helen Egan** 4. Blood test results - as part of their routine care
Data Collection	1. ePAQ questionnaire assessments summaries will be available in a qualitative format to assess the different aspects of pelvic floor dysfunction. 2. The pelvic examinations will be carried out by a gynaecology trainee under supervision. 3. Recorded semi-structured interviews 4. Blood test results – as part of their routine care
Data analysis	Quantitative data: This data with the scientifically analysed Qualitative data: The data will be analysed using thematic analysis following Braun and Clarke's (2006) model.

Patient Involvement

We invited patients to review the protocol and patient information leaflet. There was a total of 3 patients; two of them have previously had bariatric surgery and one had a raise BMI and urogynaecology symptoms. All of the patients gave positive feedback and verbal confirmation that the study would be acceptable form their view point.

Methodology

We will recruit participants seen at the bariatric clinic at Heartlands Hospital. This will be alongside their routine bariatric services care.

We seek to recruit 50 women in total (50 women for the quantitative branch of the study and 20 for our qualitative branch). After informed consent, the participants will be initially assessed pre-operatively and then followed up at 3, 6, 9, 12 and 18 months post-surgery. Participants will complete an ePAQ questionnaire. Those who consent will be extended to include a vagina assessment. Participants that consent to the qualitative element of the study will undergo a psychological interview.

The participants will be approached by member of the bariatric MDT (i.e. doctors, nursed, dietitians). We will also have posters. The participants will direct to speak to the research trainee who will give the participants more information about the study. The participant will have at least 24 hours to think about taking part and if they agree they will be consented by the research trainee.

Inclusion Criteria

To qualify for NHS foundered weight loss surgery in the Birmingham region, there are strict criteria:

1. A BMI of more than 35kg/m2 and has type 2 diabetes mellitus which has been diagnosed within the last 10 years or
2. A BMI of more than 50kg/m2.

These strict criteria allow an opportunity to study a unique set of participants who are at high risk of having urinary symptoms and pelvic floor prolapse. They would have already undergone weight loss and lifestyle modification methods which would routinely be the first line of action when managing these participants.

The participants in the research study will be

- Female participants over the age of 18
- With a BMI 35mg^2 and above who have been approved for bariatric surgery but have not yet had treatment.
- Able to give informed consent

Eligibility Criteria:

Parameter	Inclusion Criteria	Exclusion Criteria
Age	>18	<18
Gender	Female	Male
Ethnicity	All	-
BMI	>35mg^2	<35mg^2
Parity	Nulli-parus, Parus	-
Co-morbidity	-	Dementia/ Inability to consent / Severe Mental health conditions
Surgery	No previous Bariatric Surgery- Or Recent (within 3 months as 1st follow up is 3 months) Surgery with the weight loss services	Historic (over 3 months) Bariatric Surgery, previous pelvic floor surgery
Medications		Diuretics, Anticholinergics
Bariatric Surgery	Qualified for bariatric surgery	Not qualified for bariatric surgery

Data Collection

Consultation	Quantitative		Qualitative
1st consultation	Introductions		Introductions
Pre-op Consultation	ePAQ Questionnaire	Optional Vaginal Examination with POPQ	Qualitative interview with designed questionnaire
3 months following surgery			
6 months following surgery		Optional Vaginal Examination with POPQ	Qualitative interview with designed questionnaire
9 months following surgery			

12 months following surgery		Optional Vaginal Examination with POPQ	Qualitative interview with designed questionnaire
18 months following surgery			

The initial consultation will be an introduction. This will give us an opportunity to assess the pre-operative status of the participants. The women are required to attend follow up and so this will give us an opportunity to follow participants and reassess them.

The data collected will be a combination of quantitative and qualitative data. The quantitative data will compromise of an ePAQ Questionnaire and a vaginal examination with POP-Q assessment. The qualitative data will compromise of a semi structured interview schedule.

