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Weight loss, urogynaecology symptoms and psychological changes study

Submission date
19/07/2022

Recruitment status
No longer recruiting

Registration date
11/10/2022

Overall study status
Completed

Last Edited
11/10/2022

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
The rate of obesity is ever-increasing, and its impact is far-reaching. 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. It is well established that there is a correlation between being overweight or obese and urinary incontinence symptoms. With growing obesity in the UK, it is inevitable that there will be a growing number of women suffering from urinary incontinence.

Obesity has two effects; 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 do a systematic review of the literature to look at what is already known about the psychological impact of weight loss and its effects on the quality of life of people with LUTS. The main goal of our study is to see if there is a correlation between weight loss and urogynaecological symptoms and to see if there is a correlation between weight loss and self-worth and help-seeking behaviours.

Who can participate?
Women qualifying for bariatric surgery

What does the study involve?
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 with a portion of the participants prior to surgery and after. We will not be carrying out any surgical interventions ourselves.

What are the possible benefits and risks of participating?
Participants will have an extra team walking with them along their weight loss journey. They can discuss any bladder or prolapse problems that they have not had the opportunity to understand,

and treatment options should this be appropriate. Some participants will find it helpful to take part in the interview as it is an opportunity to talk about how they feel about their weight loss journey and about other things that may be on their minds. If any symptoms are identified during the research and they need further help, their GP can be informed at their request, and if appropriate they can be referred to the gynaecology team. Taking part will give them 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, they will be helping to better our knowledge and understanding in this area.

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

Where is the study run from?
University of Birmingham (United Kingdom)

When is the study starting and how long is it expected to run for?
February 2022 to December 2023

Who is funding the study?
Investigator-initiated and funded

Who is the main contact?
Philip Toozs-Hobson (United Kingdom)
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Contact information

Type(s)
Principal investigator

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
313247

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
RG_21-138, IRAS 313247

Study information

Scientific Title
The effects of bariatric surgery on urinary symptoms and the pelvic floor and the psychological changes associated with weight loss in relation to urogynaecological symptoms: A single-service, prospective, observational cohort study (WUP's study)

Acronym
WUP's study

Study objectives
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 with a portion of the participants prior to surgery and after. We will not be carrying out any surgical interventions ourselves.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/07/2022, North West - Liverpool Central Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)2071048118, +44 (0)20 7104 8222, +44 (0)2071048016; liverpoolcentral.rec@hra.nhs.uk), ref: 22/NW/0128

Study design
Single-service prospective observational cohort study

Primary study design
Observational

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
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

Interventions
We will assess their urinary symptoms with an ePAQ questionnaire before their operation and at 3 monthly 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 with a portion of the participants prior to surgery and after.

Intervention Type
Other

Primary outcome(s)
Pelvic floor disorders measured using the electronic Personal Assessment Questionnaire (ePAQ) outcome pre-op and at 3, 6, 9 and 12 months post-bariatric surgery, with vaginal examinations undertaken pre-op and at 6 months

Key secondary outcome(s))
1. Psychological changes measured using observations pre-op and at 6 months post-bariatric surgery
2. Vaginal changes measured using vaginal observations pre-op and at 6 months post-bariatric surgery

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Aged 18 years old and over
2. Female
3. All ethnicities
4. Body mass index (BMI) >35mg2
5. Nulliparous and parous
6. No previous bariatric surgery
7. No recent (within 3 months, as the 1st follow-up is 3 months) surgery with the weight loss services
8. Qualifying for bariatric surgery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

Female

Key exclusion criteria
1. Aged 17 years old and under
2. Male
3. BMI <35mg2
4. Dementia
5. Inability to consent
6. Severe mental health conditions
7. Historic (over 3 months) bariatric surgery, previous pelvic floor surgery
8. Diuretics, Anticholinergics
9. Not qualifying for bariatric surgery

Date of first enrolment
11/10/2022

Date of final enrolment
01/09/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Birmingham Heartlands Hospital
Bordesley Green E
Birmimgham
United Kingdom
B9 5SS

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type

Other

Funder Name
Investigator-initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Chioma Chilaka, chioma.chilaka@nhs.net. The datasets will be available as anonymised raw data and analysed data including Age, epaq results, PopQ results, transcription of interviews, blood tests, and statistical analyses. This will be available for 24 months post-publication via email PDFs. The participants have consented to the anonymised use of their data.

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
Participant information sheet	version 4.0	06/06/2022	22/09/2022	No	Yes
Participant information sheet	version 4.0	10/05/2022	22/09/2022	No	Yes
Participant information sheet	version 3.0	16/06/2022	22/09/2022	No	Yes
Protocol file	version 3.0	29/03/2022	22/09/2022	No	No