PARTICIPANT INFORMATION SHEET

Study title

Developing an intervention to help nurses improve the assessment and care of the sexual health needs of men with Inflammatory Bowel Disease: a mixed methods study using co-production (the MenSH-IBD Study).

Introduction

We would like to invite you to take part in a research study. Before you decide whether you would like to participate, we would like you to understand why the research is being done and what it would involve for you. Please take time to decide if you would like to take part and ask for clarification if anything is not clear or you would like more information. Our contact details are at the end of this information sheet.

What is the purpose of the study?

Inflammatory Bowel Disease (IBD) is a chronic, relapsing and remitting disease that can greatly impact health and personal well-being. Sexual health, relationships and intimacy have been raised as key concerns for those living with the disease. Men's sexual health and well-being has been identified as a neglected area. This study will lead to the development of an intervention that will help nurses to improve the assessment and care of the sexual health and well-being needs of men with IBD.

What does this study involve?

There are three parts to this study. In the first part we are conducting surveys to find out what issues there are in delivering care and where improvements can be made. In the second part we are conducting interviews and focus groups to explore in more depth the issues found through the surveys. In the third part we are running a series of workshops to develop the intervention. An intervention is a treatment, therapy or any other action taken to improve health.

These are called ‘co-production’ workshops because people with the disease and professionals work together to create learning and information materials that will support both patients and professionals.

What would taking part involve?

You will be asked to participate in one or two of the following activities depending on your experience and background. Before participating in the study, you will be asked to complete a consent form. The research team will clarify which activities you will be involved with if you are not clear.

(1) Men with IBD or partners of men with IBD:

If you are a man, or identify as male, and have IBD you will be asked to participate in an interview that will be no longer than 60 minutes. This will be held either over the telephone or via a video platform (such as Zoom or Microsoft Teams). You would need to have access to a quiet and private space. We will audio-record the interview to make it easier for the research team to analyse the information afterwards. The interview recording will be deleted once all the data collected has been analysed. During the interview we will discuss what it has been like living with IBD. We will ask about your experiences of the healthcare you have received, particularly in relation to sexual health and well-being. We will ask about what you think can be done to improve healthcare. If you are in a relationship and your partner has also decided to participant in the study you can choose to be interviewed together or separately.

(2) The partners of men with IBD:

If you are the partner of a man with IBD, you will be asked to participate in interview that will be no longer than 60 minutes. This will be held either over the telephone or via a video platform (such as Zoom or Microsoft Teams). You would need to have access to a quiet and private space. We will audio-record the interview to make it easier for the research team to analyse the information afterwards. The interview recording will be deleted once all the data collected has been analysed. During the interview we will discuss what it has been like being in a relationship with someone with IBD. We will ask about your experiences of the healthcare system particularly in relation to sexual health and well-being. We will ask about what you think can be done to improve healthcare. If both you and your partner are participating in the study you can choose to be interviewed together or separately.

(3) Healthcare professionals and/or people involved in an organisation which represents or supports men with IBD:

If you work in a professional capacity with men with IBD, you will be asked to participate in an online focus discussion group that will last no longer than 2 hours. The aim of the focus discussion group is twofold; (a) to better understand the barriers and facilitators to sexual health assessment and (b) to improve the care of men with IBD.

(4) People living with IBD and professionals:

If you are a man with IBD, a partner of a man with IBD, or a professional who works in IBD, you may also be asked to participate in a series of workshops. Workshops one and two will ideally take place face-to-face but may be supplemented by online communications where possible. Face-to-face workshops will occur in York, either at York Teaching Hospital or at The University of York. Workshop three will be online. The aim of the workshops is to agree on a suggested intervention including its format, structure, goals, and outcomes.

What are the possible benefits?

It is unlikely that you will directly benefit from this study. In the future, people with IBD may benefit from the improvements made to care that result from this study. If you are a man with IBD or a partner of someone with IBD you will be given a £20 high-street voucher for participating in the interviews. If you are a healthcare professional or represent an organisation you will be given a £20 high-street voucher for participating in the focus groups. If you have to travel or incur expenses for participation then we may be able to provide some compensation towards these costs. This is available to all participants but must be agreed prior to participating in the study.

What are the possible disadvantages or risks of taking part?

This is a low-risk study. Some people may find that the topic being covered is personal and sensitive but the study team will aim to make you feel at ease. You will also be provided with an information leaflet that lists organisations that provide free support or information. You may withdraw from the study at any time.

Who is running this study?

