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MenSH-IBD

Full 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-productions

Acronym: (MenSH-IBD)

Protocol

~~V1.1 (01/05/2024)~~ 2.0 (04/11/2024)

RESEARCH REFERENCE NUMBERS

IRAS Number:	334340
SPONSORS Number:	334340 YP
FUNDERS Number:	NIHR206347

This protocol has regard for the HRA guidance.

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: Date:

..../...../.....

Name (please print):

.....

Position:

.....

Chief Investigator:

Signature: Date:

..../...../.....

Name: (please print):

.....

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KEY STUDY CONTACTS

Chief Investigator	**Sara Ma** School of Science, Technology & Health De Grey Building, Room DG 309 York St John University, Lord Mayor's Walk York, YO31 7EX **Tel:** +44 (0)1904 876531 **Email:** S.Ma@yorksj.ac.uk
Co-CI and CI mentor	Professor Paul Galdas Department of Health Sciences University of York, Seebohm Rowntree Building Heslington York, YO10 5DD **Email:** Paul.Galdas@york.ac.uk
Study Co-ordinator	Greg Forshaw (address as above; email: greg.forshaw@york.ac.uk)
Sponsor	Dr Deborah Phillips York and Scarborough Teaching Hospitals NHS Foundation Trust Wigginton Road York, YO31 8HE **Email:** Deborah.Phillips23@nhs.net
Funder(s)	Zuzanna Tajchman Programme Manager RfPB Under-represented disciplines and specialisms highlight notices NIHR Co-ordinating center,15 Church Street Twickenham, TW1 3NL **Email:** Zuzanna.Tajchman@nihr.ac.uk
Key Protocol Contributors	Dr Peter Knapp Hull and York Medical School and the Department of Health Sciences University of York, Seebohm Rowntree Building Heslington York, YO10 5DD **Email:** Peter.Knapp@york.ac.uk Professor Mona Kannan Department of Health Sciences University of York, ARRC Heslington York, YO10 5DD **Email:** Mona.Kanaan@york.ac.uk Wayne Robinson (Patient and public representative)

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Committees	Stakeholder Advisory Group

STUDY SUMMARY

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.
Short Title	MenSH-IBD
Study Design	Mixed methods study design involving three workstreams (WS) aligned with phase 1 of MRC framework for the development of complex interventions: **WS1** (months 1-12): three cross-sectional surveys of sexual health assessment and care being delivered by (1.1) current services, (1.2) IBD nurses in the NHS and (1.3) men with IBD. **WS2** (months 1-10): qualitative study involving (2.1) interviews with men with IBD and their partners and (2.2) focus groups with health professionals. This phase will explore appropriate and acceptable ways to provide sexual health assessment and care of men with IBD. **WS3** (months 12-18): co-production workshops involving men with IBD, men's partners, specialist nurses and stakeholder, to create a prototype intervention and draft logic model to improve the assessment and care of the sexual health needs of men with IBD.
Study Participants	Men with Inflammatory Bowel Disease Partners of men with Inflammatory Bowel Disease Healthcare Professionals and stakeholders
Size of Sample	WS1: (WS1.1) n=114, (WS1.2) n=90, (WS1.3) n=378 WS2: 32 - 44 WS3: 15 – 45
Study Period	October 2024 – February 2026
Research Question/Aim(s)	**Aim:** Co-produce a prototype intervention to help nurses improve the assessment and care of the sexual health needs of men with IBD. **Objectives** 1. Identify how the sexual health of men with IBD is currently assessed and cared for by specialist nurses in the NHS. 2. Gather ideas on appropriate and acceptable ways in which men's sexual health care in IBD could be improved. 3. Co-produce a prototype intervention to improve the assessment and care of the sexual health needs of men with IBD.

KEY WORDS: Inflammatory Bowel Disease, Men's Health, Co-production, Qualitative, Mixed-methods, Nursing Practice, Nursing research

FUNDING AND SUPPORT IN KIND

FUNDER(S)	FINANCIAL AND NON-FINANCIAL SUPPORT GIVEN
NIHR	**£153,387.00**
University of York	In kind support from the Research team in arrangement of collaborative agreements, funding arrangements and study support.
York St John University	In kind support from the Research team in arrangement of collaborative agreements, funding arrangements and study support.

ROLE OF STUDY SPONSOR AND FUNDER

York and Scarborough Teaching Hospitals NHS Foundation Trust will be the study sponsor and responsible for the overall initiation, management and conduct of the study. The Sponsor will contract the relevant parties to perform the data analysis, interpretation, manuscript writing and dissemination of the results. The Sponsor is responsible for study indemnity and ensuring conduct of the study is in line with the Health Research Authority guidance “UK Policy Framework for Health and Social Care Research”.

The National Institute for Health Research is the study funder. The standard NIHR Research Contract for NHS Trusts states the terms and conditions of the funding arrangement. In the event that the Funder has reasonable opinion that the Research Data is not being appropriately managed, disseminated or used, they reserve the right to have access to and to use the Research Data compiled during the course of the Research, and will respect existing confidentiality obligations in respect of any Research Data which it obtains, and to permit any Health Service Body to access and use the Research Data in order to develop the promotion or provision.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Stakeholder Advisory Group (SAG)

Aim: To ensure the MenSH-IBD study is informed by expert knowledge and experience from people with living with IBD, health professionals and other parties that have an interest in the research.

Membership: This group will be made up of approximately 6-8 members, drawn from the following groups:

- 'Experts by experience' including people living with IBD and their partners.
- Healthcare professionals with experience of working in IBD and/or sexual health.
- Associated organisations for example Crohn's and Colitis UK.
- Individuals and/or representatives from organisations for minority and under-represented groups, e.g. according to age, sexuality, ethnicity.

Patient and Public Representative (PPI)

The SAG will involve patient and public members. Wayne Robinson (WR) will be the patient and public representative lead for the study. WR will attend project management meetings and SAG meetings and be involved in the study design, planning and delivery as well as supporting dissemination of results.

Protocol contributors

Sara Ma (SM) (York St John University): study conceptualisation, design, funding acquisition, writing
Paul Galdas (PG) (University of York): study conceptualisation, design, funding acquisition, writing
Peter Knapp (PK) (University of York): study conceptualisation, design, funding acquisition, writing
Mona Kanaan (MK) (University of York): study conceptualisation, design, funding acquisition, writing
Wayne Robinson (WR) (PPI representative): study design, protocol review
Lisa Ballantine (LB) (York and Scarborough Teaching Hospitals NHS Foundation Trust): funding acquisition
Deborah Phillips (DP) (York and Scarborough Teaching Hospitals NHS Foundation Trust): sponsor representative

Ongoing project roles

Data curation: Sara Ma, Paul Galdas, Peter Knapp, Mona Kanaan
Project administration: Sara Ma, Deborah Phillips, Greg Forshaw

Supervision: Paul Galdas

Validation: Sara Ma, Paul Galdas, Peter Knapp, Mona Kanaan, Wayne Robinson

Data analysis and interpretation: Sara Ma, Paul Galdas, Peter Knapp, Mona Kanaan

Dissemination of the results: All above mentioned parties, the Sponsor and the Funder

The sponsor controls the final decision regarding any aspects of this study.

