Development of a Core Outcome Measurement Set for pouch anal and vaginal fistulae (PAVF-COMS): modified Delphi study.

Invitation for study

The research team at the St Mark's Fistula Research Unit would like to invite you to take part in this research on developing a core outcome measurement set for pouch anal and vaginal fistulae. Your participation is strictly voluntary, meaning that you may or may not choose to take part. To decide whether or not you want to be part of this research, the risks and possible benefits of the study will be described in this form so that you can make an informed decision. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish.

Please ask us if there is anything that is unclear to you or if you would like more information. Take time to decide whether or not you wish to take part.

Aims of the research and benefits

Pouch anal and vaginal fistulae are severe complications of pouch surgery that can significantly impact an individual's ability to work and function within society. Therefore, research must be undertaken to improve overall outcomes for this subset of patients.

Research has taken place to investigate which treatments for pouch anal and vaginal fistulae are better for patients. There are currently several studies that test the same treatment, allowing researchers to combine results and reach a more confident conclusion. However, for this to be possible, the same outcomes must have been used across studies.

Core outcome sets have been developed to work out which outcomes such as pain and quality of life should be measured. Core measurement sets will determine how researchers will measure these outcomes, for example through the use of patient-reported quality of life scales. A core outcome set has already been developed for pouch anal and vaginal fistulae, and the next step is to develop a core measurement set.

We plan to conduct a Delphi study to agree on a core measurement set. This involves participation in 2 – 3 online surveys followed by the option to attend a final hybrid online/face-face meeting to generate consensus (or agreement) amongst patients and healthcare professionals regarding the best way to measure each outcome. The development of a core measurement set will standardise reporting and make it easier to compare multiple studies for a treatment. Ultimately, this will enable improved clinician decision-making and result in better patient care. We hope to undertake this study by

working with patients who have pouch anal and vaginal fistulae, in addition to healthcare professionals who treat these patients, resulting in a core measurement set that has been created with the input of patients and clinicians.

Study design.

This study will be undertaken in two phases. The first phase will be undertaken by researchers from the study team. They will conduct a review of the literature, to identify all measurement instruments that can and have been used in the assessment of pouch anal ang vaginal fistulae.

The second phase will involve patients and clinicians with experience and expertise in treating pouch anal and vaginal fistulae. This phase will involve a modified Delphi consensus, in which participants will complete two to three repeated rounds of online questionnaires over approximately three months. Participants will be able to review the results of each round, and the questionnaires will be amended depending on the results. The design of the study means that participants must take part in all two to three rounds.

After the questionnaires, there will be the option to attend a hybrid online/face-face consensus meeting involving 20 to 40 participants (patients and clinicians). During this meeting, further voting will be undertaken to agree on the best measurement instrument for each outcome, and the optimal time point at which this measurement should be undertaken. The final consensus meeting will be recorded using dedicated software and transcribed with the permission of all attendees prior to the start of the meeting. Once information from this recording has been analysed, it will be deleted appropriately.

Who can take part in this study?

You can take part in this study if you are over the age of 18 years, live in the United Kingdom, and have a pouch anal or vaginal fistula.

What will happen if I agree to take part?

If you choose to take part, you will be asked to register with the study online, which includes consenting to take part in the study. If it is not possible for you to complete this online, then there may be a potential way to fill in a paper copy instead and we can discuss this with you.

You will be asked to complete the questionnaire, which is expected to take approximately 20 minutes. You will be provided with more information regarding each measurement instrument that has been identified and asked to rank them in order of preference. You will also be asked your opinion regarding the best time point for each measurement. After each round, the answers everyone has provided will be analysed, and you will receive feedback on how the group has responded, allowing you to change or keep your answers the same for the next round. There are likely to be 2 to 3 rounds of online survey, each taking approximately 20 minutes, followed by a hybrid online/face-face consensus meeting to decide on the overall measurement set at the end of the study.

