

**NIHR Research Design Service for Yorkshire and Humber:
RDS YH Public Fund Report**

Project title: A longitudinal qualitative exploration of patient experience and healthcare professional understanding of male sexual health in Inflammatory Bowel Disease.

Short title: Male sexual health in Inflammatory Bowel Disease (MaSH-IBD Study)

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Introduction

This fund was used to create a public involvement group to help steer the clinical research project 'Male sexual health in Inflammatory Bowel Disease' (MaSH-IBD Study) and support an application for funding from Crohn's and Colitis UK.

Crohn's and Colitis UK are a national charity for people with IBD looking to fund research that considers the social or psychological impact of this chronic condition. The application is a two-stage process and we have been successful at being shortlisted for the second stage. Interview for the next stage will be conducted on the 24th of March 2020.

MaSH-IBD is a study exploring patients and professionals' experiences, perceptions and knowledge of sexual health in men with Inflammatory Bowel Disease (IBD). Data will be collected through interviews, diaries, focus-groups and potentially photovoice. We will be trying to understand;

- how the disease impacts upon sexual health and function,
- what the barriers are to managing sexual health issues in IBD,
- what information is needed by patients and healthcare professionals,
- whether there is scope for nurse-led assessment, treatment and care in this area.

IBD is a long-term condition of the digestive system. People with the disease can suffer from pain, embarrassing changes in bowel habits and extreme tiredness. Although IBD can be diagnosed at any age, it is often first discovered between 16-30 years. There is no cure for IBD and sometimes the disease can be very serious causing hospitalisation and surgery. The disease can greatly impact on a person's quality of life, including their ability and desire to have sex.

'My perianal fistula can be awkward to talk about and makes me very self-conscious, especially when naked with another person'

Patient quote

(McDermott et al., 2015)

Sexual function is a sensitive and hidden subject and some patient's will turn to their nurse for guidance and support in this area.

'Nurses are in an ideal position to assess the degree of impact IBD may have on a client's sexual health....perhaps the most important care nurses can offer is awareness of the sexual issues that often go unspoken.'

(Giesen and Terrell, 1996)

There are no published detailed personal accounts or narratives of how IBD might impact specifically on the ability to have sex. Sexual function is often measured in the frequency of having sex or (for men) the ability to have an erection. However, sexual health and well-being is far more complex than just these two issues. There is no detailed guidance for patients or professionals that is based on what patients have said they needed. Women's health has had some attention but sexual health in men with IBD is very poorly understood.

Public involvement (PI) is essential for this sensitive and taboo subject matter. Consideration of public and patient views will not only improve the potential impact of the study but also aid recruitment and help us to moderate the potential burden of study participation. It is also important that adequate resources for continued PI are considered and accounted for within the research grant application and this can be done most effectively with guidance from a PI group at this stage of the process.

Aim

The primary aim was to create and develop a public involvement group for this study and gain feedback on the CCUK application grant. This included:

- Recruiting members to be involved.
- Three meetings with members:
 - Training day
 - Meeting for develop research ideas & feedback on protocol
 - Meeting to feedback on application
- Develop a strategy for on-going PI

Methods

An information leaflet for PI participants was created alongside a PI strategy. This was reviewed by the local NHS Trust R&D Department and sent out to potential members. It was decided that a four-member PI group would not only allow the research team to develop an effective working relationship with all members but also provide a range of detailed feedback.

The lead researcher, who works as a clinician at the hospital, was able to identify potential members, selecting people for their experience of the disease. Potential members were provided with an information sheet and the contact details of the lead research. A brief face-to-face or telephone conversation was conducted to ascertain interest in participation and run over the aims of the group and what was expected from membership. We considered whether an informal interview/meeting should be conducted to assess the suitability of the potential members, but it was felt this would be too onerous and unnecessary. The information leaflet clearly laid out what involvement in the project would include and the lead researcher was able to discuss and clarify any details. After willingness and interest to participate was established a formal meeting was arranged. A member of the PI group suggested a confidentiality agreement should be used and this idea was adopted.

The PI group was invited to attend a research meeting while the project proposal was under development. This was to discuss whether they felt that the objectives and methods were appropriate, sensitive and acceptable. There was also discussion on how the study may impact on study participants and detailed consideration of methods including where the interviews should be held, the length of the interviews, the subject guides and the provisions required to make the interviews accessible and manageable.