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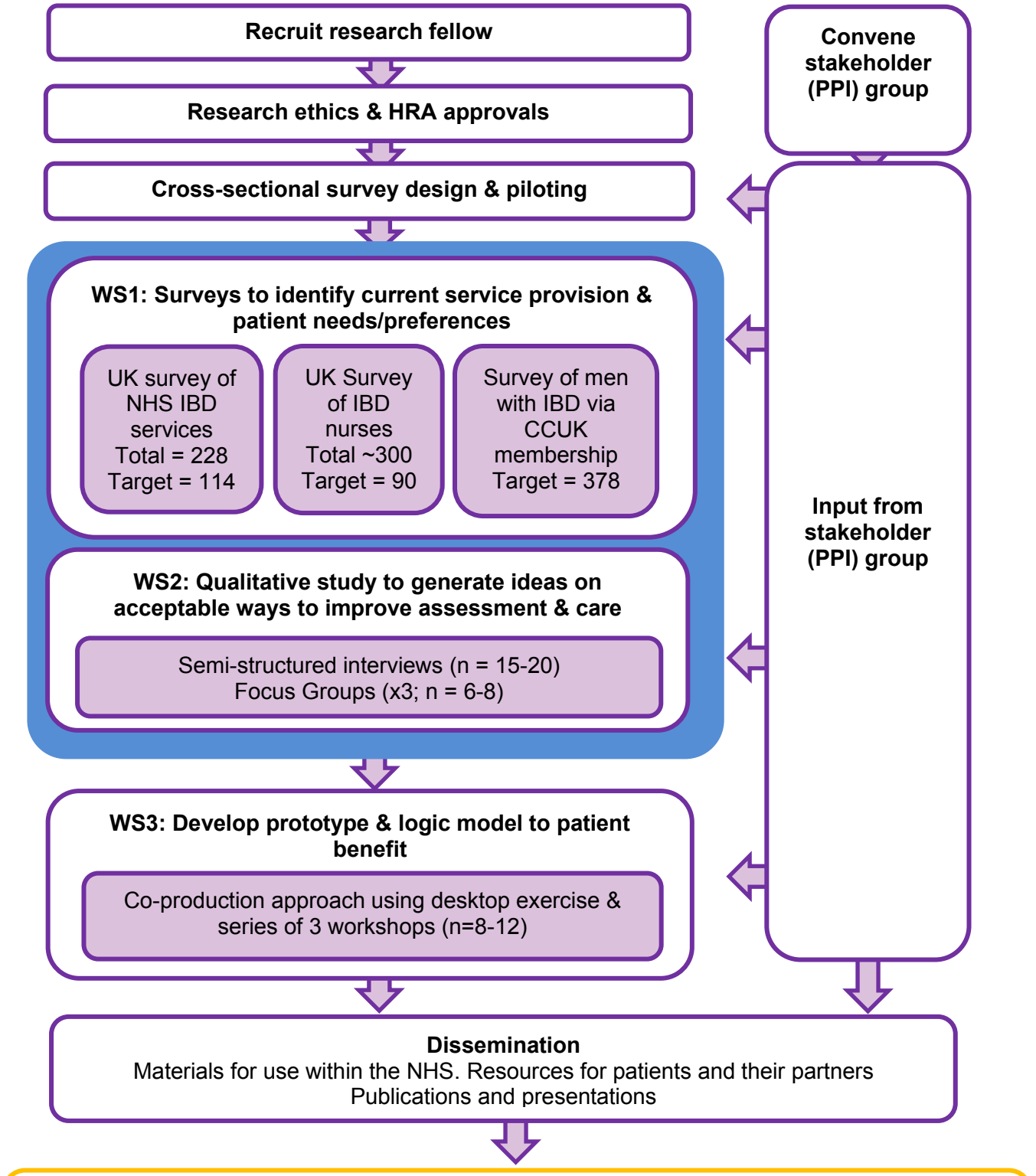
STUDY FLOW CHART



IRAS Number: 334340

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MenSH-IBD

STUDY PROTOCOL

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.

1 BACKGROUND

Inflammatory bowel diseases (IBD) are a group of related gastrointestinal disorders, divided into two main types: ulcerative colitis (UC) and Crohn's disease (CD). IBD is commonly diagnosed between the ages of 15-30 years, with a UK population prevalence of 0.81% (i.e. around 540,000 people, or 1 in 123 of the population) (Crohn's & Colitis UK, 2022). A lifelong disorder, IBD is typically manifested by relapsing-remitting symptoms including faecal urgency, incontinence, bloody diarrhoea, abdominal pain, and fatigue, which can substantially affect the sexual health of patients (Chen et al., 2022, Leenhardt et al., 2019, Zhao et al., 2019).

Sexual health is defined as a state of physical, emotional, mental and social wellbeing in relation to sexuality, and is an important determinant of quality of life (World Health Organization, 2006). Both men and women with IBD have an increased risk of sexual health problems, but variations in anatomy, physiology and psychology mean the disease produces different challenges and needs in men and women (Zhao et al., 2019, Maunder et al., 1999). Recognising and addressing the sexual health needs and concerns of people based on biological and gender differences is a key objective of the WHO's Action Plan for Sexual and Reproductive Health (World Health Organisation, 2016). However, whilst many studies have addressed the sexual health needs of women with IBD (including sexuality, pregnancy, and fertility), insufficient attention has been paid to the needs of men (Ma et al., 2020, Allocca et al., 2018).

Several research reviews have been conducted on sexual dysfunction in patients with IBD (Chen et al., 2022, Ma et al., 2020, Zhao et al., 2019, O'Toole et al., 2014). Reported rates of dysfunction in men range from 10% to 50%, with one male-focused review finding a deterioration in sexual desire and satisfaction in 33-50% of patients after IBD diagnosis, and that half of men with IBD who were sexually inactive attributed this situation to their underlying disease (O'Toole et al., 2014). These results are consistent with the most recent and comprehensive systematic review to date, which identified significant decreases in the satisfaction, quality and overall sexual function of male patients with IBD

(Chen et al., 2022). Younger male IBD patients have been found to experience greater impact (Chen et al., 2022), reflecting epidemiological data showing that the impact of IBD is greatest at a crucial time of patients' sexual functioning (Park and Kim, 2020).

At present no evidence-based tools or guidance exist to support nurses to detect, assess, and provide care for the sexual health and well-being in men with IBD, despite guidelines for the comprehensive management of IBD recommending that nurses should routinely assess patients' sexual health (Kemp et al., 2018). Our preliminary research shows that men frequently receive inadequate assessment, care and support for managing these concerns during routine NHS IBD consultations . This study aims to address this problem by co-producing a prototype intervention to enable nurses to focus on these unmet needs through information, assessment, and support.

2 RATIONALE

Sexual health is a critical part of psychosocial functioning. It has a major impact on overall quality of life in patients with IBD, particularly as peak onset of IBD is during adolescence or young adulthood when people are developing their sexual and personal identities (Chen et al., 2022, De Rooy et al., 2001). Sexual health problems can cause distress through their impact on psychological wellbeing and relationship satisfaction. This is the case not only in people with IBD who are in relationships, when sexual activity is important to the patient and their partner, but also in single people who want to be in an intimate relationship (Hinchliff et al., 2023). For men, our review of the literature showed that IBD treatments, disease activity, and lifestyle and psychological factors have been found to disrupt erectile function, intercourse frequency, sexual satisfaction, and interpersonal relationships (Ma et al., 2020) (see figure 1, below). Emotional impacts include concerns about body-image, feeling unattractive, and having low self-esteem (De Rooy et al., 2001, Chen et al., 2022, Kemp et al., 2018, Ma et al., 2020).