The interview structure has been agreed with Dr Helen Egan to ensure psychological relevance. We know that mindfulness-based interventions have been found to assist people with weight regulation and eating disorders (Proulx, Helms et al. 2007, Ferreira, Pinto-Gouveia et al. 2013, Mantzios and Giannou 2014). An extension to mindfulness and mindful eating is compassion and self-compassion. It does not only relate to patients and the way eating behaviours and attitudes can be improved to enhance weight regulation(Mantzios and Giannou 2014, Mantzios, Wilson et al. 2015, Mantzios 2020), it also relates to a healthier perception of oneself overall ((Neff and Vonk 2009, Raes, Pommier et al. 2011). The interviews will be transcribed partially by the research team and partly from other professional means. We will analyse what is said in the interviews and language used. This will inform the development of a tool kit to identify patients who ate more ats risk of psychological distress problems post-surgery.

The interviews will be transcribed partially by the research team and partly from other professional means. We will analyse what is said as well as the scales and grids. We will look at the themes, contact and language used by the participants.

Our greatest limitation in this study is the recruitment of participants. The impact of COVID19 on the NHS means that the clinics are tightly run and our research population is ahigh risk which may limit uptake to our research. The study will require ethics approval. The interviews are planned to be conducted in clinic and via virtual communication in view of COVID-19 and at the convenience of the participants

Anonymisation

Each participant will be assigned a trial number. This number will follow them throughout their interviews and ePAQ questionnaires so they are not identified from the information collected. This

will allow for anonymity and continuity of the participant. Adequate records will be kept of how, when and from whom informed consent was obtained. A coding method will be used; participants will be given a number which will be present on their consent form with their name. The researcher will state this number at the beginning of the interview recording and will write this number on their interview transcript (all data will be anonymised and confidential; pseudonyms will be used when writing this research up). Participants contact details (email address) will have been collected to conduct the research (via Microsoft Teams) and also so the researcher can contact participants at the end of the research to share the overall research findings. All confidential information and personal data will be stored securely on encrypted, password protected devices via OneDrive. The interviews themselves will be recorded via MS Teams, or encrypted Dictaphones, they will be downloaded from Streams and stored securely on encrypted, password-protected devices via OneDrive and deleted from the download file.

Safety considerations

There are minimal risks in volved in this study.

Physical safety: There is minimal participants contact involved.

The vaginal assessment is totally voluntary, and the participants can decide to decline at any stage. It involves the use of a speculum and digital assessment. This will only be done with consent and with a chaperone. It is part of a routine gynaecological assessment and an already accepted form of assessment for vaginal prolapse.

Mental: We will be asking question in relation to weight. Some participants may feel sensitive about these questions. **They have the option of not answering the questions if they choose**. There is already a psychologist as part of the bariatric services MDT. We will ensure to refer them onward if the participant wishes. We have developed a distress protocol.

Medical: Our assessment and questions will not obstruct the treatment our participants receive. If any sinister findings are met during vaginal assessment, we will offer the participant a referral for further examinations with their consent.

We do not anticipate any adverse effects nevertheless; any will be escalated to the chief investigator and the sponsor as appropriate.

Follow-up

Following the data collection, if participants are suffering with urinary symptoms and want further help, the participant can ask their GP to refer them to Mr Toozs-Hobson's urogynaecology clinic for further assessment, or their local clinician.

Data management and statistical analysis

Quantitative data:

Statistical analysis

Initially, analyses will only include data from the immediate preoperative assessment, and subsequent postoperative follow-up assessments. The changes in the severity of LUTS after bariatric surgery will be assessed using a repeated-measures approach. Similar models will then be produced with weight and other participant factors as covariates, in order to identify other factors that are associated with the severity of LUTS. Secondary analyses will also be performed, which additionally include the data from the initial baseline assessments, and subsequent three-monthly assessments, to quantify trends in LUTS over the preoperative period. We will be using the SPSS system to analysis the data.