You will be notified by email regarding the start of each round, which will include a link to the questionnaire. You may also receive reminders by email, and possibly telephone or SMS reminders, during each round if you have not completed and submitted the questionnaire after approximately two weeks.

You will also be asked to fill in additional demographic data (date of birth, gender, ethnicity, speciality etc).

Patients will be reimbursed for any travel expenses incurred if they choose to attend the face to face final consensus meeting. There will also be the option of attending the meeting virtually online so that participants do not need to travel to attend.

How will we use the data?

We will need to use information from you such as your name, age range, underlying diagnosis, ethnicity and contact details. 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 code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data 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. When the final outcome of the study is reported, you will not be identifiable in any presentations or publications.

What are the possible disadvantages and risks of taking part?

Completion of the questionnaires will take no more than about 20-30 minutes for each round. Additionally, if any of the outcomes listed in the questionnaire lead you to experience distressing emotions as they relate to sensitive or embarrassing issues that you may have experienced, please do get in touch with one of the researchers. We will provide you with contact details of support groups should you feel the need to contact them.

What about confidentiality and anonymity?

During the study, we will collect your personal demographic details, such as your name, address, and date of birth. Your details will be stored in a password-protected computer in our research office based at St Mark's Hospital. Data will be protected in accordance with the Data Protection Act of 2018. Your personal details will be used so that we can make contact during the study. We will allocate you a study ID number. This number will be used to identify you; therefore, you do not need to put your name on any of the documents you send back to us. All documents will be stored in a locked filing cabinet in our research office based at St Mark's Hospital.

What are my choices about how my 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 won't be able to let you see or change the data we hold about you. However, any information stored will be safe and

secure and as explained above your data will have a code number so that no one could work out if you took part in the study or if you left the study at any point.

Where can I find out more about how my information is used?

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team (Easan Anand - lnwh-tr.pavfcoms@nhs.net or lnwh-tr.sponsorship@nhs.net)

What are the possible benefits?

This study will have no direct benefit to you; however, your contribution will help us to develop a core outcome measurement set that can be used to standardise outcome measurements within clinical studies. This will help us to guide future researchers setting out on developing a research study, and also aid in decision-making and patient care for this subset of patients.

All participants who complete all three questionnaire rounds will be recognised as a PAVF-COMS Delphi panellist in the study report and any associated publication if you consent to be named.

Anticipated plans for publication of our research study

We will update you with the results at the end of the study. The information from the questionnaires will be taken forward to the final consensus meeting. This will help guide the decisions made during the meeting regarding the optimal measurement instrument for each outcome within the COS for pouch anal and vaginal fistulae.

We aim to publish at least one academic paper reporting this new core outcome measurement set for pouch anal and vaginal fistulae. We aim to present this study at various national and international gastroenterology and surgical conferences. Everyone who takes part in this study will remain anonymised and will not be identifiable within published data.

We will produce an appropriate patient-friendly lay summary report for dissemination on social media, patient group websites and charity websites where recruitment for the study has been advertised.

Who is organising and funding the research?

This research is being conducted as part of Mr Easan Anand's research MD project and is sponsored by London North west University Healthcare NHS Trust. The doctor conducting this research project is not being paid for including you in the study.

Who has reviewed the study?

PAVF-COMS
IRAS: 337566

Patient Information sheet: IRAS: 337566 March 2025

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the North – East Research Ethics Committee. (REC Reference: 24/NE/0042)

What happens now?

If you DO NOT wish to take part in this study, you do not need to do anything.

If you DO wish to take part in this study, you may access the Delphi survey online using the following link: XXXX.

What if I need to know more information before I decide to take part?

If you wish to know more information about the study, please contact the research team:

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Tel: 020 8965 5733
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For more information regarding data protection please contact :

lnwh-tr.sponsorship@nhs.net

If you have any concerns or complaints during the research study, please contact the research team or chief investigator of the study:

lnwh-tr.sponsorship@nhs.net or philtozer@nhs.net