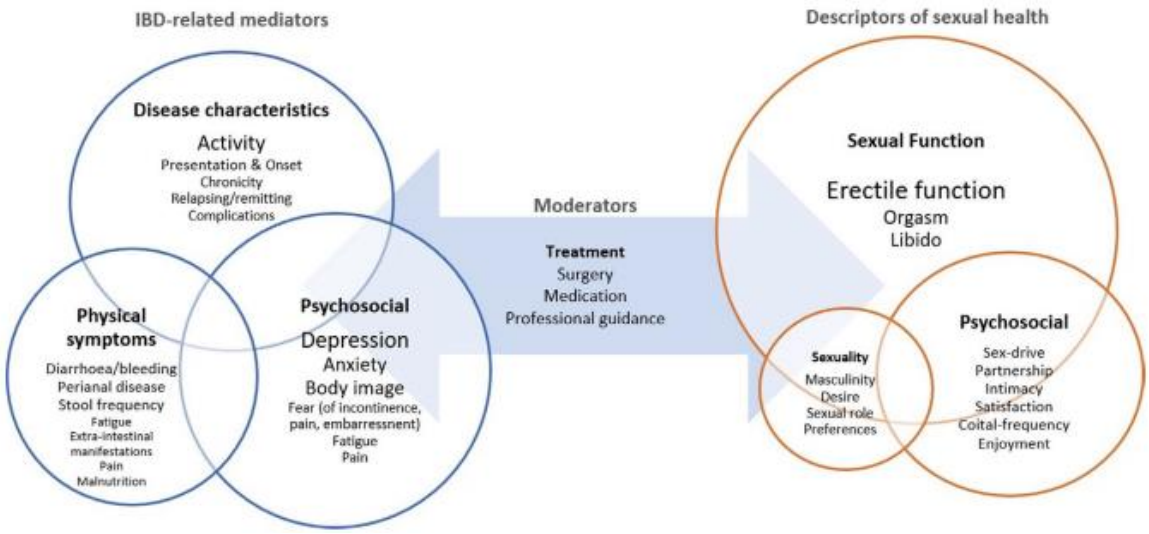

Figure 1: Mediators, moderators and descriptors of sexual health in men with IBD

Since sexual health has a significant and specific impact on the quality of life of men with IBD (O'Toole et al., 2014, Jedel et al., 2015), its assessment and care are essential to improve overall wellbeing. Unfortunately, evidence suggests that men's sexual health concerns are rarely considered during routine IBD nursing care, with few men being provided with helpful information or support (Ma et al., 2020, O'Toole et al., 2014). It is widely acknowledged that the discussion of sexual health concerns with patients is a challenge in a range of long-term conditions (O'Connor et al., 2019, Barnhoorn et al., 2022). A key theme across the published research reports nurses lacking the knowledge, time, and confidence to address psychological, social, and sexual aspects of patients' illness experience (O'Connor et al., 2019) although there is limited evidence specific to IBD care. These issues are likely compounded for men, as masculine gender norms can create additional barriers to seeking and receiving adequate sexual health care (Persson et al., 2022). Gay or bisexual men with IBD appear particularly disadvantaged because of fear of judgement, lack of inclusion of same-sex partners in healthcare interactions, and the absence of information on the safety of anal sex in active disease (De Rooy et al., 2001, Dibley and Norton, 2013).

The European Crohn's and Colitis Organisation (ECCO) recommends that IBD nurses assess patients' sexual health concerns during routine care so they are able to offer information, advice, and identify the need for more structured support or specialist counselling (Kemp et al., 2018). ECCO guidelines emphasise the importance of nurses' understanding and feeling comfortable discussing aspects of sexual practices of this patient group; particularly with gay and bisexual men, who require precise

information about sexual activity and restrictions (Kemp et al., 2018). Currently little is known about the practice patterns of IBD nurses regarding sexual health for men, and there is scant evidence to guide care in this important aspect of patient wellbeing. There is great potential to address these issues and improve patients' quality of life (Barnhoorn et al., 2022, Allocca et al., 2018, O'Toole et al., 2014, Galdas et al., 2014) and their capacity to cope with their long-term condition (Træen et al., 2017) through the co-production of tailored, gender-sensitised tools and interventions designed to improve nurses' assessment of the sexual health concerns of men with IBD. Consideration of the diversity of men's needs will be a key focus of our study, recognising that gender identity, sexual orientation and bodily characteristics exist across a spectrum of diverse identities, expressions, and bodies, rather than as a binary male-female system. Following the co-production of the prototype nursing intervention, we will apply for research funds to undertake a definitive evaluation of the intervention in practice, when compared to current care.

3 THEORETICAL FRAMEWORK

The three workstreams (WS) set out in this study are aligned with the 3 research objectives and overall address the core elements of 'Develop intervention' in the revised MRC framework for the development and evaluation of complex interventions (Skivington et al., 2021b). It is expected that the prototype intervention created by this project will likely address a range of sexual health issues in men, require expertise and skill to be delivered and need to be flexible so that it may be adopted by different services and applicable to diverse populations. Framing the creation of the prototype in line with the MRC framework will support consideration of the varying health systems that may be involved in the delivery of the intervention in order enhance feasibility and rapid implementation. Figure 2 provides the framework schematic devised by Skivington et al. (2021). The core components of framework have been carefully considered in the design of this work. For example, stakeholder engagement is central to the project while the multiple focus groups and workshops support development, refining and retesting.

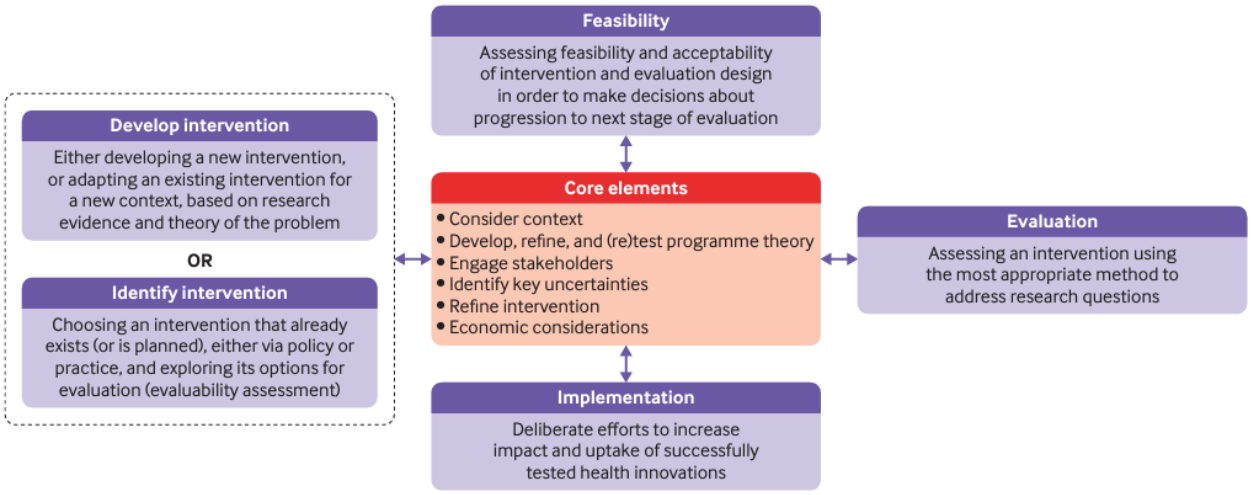

Figure 2: MRC Framework (Skivington et al. 2021)

Global health organisations have called for the development of gender-transformative interventions for men and boys to improve sexual and reproductive health and rights for all (United Nations Fund for Population Activities, 2023, World Health Organisation, 2016). Gender-transformative interventions seek to challenge gender inequality by transforming harmful gender norms, roles, and relations through the inclusion of strategies to foster progressive changes in power relationships between women and men (Ruane-McAteer et al., 2020). To achieve this in this work, the development of the prototype intervention in WS3 will be guided by the 5C framework (figure 3) for developing gender-transformative men's health programmes (Galdas et al., 2023). Further detail on how this is applied is provided in the study design.

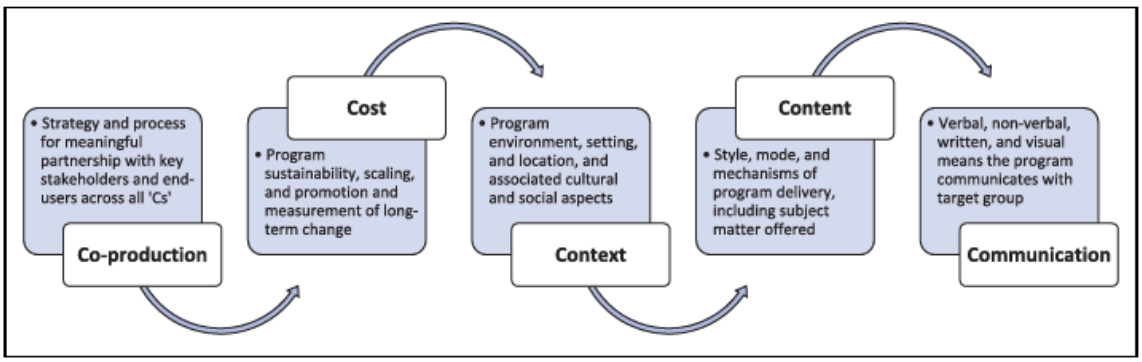

Figure 3: 5C Framework (Galdas et al, 2023)

4 RESEARCH QUESTION/AIM(S)

Key research questions:

- What is the current state of NHS provision of sexual health assessment and care to men with Inflammatory Bowel Disease?
- What are the barriers and facilitators to specialist nurses' assessment of the sexual health needs of men with IBD?
- What type of intervention(s) are likely to be effective and acceptable in improving nurse-led sexual health assessment and care of men with IBD?