Sample size calculation

Based on historical clinic flows, it is anticipated that it will be possible to recruit N=50 participants meeting the inclusion criteria. In order to test the viability of this sample size, a statistical power calculation was performed for the primary study aim, namely an assessment of the change in the severity of LUTS between the preoperative and postoperative follow-ups. In the absence of pilot data to estimate the likely distribution of ePAQ scores, a generic power calculation was performed, based on a sign test of the proportions of participants seeing an improvement vs. no change vs. worsening of LUTS between the preoperative and six-month postoperative assessments. It is not anticipated that participants will see a worsening of LUTS as a result of the surgery; hence, the calculation initially assumed 0% of participants would have more severe LUTS at the six-month follow-up, compared to the preoperative assessment. Based on this assumption, the study would be sufficiently powered to detect a success rate (i.e. the proportion of participants with improved LUTS) of 15% at 80% power. If some participants do report a worsening of LUTS, then the minimal detectable difference will increase, as visualised in ***Figure 2***. For example, if 10% of participants report a worsening of LUTS postoperatively, then 36% would need to report an improvement in order to detect an effect at 80% power.

Figure 1 – Study flowchart

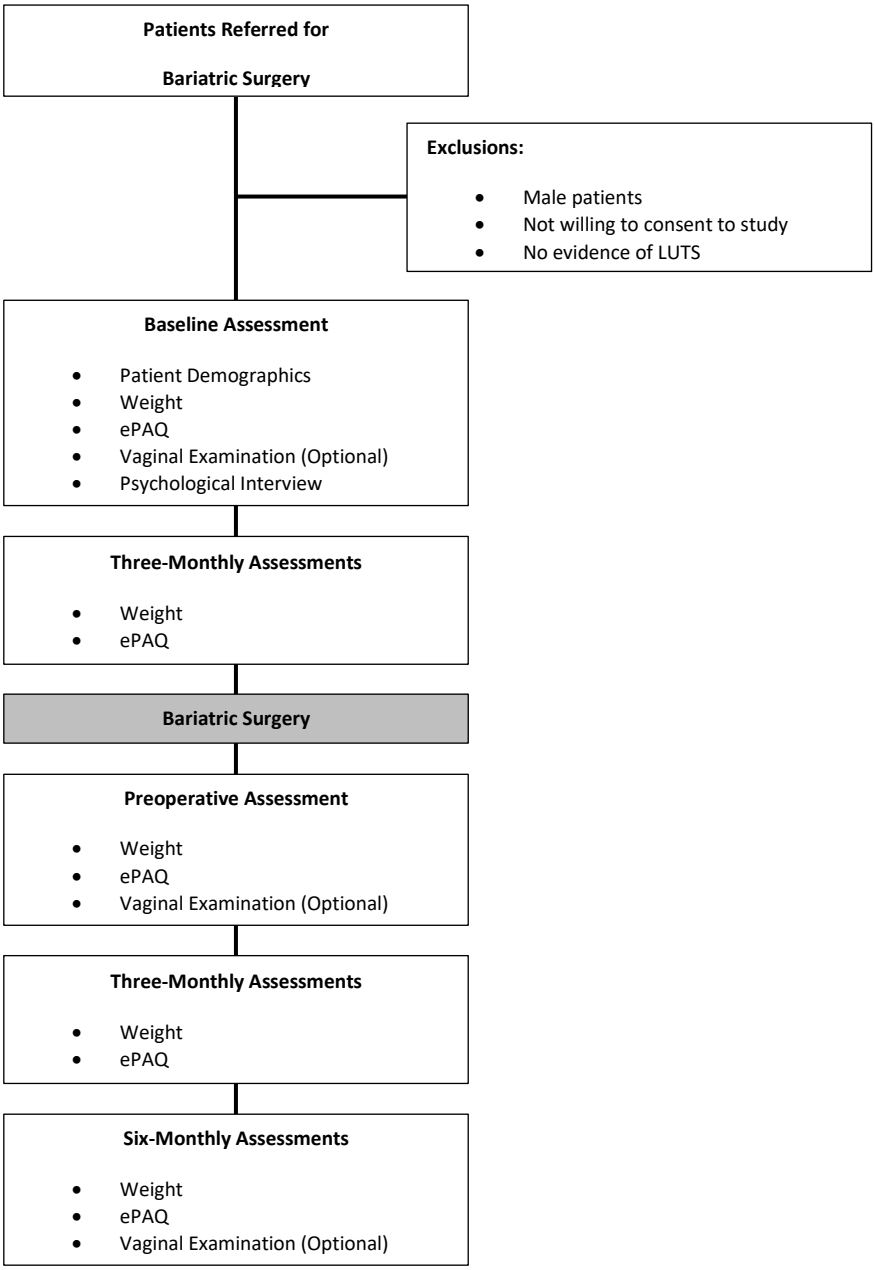
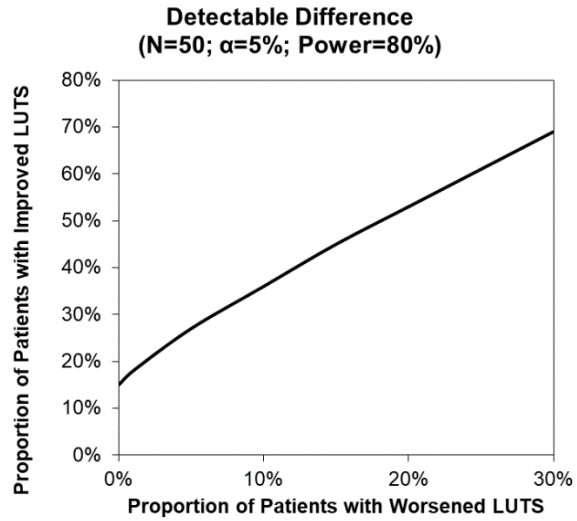