This study is being conducted by York and Scarborough Teaching Hospitals NHS Foundation Trust. They are the Sponsor of this study, which means that they are legally responsible for it. The University of York and York St John University are supporting the running of the study. The study is funded by a grant from the National Institute for Health Research.

Who has approved this study?

To protect you and your data, all NHS research is reviewed by an independent group of people, called a Research Ethics Committee (REC). **This study has been approved by the Cambridge South REC**. Prior to that, this study was also reviewed and approved by a research ethic committee at York St John University and a research advisory group at York and Scarborough Teaching Hospitals NHS Foundation Trust.

Further General Data Protection information

How will we use information about you?

We will need to use information about you for this research project. Your name and contact details will be stored electronically by York and Scarborough Teaching Hospitals NHS Foundation Trusts to enable us to contact you during the study, to provide you with the results of the study, and to invite you to participate in future studies if you have consented to this. People will only use your information to do the research or to check that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. You will be given a code name instead. Any information about you will be kept safe and secure in line with data protection laws. Any information made publicly available will be anonymised.

Once we have finished the study, we will keep some of the data so we can check the results. We will delete any information that identifies you, unless you have consented to be contacted about future studies. Any information of yours that we have anonymised will be kept in an archive for a total of 5 years.

Data sharing

It is good practice in research to have data sets available to ensure transparency of the research process. In the future, other researchers may request to look at the data and conduct further analysis. We will only share anonymised data where you will not be identifiable. Interview transcripts will be redacted for any identifiable information. Our findings will be uploaded to the data repository **'clinicaltrials.gov'** where anyone can access them, but the interview transcripts will only be shared with other researchers who have been approved by a member of the MenSH-IBD research team.

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 these national websites - hra.nhs.uk/information-about-patients/ or hra.nhs.uk/patientdataandresearch
- visiting the sponsor's website - research.yorkhospitals.nhs.uk/about-us1/patient-information-amp-health-and-care-research/
- emailing the sponsor's Data Protection Officer, Rebecca Bradley, on rebecca.bradley20@nhs.net
- visiting the study's website – **research.yorkhospitals.nhs.uk/mensh-ibd/**
- asking one of the research team or sending us an email at **mensh-ibd-project@york.ac.uk** or ringing us on **01904 323 331**

What if we have safety concerns?

During the research, if we have any concerns over the safety of a participant or of any other person, then we are legally and ethically obliged to take appropriate action. We understand the sensitivity and potential implications of such actions and assure you that every effort will be made to handle any concerns with discretion and professionalism. In the first instance, we would seek advice from the safe-guarding teams at York and Scarborough Teaching Hospitals NHS Foundation Trust. We may need to share your contact details with them or with other relevant authorities.

What will happen to the results of the research study?

We intend to publish the results of the study in reports and specialist journals. The results of the study will not reveal the personally identifiable details of participants. We will also put a final study report on our website (**research.yorkhospitals.nhs.uk/mensh-ibd/**) when the study is finished.

What if there is a problem or I want to withdraw from the study?

You can withdraw at any time from the study. All data collected up to the point of withdrawal will be kept but this data will be anonymised. The rights to access, change, or move the information are limited, as we need to manage the information in specific ways in order for the research to be reliable and accurate. If you are unhappy about any part of the study you can contact us directly (our details are on the following page).

If you would prefer to speak to someone outside of the study team, you can contact the sponsor's Research Advisor, Dr Deborah Phillips, in the following ways:

- **Post:** R&D, LaRC, York and Scarborough Teaching Hospitals NHS Foundation Trust, Wigginton Road, York, YO31 8HE
- **Telephone:** 07464 491875
- **Email:** Deborah.phillips23@nhs.net

If you would prefer your complaint to be heard by someone not involved in the research, you can contact the Patient Advice and Liaison Service at York and Scarborough Teaching Hospitals NHS Foundation Trust in the following ways:

- **Post:** PALS, York & Scarborough Teaching Hospitals NHS Foundation Trust, Freepost**,** NEA 11112, York, YO30 7ZZ
- **Telephone:** 01904 726262
- **Email:** yhs-tr.PatientExperienceTeam@nhs.net

If you are not satisfied with the response, you have a right to complain to the Information Commissioner's Office. For information on reporting a concern to the Information Commissioner's Office, see ico.org.uk/concerns.

Study Contact Details

For general information the study email address is **mensh-ibd-project@york.ac.uk**

The study website is **research.yorkhospitals.nhs.uk/mensh-ibd/**

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