Aim:

- To co-produce a prototype intervention to help nurses improve the assessment and care of the sexual health needs of men with IBD.

4.1 Objectives

- Identify how the sexual health of men with IBD is currently assessed and cared for by specialist nurses in the NHS.
- Gather ideas on appropriate and acceptable ways in which men's sexual health care in IBD could be improved.
- Co-produce a prototype intervention to improve the assessment and care of the sexual health needs of men with IBD.

4.2 Outcome

A prototype intervention to improve the assessment and care of the sexual health needs of men with IBD. The intervention will provide nurses with improved understanding of the support, knowledge, and skills required to effectively assess the sexual health needs of men with IBD and provide appropriate patient-centred care that has the potential to have important immediate benefits to the quality of life of men and their partners, as well as act as a catalyst for further research studies with a clear trajectory to scalable patient benefit.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

This is a mixed-methods study involving three workstreams (WS) aligned with the 3 research objectives, which overall address the core elements of phase 1 of the revised MRC framework for the development and evaluation of complex interventions (Skivington et al., 2021a).

WS1. Cross-Sectional Surveys

Three cross-sectional surveys evaluating current sexual health assessment and provision are to be conducted. The surveys will be open to recruitment for up to 12 months and each should take no longer than 15 minutes to complete.

(WS1.1) Survey of NHS IBD services

A cross-sectional national survey of IBD services in the UK. Data will be collected using an online survey instrument distributed via email to clinical lead/service managers at each NHS Trust. The survey will cover several domains, including the current provision of sexual health care and assessment, availability of specialist nursing services, access to psychological and other support services, and patient education and information provision. The survey will determine whether there are services focused on sexual health and if/how the provision of these differ between male and female patients.

(WS1.2) Survey of IBD nurses

A national cross-sectional survey of IBD nurses working in the 228 known adult services in the UK. The survey will be distributed to IBD nurses working in each service via the clinical lead/service managers contacted in 1.1 and via the Royal College of Nurses IBD network, CCUK and IBD Specialist Nurse regional meetings and conferences. Advertising the survey will be repeated at different intervals within a 6-month period to improve visibility. There will be a direct follow up with clinical leads when there has been no nurse response. The survey will cover several domains, including the current practice, assessment tools, facilitators, barriers, and confidence in delivering sexual health assessment, care, and advice to male patients with IBD.

(WS1.3) Survey of male IBD patients

A cross-sectional national survey of men with IBD across the UK. The survey will be mainly distributed with the support of CCUK and social media networks. The NHS sites identified in survey 1.1 will be asked to display adverts for the survey but will not act as participant identification sites. The survey will

cover several domains, including the experience of sexual health care assessment and intervention, and perceived needs, preferences, and barriers.

Analysis of quantitative data

Data will be analysed descriptively using appropriate summary statistics (frequencies/percentages for categorical variables; means/standard deviations or medians/quartile ranges for continuous variables, depending on their distribution). For key variables and scores, 95% confidence intervals will be presented and differences between geographical regions evaluated. Differences between centres that responded and those that did not will be tested using available information. Several associations including barriers and facilitators with the offer of a sexual health assessment for men will be tested using logistic regression. A similar approach will be applied to other key variables and scores as identified by the advisory group and across the three surveys. In each case, estimates of the magnitude of association, for example odds ratio, and corresponding 95% confidence intervals will be presented. Where it is feasible to do so differences between geographical regions and demographic characteristics, such as ethnicity and under-researched populations will be presented. We will assess the mechanism of missing values: if there is a need to impute missing values we will use multiple imputations as a sensitivity analysis.

WS2. Qualitative study

Concurrent with WS1 a qualitative study will be carried out. This will involve: (i) in-depth individual semi-structured interviews with men with IBD and their partners; and (ii) focus groups with nurses and other clinicians involved in the provision of care to men with IBD. The aim of this stream is to explore factors identified in our preliminary PPI work that influence the sexual health assessment and care of men with IBD, and generate ideas on appropriate and acceptable ways in which this could be improved as a basis for the design of the intervention in WS3.

(WS2.1) Interviews with Patients & Partners: individual, semi-structured interviews will gather in-depth data on men's needs and experiences, and how practice could change to improve sexual health care. Men who are married or in a relationship will be offered the opportunity to invite their partner to join them in the interview, which will then be conducted conjointly. Single men and those who prefer not to involve their partner will be interviewed individually. In addition, we will also seek to conduct individual, semi-structured interviews with a sample of men's partners alone (determined by saturation/number of conjoint interviews), recognising the challenges that can occur when couples are interviewed together,

such as one partner dominating the interview or producing a simplified 'official' account (Oliffe et al., 2015), or the challenge of covering topics that may be a source of conflict within a relationship.

Semi-structured interview guides will be developed for (i) men/couple interviews; and (ii) partners, based on themes identified in our review of the literature (Ma et al., 2020), preliminary PPI work, and consultation with our stakeholder group. Interviews will take place via videoconferencing or telephone, according to participant preference. Interviews will be digitally audio-recorded, transcribed, imported into NVivo qualitative data management software and subjected to thematic qualitative analysis involving interpretive coding (Thorne, 2016).

(WS2.2) Focus Groups with Healthcare Professionals: following the interviews, 3 focus groups with healthcare professionals (n=6-8 per group) will be carried out. The aim of this work is to enhance understandings of the barriers and facilitators to sexual health assessment and how to make care more appropriate for men. A multidisciplinary sample of participants (e.g., nurses, doctors, allied health professionals, psychologists) involved in the provision of IBD care in the NHS setting will be purposively recruited. Focus groups will be conducted online. Rather than multiple live focus groups, we will use an asynchronous method, via a platform like Quallie, which will facilitate the scheduling of busy healthcare professionals and decrease the burden of participation on them. These focus groups will be informed by a topic guide based on current published research, on themes identified in patient interviews (2.1), and in consultation with the stakeholder advisory group. Discussions will be digitally audio-recorded, transcribed, imported into NVivo and subjected to thematic qualitative analysis involving interpretive coding (Thorne, 2016).

Analysis of qualitative data

Analysis of qualitative data will be guided by Interpretive Descriptive methodology (Thorne, 2016) and follow the six stages of thematic data analysis (Braun and Clarke, 2006). Thematic analysis (Figure 4) will involve a systematic approach to identify and translate patterns of meaning in the data and is widely used in qualitative health research. As this field is poorly understood, an inductive approach has been favoured over a framework analysis.

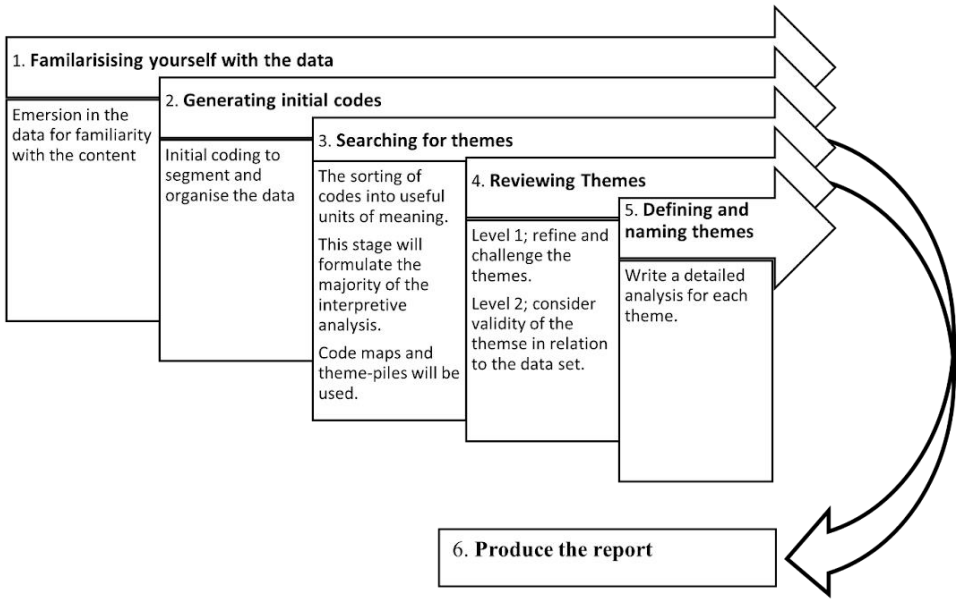

Figure 4: Thematic Analysis (Braun and Clarke, 2006)