Figure 2 – Sample size calculation



The power calculation was based on a sign test, analysing the change in the severity of LUTS between the preoperative and six-month postoperative assessments, classified as worsening, no change, or improved. Calculations were performed for a sample size of N=50 and alpha of 5%. The trend line represents combinations of the proportions of participants with improved vs. worsened LUTS that would yield 80% power.

Qualitative data

From our qualitative data, the interviews will be transcribed partially by the research team and partly from other professional means. We will analyse what is said in the interviews and language used. We will look at the themes, contact and language used by the participants and analyse.

This will inform the development of a tool kit to identify participants who are at mor risk of psychological distress post-surgery.

Analysis

The audio recordings will be transcribed by the researcher utilising the Jefferson transcription coding to focus upon phonetic and paralinguistic features as well as spoken words, recording what was said and how it was said (Heath & Hindmarsh, 2002). To reduce the occurrence of omissions and mistaken words within the transcripts, the researcher will transcribe each recording within five days of conducting the interview, improving the quality of the transcripts as the memory of what happened during data collection (e.g. body language) rapidly fades (Braun & Clarke, 2013). The data will be analysed using thematic analysis following Braun and Clarke's (2006) model as this is a flexible method. Thematic analysis will be used as a contextualist method, positioned between the two poles of essentialism and constructionism, characterised by critical realism (Willig, 1999).

Missing data: We will be able to identify any missing data/ spurious data will be account for.

Quality assurance

Data Collection: Those involved in collecting data will be GCP trained. The main data collector is a senior doctor with six years of gynaecology experience. There has been and will be input from Dr Egan in regards to the qualitative data. In the protocol we have incorporated a standardised protocol for each interview to ensure that it is a repeatable as possible. We are using a national recognised e-questionnaire to ensure high quality consistent data is collected. The person undertaking the qualitative interviews will undergo training for psychological interviews.

Data Storage: There will be minimal participant information needed. The e-questionnaire will involve an anonymised weblink to the questionnaire that the patent can log into anonymously. The questionnaire is hosted on a server withing the N3 spine so securely within the NHS meeting all data storage requirements of the NHS. Our data collection will be password protected and stored on an NHS server at Birmingham Women's Hospital. The interviews will be carried out on an encrypted Dictaphone. All data that have participants details will be securely stored at Birmingham women's hospital.

Expected Outcomes of the Study.