WS3. Develop prototype intervention & logic model to patient benefit

Utilising a co-production approach (Hawkins et al., 2017), the findings from WS1 and WS2 will be used to develop a prototype intervention to improve the assessment and care of the sexual health needs of men with IBD. This will be accompanied with a draft logic model describing how the intervention is expected to lead to patient benefit including inputs (e.g., resources required), outputs (e.g., changes in knowledge, attitudes, behaviours, and skills), and outcomes (e.g., health status, quality of life).

(WS3.1) Desktop exercise: Members of the research team in partnership with our stakeholder group will first undertake a virtual desktop exercise to triangulate findings from WS1 and WS2 and map the barriers and facilitators to men's sexual health assessment to the Capability, Opportunity, and Motivation-model of Behaviour (COM-B) as a basis for intervention development (Michie et al., 2011). The output will be a summary report of the findings, including a list of candidate interventions/key components likely to be effective and acceptable in improving nurse-led sexual health assessment and care of men with IBD. Based on preliminary work it is anticipated that candidate interventions will include:

- A structured education/training programme for nurses to increase preparedness, confidence, and best practices.
- An evidence and expert opinion-based framework to help clinicians assess and manage men's sexual health.

- A gender-sensitised patient information resource to facilitate shared decision-making between clinicians, patients, and partners.

(WS3.2) Co-production Workshops: A series of 3 co-production workshops will iteratively develop the prototype intervention and logic model using a range of co-production tools and techniques including brainstorming, mind mapping, and group discussion. Workshops will be guided by the 5C framework for developing gender-transformative men's health programmes (Galdas et al., 2023). Particular emphasis will be placed on intervention context, content, and communication strategies that can improve accessibility and acceptability whilst working to transform gender norms and relations that can harm sexual health (e.g., ideas of "manhood" that are predicated on taking risks, being strong, not seeking help, and exerting power or dominance), to promote positive health changes for men and their partners (Galdas et al., 2023).

Workshops will be attended by members of the research team, patients, partners, IBD specialist nurses and other relevant key stakeholders, e.g. CCUK (n=10-12 participants). Workshops one and two will take place face-to-face, supplemented by communications via email or videoconferencing when face-to-face meetings are not possible, or when matters arise that require discussion between meetings. Workshop three will take place via videoconference. In workshop one, the co-production process will be introduced, and initial feedback sought on the list of candidate interventions/key components (distributed to attendees in advance) with the aim of building consensus around intervention goals, outcomes, format, and structure. Group discussion and consensus methods will be used to agree on a final candidate intervention and its associated content, context and communication/delivery mechanisms. A stance of 'researchers as partners' will be adopted to co-produce an understanding of what an accessible and acceptable intervention might look like by working with people who would provide, support and receive it. Notes, flip charts, doodle-sheets and post-it notes will be used to co-produce themes in small groups, which will then be analysed and summarised in report format.

In workshop two participants will discuss how the intervention is intended to work, with discussion and feedback on design, content, and usability of the prototype, informed by the 5C framework (Galdas et al., 2023), with additional adaptations made. In the third and final workshop participants will be sent the final iteration of a prototype intervention and draft logic model for discussion and refinement, with a simple evaluation including basic user feedback. User-ratings and narrative comments on acceptability

and usability will be recorded using Qualtrics survey software. Quantitative data will be analysed descriptively, while qualitative data will be analysed thematically.

6 STUDY SETTING

York and Scarborough Teaching Hospital Foundation Trust NHS Hospital is the primary study site. Although the three workstreams will include participants from across the country, the design of the study does not require the opening of multiple research sites as the majority of data will be collected online and there is no change to patient care. The location of the in-person workshops in WS3 will be selected considering accessibility and suitability for the planned activities. These do not need to necessarily be held within NHS facilities and this has been budgeted accordingly.

Recruitment of participants is described in more detail in section 7 but can be undertaken centrally. Participants will be accessed via an advertising strategy supported by charitable and professional organisations as detailed in section 7.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

	Inclusion	Exclusion
Men with IBD	A diagnosis of Crohn's Disease, Ulcerative Colitis or IBD-U. Identify as male	Unable to provide informed consent. Less than 18 years old. Does not speak English. Not able to participate in the research activity (interview, focus group or workshop).
Partners of men with IBD	Currently in (or in the last 5 years) an intimate partnership with a person who identifies as male and has a diagnosis for Crohn's Disease, Ulcerative Colitis or IBD-U.	
IBD service manager	An NHS employee whose current employment involves oversight of the delivery and provision of a secondary care IBD patient service within their employing organisation. This may be a healthcare professional or non-clinical manager.	
IBD nurses	A registered nurse who as part of their role is responsible of the provision of care to patients with IBD.	
IBD health professionals	A health professional registered with the GMC, NMC or HCPC who's professional role is considered part of the IBD multidisciplinary team. Currently or previously employed in a role that directly provides care, support or advice to men with a diagnosis of IBD.	
IBD stakeholders	A representative of a charitable, not-for profit, professional, public or governmental organisation that is engaged with men who suffer from long term conditions or IBD specifically.	

7.2 Sampling

7.2.1 Size of sample

WS1. Cross-Sectional Surveys

(WS1.1) For the survey of NHS IBD services, the **target sample size is 114**. Population estimates have been based on the information provided in the IBD-UK 2019/20 audit report which had a response rate of 72% (IBD-UK, 2021). In a personal communication, IBD-UK confirmed that the response rate for the most recent audit (not yet published) is 66%. Given the current NHS pressures, sample size calculations have been based on a lower response rate of 50% of the 228 services. Given the current NHS staffing challenges, we anticipate the response rate to our survey will be lower and have based our sample size calculations on a response rate of 50% (which we think is a conservative estimate). A response rate of 50% would allow estimation of key binary indicators (assuming a 50% proportion, which is the worst-case scenario) with a margin of error (MoE) of 6.5% for a 95% confidence level (CL).

(WS1.2) For the IBD nurses survey the **target sample size is 90**. The findings from the Caseload Report Standards for IBD Specialist Nurses in the UK (Crohn's & Colitis UK, 2017) and the survey by Leary and colleagues (Leary et al., 2018) estimated that there are 300 IBD nurses in the UK. The estimate was based on national data curated from the IBD audit and the Crohn's and Colitis UK. The response rate for that survey by Leary et al. (2018) was 55% (168 responses received). As the survey was conducted in 2017 and given the impact of the COVID-19 pandemic and ensuing challenges in the IBD workforce as highlighted in the survey by Kennedy et al (2020) of IBD services across the UK, we have assumed that the response rate might be lower and have assumed it to be 30%.A response rate of 30% (n=90) would allow estimation of key binary indicators (assuming a 50% proportion) with a margin of error (MoE) of 8.7% for a 95% confidence interval (CI). If instead the response rate is 20% (n=60) then the MoE increases to 11.3%.

(WS1.3) An estimated total **sample size of 378** adult male respondents is required to provide an estimate for the proportion of IBD patients who have had their sexual health needs assessed or discussed with an IBD clinician, with a margin of error of 5% and 95% CL. The IBD-UK survey (IBD-UK, 2021) was completed by approximately 3236 adult male respondents over the course of seven months; this survey will also run for seven months. It is anticipated that the number of respondents will be lower than that of IBD-UK survey for adult male respondents. At 4 months a review of recruitment numbers will occur. If the number of respondents is less than 50% of the target, then the recruitment strategy will

be amplified. Any responses received beyond 378 would enable us to estimate this proportion with further accuracy and potentially enable us to provide reliable estimates stratified by various characteristics such as age group, sexuality and ethnicity.