Overall: We predict that we will have a reasonable uptake of participants for our study. Our biggest limitation to this is the COVID-19 pandemic and restarting bariatric services to the level prior to COVID-19. We do not anticipate any adverse incidents. Due to the flexibility of the study, we predict a low dropout rate as participant can do questionnaires electronically and interviews virtually.

From the known research we predict that there will be an improvement of symptoms as weight loss occurs. We predict that the participants will have an improvement in self-worth as well as help seeing behaviours.

Quantitative branch: From the research that is already present we predict that there should be an improvement of urogynaecology symptoms.

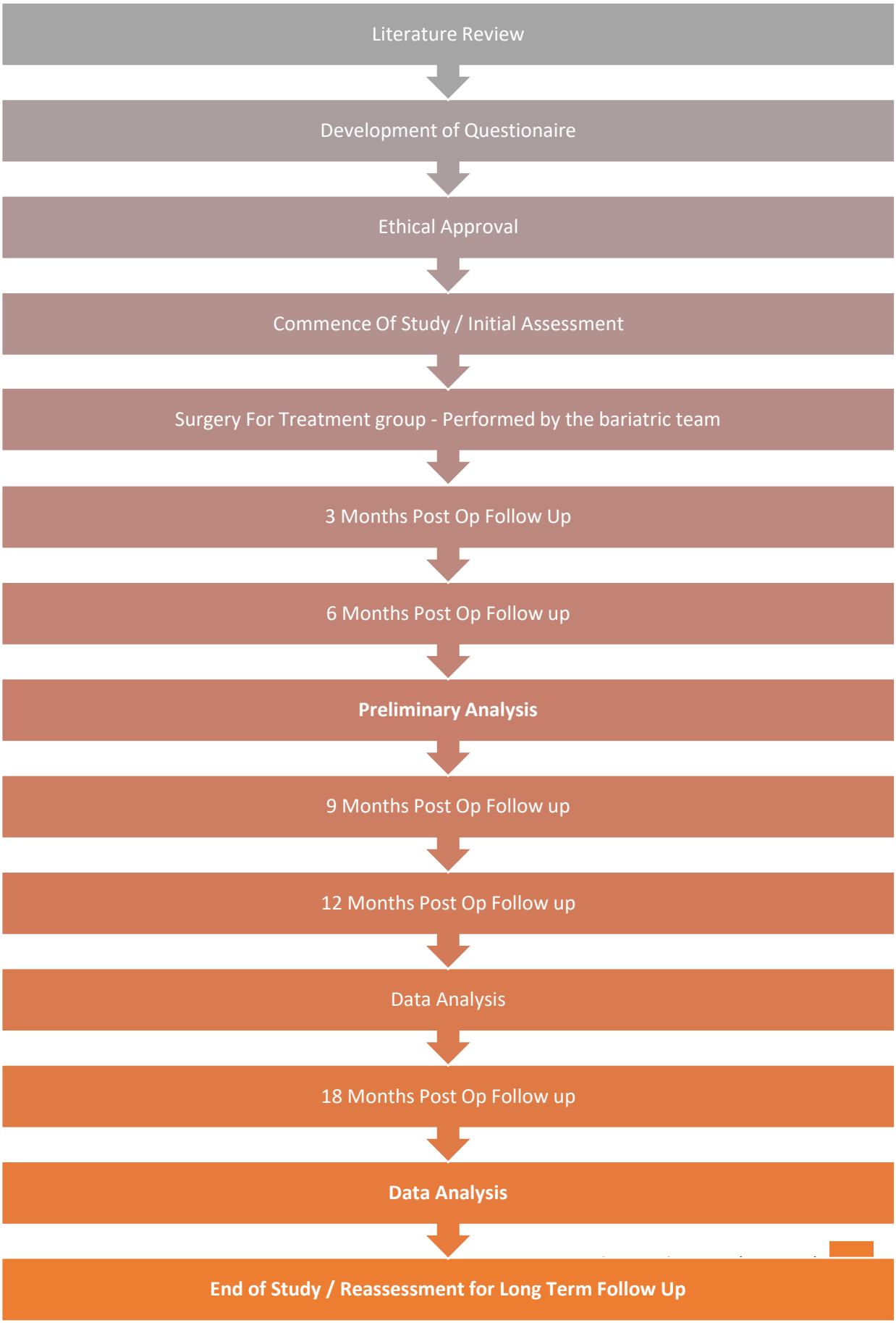
Qualitative branch: We feel that we will see an improvement in participant self-compassion and help seeing behaviours.