WS2. Qualitative study

(WS2.1) An estimated sample size of 15-20 participants, determined by data saturation (Hennink et al., 2017). This number will enable a heterogenous sample sufficient to address our research question, taking into consideration variation in disease presentation and possible variation in participant demographics including age, race, sexual orientation, and relationship status.

(WS2.2) 6-8 participants per focus group, with a total of three independent groups. This group number will allow diversity in the professional groups and stakeholders participating while safeguarding effective running, facilitation, and output of the workshop.

WS3 Co-production workshops

The estimated sample size is 8-12 participants who will participate in three sequential workshops. This allows for variation in public, stakeholder and professional representation while ensure facilitation of the workshop if effective leading to tangible outputs.

7.2.2 Sampling technique

WS1. Cross-Sectional Surveys

(WS1.1) Census approach of all IBD services as identified by the 2019 IBD-UK audit.

(WS1.2) Census approach of all IBD specialist nurses.

(WS1.3) Targeted convenience sampling of men with IBD via established networks.

WS2 and WS3 Qualitative study and co-production workshops

Purposive sampling will be adopted in workstreams 2 and 3. For the interviews a heterogenous sample who indicate a willingness to be interviewed in the patient survey in WS1 will be purposively recruited based on a range of characteristics including age, ethnicity, marital/partner status, sexuality, and IBD type (UC or Crohn's). Participants with partners will be asked to invite them to participate should they wish. For the focus groups a multidisciplinary sample of participants (e.g., nurses, doctors, allied health professionals, psychologists) involved in the provision of IBD care in the NHS setting will be purposively recruited.

7.3 **Recruitment**

WS1. Cross-Sectional Surveys

To identify and sample respondents we will use social media. For surveys WS1.1 and WS1.2, we will also replicate the approach taken by the national IBD-UK audit, last completed between July 2019-January 2020 (IBD-UK, 2021). IBD-UK have identified all 228 secondary care IBD services in the UK and have provided us with this list so that we are able to contact services directly via email. For survey WS1.3, we will also identify and sample respondents through the membership of Crohn's and Colitis UK's (CCUK) (n~50,000), advertising the survey via their website, e-newsletters, and distributing it via wider networks and partners, e.g. promoting the survey in geographic regions with a high density of under-represented groups or those less likely to be exposed to traditional and online focused methods of study advertising. CCUK have established procedures for advertising research to their membership group and have already agreed to distribute the survey when ethical approval is received. This approach has been previously successful in several IBD-UK surveys of patient experience, yielding >10,000 patient responses. We will also ask all the IBD services contacted in the first two surveys to advertise the study using posters, leaflets, social media and other methods. Patients scheduled for appointments who meet the inclusion criteria may receive the study poster with their appointment information, or the poster may be given out at appointments by IBD nurses. During normal working hours, a member of the research team will be available to answer any questions. If the number of respondents is less than 50% of our target, then we would amplify our recruitment drives to target populations that are under-represented and achieve the required sample size. This could include promoting the study in particular geographical regions or through specialist community groups, or using channels and connections made by CCUK in their attempts to tackle under-representation in their membership group and research, where feasible.

WS2 and WS3 Qualitative study and co-production workshops

During the WS1 surveys there will be the opportunity for respondents to express an interest in participating in WS2 and WS3. From those who express an interest a heterogenous sample of approximately 15-20 men (based on a range of characteristics including age, ethnicity, marital/partner status, sexuality, IBD type) will be invited to participate. We will also recruit participants by advertising the study using posters, leaflets, social media and online methods. A similar approach will be utilised with the focus groups and will also include an element of snowball sampling of professional colleagues. To ensure the focus groups and workshops are attended by a range of stakeholders and professionals we will advertise the study through professional networks. This approach will enable us to access a

larger, more diverse sample, whilst also mitigating time and cost constraints associated with setting up multiple NHS study sites within the region, and removing the effect of variations in how different NHS Trusts manage their IBD caseload.

7.3.1 Sample identification

All the IBD services have been identified via the IBD-UK audit, the data of which is publicly available. Identification of IBD nurses will be via the IBD services. Men with IBD will be identified through Crohn's and Colitis UK, poster and leaflet advertising in IBD services and targeted advertising in health and social care organisations that serve under-represented regions and demographic groups. There will be no payment for participation in the survey. However, a prize draw will be offered both for IBD nurses and patient participants offering 1x £50 high-street voucher for the IBD nurse survey and 5 x £50 high-street vouchers for men with IBD. To enter the prize draw a separate part of the survey will collect contact details, which will be stored separately from the survey data and deleted as soon as the prizes winners have been randomly selected and contacted.

Identification of participants for interviews and focus groups will be through the survey and/or study advertisements where participants will be provided the opportunity to express an interest and provide their contact details. Men with IBD and partners of men with IBD will be offered a £20 high-street voucher for participation in the interviews. Professionals will be offered a £20 high-street voucher for participation in the focus groups. All participants will be compensated for travel and other reasonable expenses such as childcare.

Participants for the co-production workshop will be identified by the study team and stakeholder advisory group. Those who participated in interviews and focus groups may also be purposively identified and invited to participated.

Throughout this study, no NHS patient records or data will be used for the identification of participants. NHS sites will be asked to advertise the study using posters, leaflets and social media but no patient details will be passed from NHS sites to the study team.

7.3.2 Consent

WS1: Surveys

The online survey data is anonymous at point of entry and therefore written informed consent will not be taken. However, the survey will have an opening information page explaining the study and how the data will be used. Participants will be asked to select a box to confirm they have read and understand this information. At the end of the survey there will be two further optional additions (1) to enter a prize draw: participants will be asked to select a box to consent to their contact details to be held separately from the survey responses, only for the purpose or awarding the prize and until completion of the survey, after which all data will be deleted, (2) to express an interest in participating in an interview: participants will be asked to select a box to consent for their contact details alongside the demographic details page to be sent to the study team and stored until the end of the study for the purpose of contact the participant about this study only.

WS2 and WS3: Interviews, focus groups and co-production workshops

Written informed consent will be obtained prior to participation in interviews, focus groups or co-production workshops. The process of obtaining informed consent will be in accordance with Good Clinical Practice (GCP). Participants will be provided with a participant information sheet and given time to consider the information and the opportunity to ask the study team questions. As most of this work will be conducted remotely, on-line consent will be available in this study.

8 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Assessment and management of risk

Risk to participants: This is a low-risk study as no clinical intervention is being performed. There is no expected risk to participants, but for those participating in the surveys or interviews there is potential for an emotive response to be elicited. The final page of the public-facing survey will signpost people to relevant organisations that can provide additional support. For the interviews and focus groups, the researcher will be either a registered nurse or experienced qualitative researcher and can respond to any emotional distress and escalate accordingly. Interviews will be terminated if it is felt that they are negatively impacting on a participant. Participants will be offered the Participant Support Leaflet which will provide a list of helpful resources and signpost access to support for depression, anxiety and stress. If any safeguarding issues are disclosed during the interviews they will be escalated via the appropriate channels. There may be some inconvenience to participants regarding the time taken to participate. Participants will be offered a range of possible dates and times.

Risk to researchers: The study setting carries very little risk to the researchers. Researchers interviewing or facilitating focus groups will be supported by SM or PG who are experienced nurses and researchers. Research debriefs will be offered with either SM or PG.

Informed consent: The process for obtaining informed consent will be in accordance with Good Clinical Practice. In WS1 no identifiable information is collected and therefore there will be no associated consent form. Surveys will instead have an opening page explaining the details of the study and how data collected will be stored and used. The participant will have to select a tick box to say they have understood the information and then completion of the survey will indicate consent. At the end of the surveys, participants may opt-in to a prize draw for participation by providing their email and providing consent for this to be stored until the prizes are allocated. This list will be kept separately to the research data and deleted as soon as the prizes have been randomly allocated.