Dissemination of results and publication policy

We aim to analyse the three months follow up data for a preliminary result. We with re-analyse the data at three-to-six-month interval till we have completed the eighteen months follow up. We plan to publish the result in peer-reviewed journals. We will produce a summary of the results for the participants to let them know the results. We will aim to present the findings at conferences relating to urogynaecology, bariatric surgery and psychology.

Duration of the project

The project will run for 18 months.



Funding: Not secure yet. Applications have been made. Fortunately, the project is extremely low cost.

Project management

Mr Philip Toozs-Hobson - Lead investigator: He will oversee the whole project and give directional support.

Dr Chioma Chilaka - Research trainee: The project will be managed by the research trainee. She will recruit the participants and examine them. She will collate and analyse the data. She will transcribe the dictated interviews.

Dr Helen Egan – Will give support and direction regarding the qualitative branch of the study. She will give direction in the analysis of the data.

Dr Tom Wiggins – Help with recruitment of participant from his clinic.

Ethics

The Study will receive a favourable outcome from the Research Ethic Committee before starting.

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Appendices

Appendix 1 **The Interview Qualitative questionnaire** Page

Qualitative Branch Pre-Operative Questions

Date: **Participant Identification Number for this trial**:

	Question	Question Answered	
		Yes	**No**
A1a	So, just to get started then, what were your first thoughts when you were asked to take part in the research?		
	Element: Weight Management		
B1a	Can you tell me about some of the challenges that you have faced in your life in regard to weight management?		
B2a	Has someone spoke to you about what to expect after surgery?		
B3a	How do you think weight has impacted on your health?		
B4a	And how would you describe your relationship with food?		
B5	How confident are you in going to your GP with other medical conditions? Prompt – Urinary symptoms,		
	Element: Bariatric Surgery		
C1	What are your thoughts and feelings towards bariatric surgery?		
C1a	How are you feeling about that now?		
C2a	What is your hope the surgery? (Prompt: weight loss)		
C3	Is there anything else that could have been done that would have helped?		
C4	Do you have good support along your bariatric journey?		
	Element: Self Kindness		
D1	Would you describe yourself as a self-critical person?		
D2	What does self-kindness mean to you?		
D3	How do you practice self-care?		
E1	Is there anything that we haven't spoken about that you would like to add, anything else?		

(30-40minutes)

Qualitative Branch Post-Operative Questions

Date: **Participant Identification Number for this trial**:

	Question	Question Answered	
		Yes	No
A1b	So, just to get started how did you find your operation?		
	Element: Weight Management		
B1b	Could you tell me a bit about some of the challenges that you have faced since your operation?		
B2b	Have your post-surgery expectations been met?		
B3b	What impact, if any, do you think that the operation has had upon your health?		
B4b	Since the operation, how would you describe your relationship with food, what has that been like?		
B5	How confident are you in going to your GP with other medical conditions? Prompt – Urinary symptoms		
B6	How are you adapting to your new lifestyle?		
	Element: Bariatric Surgery		
C1	What are your thoughts and feelings towards bariatric surgery?		
C2b	Has the surgery achieved what you hoped? (Prompt: weight loss)		
C3	Is there anything else that could have been done that would have helped?		
C4	Do you have good support along your bariatric journey?		
	Element: Self Kindness		
D1	Would you describe yourself as a self-critical person?		
D2	What does self-kindness mean to you?		
D3	How do you practice self-care?		
E1	Is there anything that we haven't' spoken about that you would like to add, anything else?		

(30-40 minutes)