In WS2 and WS3, potential participants will be given suitable time to consider the written information provided to them and discuss any queries with the research team or others. Participants will be given the opportunity to ask any questions and have any queries answered. The study consent form must be signed and dated by the participant before participation in the interview, focus group or workshop and the collection of any data. This study will offer electronic consent which is proportionate to these non-interventional studies low risk of harm to participants.

Enrolment log: there will be an enrolment log for WS2 and WS3. This (alongside the consent forms) will be the only location of written personal information that is not anonymised. It is necessary for the purpose of contacting participants and quality assurance of the research. It will be password protected and kept on the secure digital network of the Sponsor separately to the research data. It will only be accessible to those signed on the delegation log.

Audio recordings: these are required for audio-transcription of the interviews and focus groups. These must be immediately downloaded onto the secure network drive of either York and Scarborough Teaching Hospitals NHS Foundation Trusts or the University of York (both of whom have security arrangements and standard operating procedures for the storage of data in research trials at the end of the interview and deleted from the original recording device or one-drive if video conferencing. Audio recordings may be identifiable so for additional security these files should be password protected and deleted at the end of the study. Audio recordings will be deleted once data analysis is complete.

Recruitment: No coercion or undue influence to take part will be used. Participants will be made aware that participation is voluntary, and they are free to withdraw at any point without giving a reason. Any participants who are experts through experience of living with IBD will be informed that participation in the study will not alter their clinical care. Participants that are experts through experience who are involved in interviews or co-production will be offered a £20 high-street voucher for participation. Professionals who are involved in focus groups will be offered a £20 high-street voucher. There will be a £50 prize draw for participation in the on-line surveys.

Deception: No misleading information will be given and no intentional deception used.

8.2 Research Ethics Committee (REC) and other regulatory review & reports

This study will be subject of NHS REC review via the Health Research Authority Approval process. A favourable opinion must be received prior to the study commencing.

Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to be implemented at site. All correspondence with the REC will be retained. It is the Chief Investigators (CI) responsibility to produce the reports required for the REC and Funder. The CI will notify the REC of the end of the study. If the study is ended prematurely, the CI will notify the REC and Funder, including the reasons for the premature termination.

Regulatory Review & Compliance

Before recruitment of participants into the study, the CI will ensure that appropriate approvals from York and Scarborough Teaching Hospitals NHS Foundation Trust is in place.

Amendments

Substantial amendment will be submitted to the HRA for appropriate review. The CI will be responsible for amending any study documentation. The stakeholder advisory group and Funder will be notified in writing of any substantial amendments. Amendments will be tracked in version control and Appendix 3 of the protocol.

8.3 Peer review

The design of this project has been reviewed by The Funder (National Institue for Health Research Research) as part of the Patient Benefit funding application.

8.4 Patient & Public Involvement

A PPI group, which was established with support from an NIHR RDS Public Involvement Fund award and advertised by CCUK and instrumental in the development of the study design and funding application. The group comprised UK men with a diverse range of diagnoses (UC/CD), ages, sexualities, and ethnicities.

The PPI group has played a key role in shaping the direction of the study and encouraging the project team to focus on areas of concern which reflect the needs and priorities of men who live with IBD. Specifically, the PPI panel prioritized sexuality as an important but often overlooked aspect of sexual health support for men. Members of the panel were also keen that men should be offered the opportunity to choose qualitative interviews alone or with their partner in WS2. These insights have helped to inform a research design which is sensitized to the concerns of men with IBD, which extend beyond traditional clinical outcomes (e.g. erectile dysfunction) and are grounded in the practical realities of health management and many men's desires to lead a life compatible with key aspects of masculine identity while managing a long-term condition.

The PPI group has provided favourable feedback on the research aims and objectives and the design of the study and made important contributions to this application in many other areas. As well as helping to shape the research direction, the panel has provided input on the acceptability and relevance of the workstreams, particularly emphasizing the need to explore effective ways of identifying and recruiting men from diverse backgrounds as a key element of our developmental work. The panel have also advised on ways to ensure their ongoing inclusion in the study, so that the 'voice' of patients is present throughout the research project. This is reflected in the contributions of our stakeholder group that will involve patient and public members moving forward.

The research will involve three types of PPI defined by the NIHR as collaboration, consultation, and co-production:

Collaboration: patient co-applicant, Wayne Robinson (WR), draws on lived experience of IBD, WR will assume the same level of responsibility as other co-applicants on the team, with particular responsibility

for co-chairing the stakeholder group (with SM), in addition to a broader role advising on study design and conduct (e.g. data collection, recruitment materials, data interpretation, dissemination). WR has been allocated a budget that reflects payment of fees, expenses and support for training.

Consultation: Prior PPI work will be developed by convening a large and diverse stakeholder group inclusive of PPI members which will provide ongoing input into the research process. The advisory group will meet four times at key project stages to ensure the research is patient-centred and accessible to diverse populations, e.g., advising on recruitment strategies and developing/piloting data collection instruments in WS1; advising on recruitment and semi-structured interview guides in WS2; desktop exercise in WS3 as a basis for intervention development. Meetings will be held remotely. Public attendees will be paid £75 for each meeting (and associated pre-reading). Before the first group meeting a training, event will be organised to brief people about what is involved and provide guidance, including education on research concepts and processes (specifically addressing the MRC framework for complex interventions and the 5C framework for developing men's health programmes).

Co-Production: In WS3 we will collaboratively develop and refine the prototype intervention by working with people who will provide support and receive it. Public members involved in this stage will also be paid £75 for each meeting.

8.5 Protocol compliance

Protocol deviations, non-compliances, or breaches are departures from the approved protocol. Accidental protocol deviations can happen at any time. They will be documented on the relevant forms in the site file and reported to the CI and Sponsor immediately.

Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach. Serious breaches of the protocol will be reported the to the sponsor, the research ethics committee and the funder.

8.6 Data protection and patient confidentiality

Data management will comply with the Data Protection Act (2018), GPDR regulations (2016) and York and Scarborough Teaching Hospitals NHS Foundation Trust research SOPs. All investigators and study staff will comply with the Data Protection Act in regards to the collection, storage process and disclosure of personal information.

All data will be stored and archived by York and Scarborough Teaching Hospitals NHS Foundation Trust in line with their current research SOPs. In WS1 no identifiable information will be collected as part of the research. Participants can opt-in to a prize draw for completion of the survey at which point they will be asked to select a tick-box allowing their email address to be kept until the prizes have been randomly awarded. This list will be kept separately from the study data and deleted once the prizes have been awarded.

In WS2 and WS3 study number and pseudonym will be assigned to each participant. The study number will be allocated by the research team and used on the study documents including the CRF and transcripts. A pseudonym will be used within the interviews and transcriptions and will be selected randomly from a pre-defined list. A separate document will provide a list of study numbers and participant names. As this document will contain identifiable information it will only be accessible by appropriate study members signed on the site delegation log for the purposes of conducting the research and auditing. This will include the CI and York Teaching Hospital Quality Assurance Lead. The document will be stored separately from the site file and trial data and be password protected.

Patient confidentiality may be broken in the event of a disclosure of harm or potential harm that needs to be investigated. This will be escalated by the research teams through the appropriate safeguarding channels at York and Scarborough Teaching Hospital, NHS Foundation Trust who will then advise on whether further escalation to other authorities is required. All participants will be informed that the data they provide will be handled sensitivity and confidentially and the possible conditions under which confidentiality may be broken. During the course of interviews and focus groups any identifying information that is discussed will be redacted from transcripts.

Access to the data will be limited to those signed on the delegation log with specific research duties. Individuals from the Sponsor or Funder will be granted access to the data for the specific purpose of quality control and monitoring of study conduct. Any paper documents will be kept within a locked cupboard in a locked room at York and Scarborough NHS Foundation Trust. Electronic documents can only be stored on either the York and Scarborough NHS Foundation Trust networks or University of York networks both of which are secure and backed by up IT services. Files will be stored within a dedicated research file store (drive) which is regularly backed by IT services and at the end of the study deleted permanently after archiving has taken place. The CI or delegated researcher may use a

VPN to connect to the filestore when working within one of the partner institutions or from home, however access to the data must always been within a private setting to ensure there is not accidental viewing of the data by persons not on the delegation log.

Audio files will be stored as MP3 files and downloaded onto filestore as soon as is reasonably possible after the interview. In most cases it is envisaged that this will occur on the same day of the interview. The original digital file on the Dictaphone will be deleted immediately after downloading. Audio and video files from virtual interviews will be stored as MP4s and transcribed into an Office Word file. A University of York approved external transcription service may be used and will be bound by a confidentiality agreement. A SOP will be created for the storage and transfer of audio files in the case of external transcription. Audio and video files will be deleted once data analysis is complete. Written transcripts will be reviewed by the research team so that any identifiable information removed, these will be stored with the study data for 5 years after the completion of the study.

At the end of the study data will be archived for 5 years. If a participant decides to withdraw from the study, all data collected to the point of withdrawal will be kept as above and may be used within the study.

The copyrights and associated intellectual rights of the data are set out as per the collaboration agreement for the study. York and Scarborough Teaching Hospitals NHS Foundation Trust will act as the data custodian.

8.7 Indemnity

NHS indemnity will be apply through the sponsor.

8.8 Access to the final study dataset

The Sponsor will have access to the full dataset for the purposes of study monitoring. All researchers in the core study team will have access to the full dataset. This includes SM, PG, PK, MK and researchers employed to work on the study. Members of the Stakeholder Advisory Group may be granted access to the full dataset by the CI if requested for the purposes of monitoring of study conduct and validation of results.

Participant consent will be obtained for secondary analysis of the data. Requests for provision of the dataset for the purpose of secondary analysis will be reviewed by The Sponsor, SM and PG. The Sponsor owns the dataset and will be responsible for granting access if appropriate.

9 DISSEMINIATION POLICY

9.1 Dissemination policy

York and Scarborough Teaching Hospitals NHS Foundation Trust will own all data arising from the study. Publications must occur in line with the collaboration agreement between York and Scarborough Teaching Hospitals NHS Foundation Trust, York St John University and The University of York. The Funder and Sponsor will be acknowledged in all publications. A summary newsletter reporting an overview of the study outcomes will be made available on the study website. The protocol will be made publicly available either through publication in an appropriate journal or by making this document accessible on a public facing websites hosted by the involved organisations.

Dissemination of the findings beyond traditional academic audiences is essential for establishing a pathway to patient benefit. The research team has a highly successful track record of engagement and knowledge translation in health services research. We will develop a multi-pronged evidence-based dissemination strategy that reaches out to key stakeholders, working with our partners in CCUK and our stakeholder group to ensure learning from the project is effectively communicated widely to relevant clinicians, service user groups and the public.

Publications & Presentations

We will seek to publish the findings from the survey and qualitative research in high quality, peer reviewed journals that are likely to have an impact on the clinical field. In the final month of the project we will organise an in-person dissemination event in partnership with our stakeholders, as well as presenting at national and international meetings and research conferences, including the annual conference of the European Crohn's and Colitis Organisation. If progression to further evaluation is warranted, we will design a definitive evaluation of the prototype intervention in practice when compared to current care, in a randomised controlled trial.

9.2 Authorship eligibility guidelines and any intended use of professional writers

Any individual who mees the criteria for authorship as set out by the International Committee of Medical Journal Editors (ICMJE) will be granted authorship on publications associated with this study.

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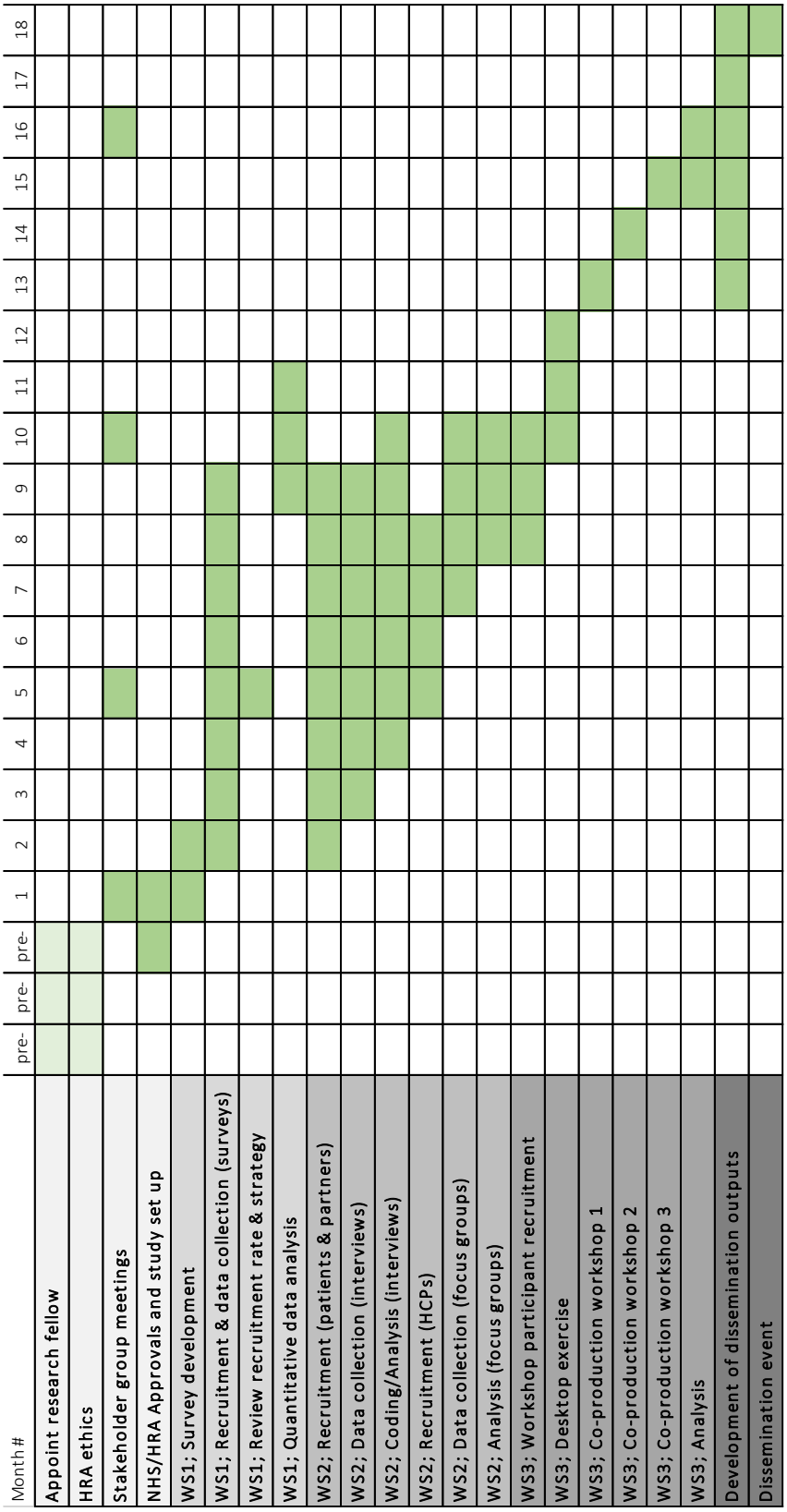
11 APPENDICIES

11.1 Appendix 1- Required documentation

11.1.1 Participant Information Sheet
11.1.2 Consent form
11.1.3 Survey of IBD Services
11.1.4 Survey of IBD Nurses
11.1.5 Survey of men with IBD
11.1.6 Interview guide
11.1.7 Focus group guide
11.1.8 Sara Ma (CV)
11.1.9 Paul Galdas (CV)
11.1.10 Peter Knapp (CV)
11.1.11 Mona Kanaan (CV)

11.2 Appendix 2 – Schedule of Procedures



13.3 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
01	1.1	03/10/2024	G Forshaw	Minor changes to the participant surveys
02	2.0	04/11/2024	G Forshaw	Minor changes to the recruitment strategy & to the method for staging our focus groups