Members completed a questionnaire to identify training and support needs. All members were offered the opportunity to attend an educational/training day at the local hospital. Unfortunately, this was not taken up by any member and this was of great disappointment to the team. On

gaining feedback one member felt that such training was not suitable for them and expressed a preference for one to one training which was honoured. The other three members all expressed a desire to attend the training but were unable to or not willing to take annual leave or reduce other voluntary commitments to attend during working hours. It was challenging to arrange such a meeting inside of working hours. However, members were willing to have a one-to-one training session at a time and location suitable for them and therefore training was delivered in this manner by the lead researcher.

Members were asked to provide verbal or written feedback on the following:

- Research proposal and protocol
- Patient facing documents (invite letter, information sheet, consent form)
- Grant application to CCUK
- Future PI budget and activities

Members also completed the quality involvement questionnaire and the NIHR evaluation questionnaire.

A total of 14 meetings occurred between the lead researcher and PI members. The number of meetings varied depending on the member. Some members were willing to provide feedback on the documents via email while others preferred the opportunity to discuss them face to face. Although it was not intended that there would be this number of meetings as only one member claimed back travel there was the budget to do this. The downside was this created a high work demand on the lead researcher. However, now the group is established, and this introductory state has passed and the working relationship and training has been conducted we envisage that future PI involvement will be more manageable as the project develops. The need to allocate sufficient time and recourse PI at the start of the project was a valuable learning outcome for the research team.

Refreshments and food were offered at meetings (but not always accepted). The offer for travel to be claimed back after the meeting via BACS transfer was provided but only accepted by one member. Meeting locations varied depending on the participant. Meetings were either conducted in a public place or on the hospital grounds. Public places were selected for their accessibility, provision of parking or ability to walk/cycle to the meeting place was paramount to all members. Three members noted the challenge of meeting at the hospital due to traffic and parking. There was concern from the research team over discussion of the sensitive topic matter in public places, but this did not concern any of the PI members. When offered with the choice of a hospital or a public meeting place, the preference was mostly to meet away from the hospital (the couple of occasions this place was accepted was purely because the meeting has been arranged around another appointment at the hospital). We did consider whether this may have been because the hospital is associated with experienced of ill-health but did not probe our PI members regarding this. Interestingly, all members felt the hospital would be an appropriate place to conduct the interviews for the study itself with one member noting that this felt like a suitable location for the discussion of private matters and more familiar than a room at the university.

Vouchers for participation were provided after involvement in each key activity (research meeting, training meeting and feedback on protocol/grant application). Members were asked to sign a form to say they had received the vouchers.

All members have expressed they would like to continue to be involved in the project even if funding is not secured. One member expressed they would like to continue to be involved but may not be able to give the same level of input due to employment and other voluntary commitments. However, the study team would like to facilitate ways to keep this member involved as they had some very valuable input. Another learning outcome was recognising that although not all member

may be able to have the same level of input this should not exclude membership as some members may bring value even if in smaller quantity (aka quality not quantity).

People involved

In total, six people were approached to participate. One person declined, noting that they felt the subject matter was too close to home. The team has felt this person may have been able to provide a good insight into the topic matter, but the response was not unexpected and reflects the barriers this project needs to overcome and the importance of PI in designing a study that appropriate patients want to participate in. One person failed to respond after initially showing interest.

Three members of the final panel had first-hand experience of IBD specifically, the fourth member had experience of living with a chronic health condition.

Members were all above the age of 40 which unfortunately does not mirror the typical age range of our patients. Conversely, all members received the diagnosis of their condition either in adolescence or early adulthood and thus had experience valuable of living with the condition. In the group were two men and two women. There was a range of socio-economic backgrounds, employment status, life experiences and a mixture of relationship status which is of relevance to the subject matter. Two members had previously participated in similar public involvement groups either at the hospital or within a GP surgery. One member also participates in a local IBD patient group and has experience of working with CCUK on a project designed to elicit the experiences and needs of adolescents with the condition. A further member is a retired researcher.

The selective recruitment of PI members worked well in this context. We wanted to approach people we felt would be willing to discuss this sensitive topic but also not limit our potential recruitment pool for the study itself. We were also limited by time and resources, so this selective approach was time effective. If we had more time or were considering a larger funding application, we may have considered providing the opportunity to help steer the project to a wider group of participants by advertising. The range of experience of the group provided breadth of contribution and insight which overall was positive.

Contributions

One success of the group was the input into the topic matter itself and research ideas. Gaining public and patient perspectives was of value at this phase of study development and helped shape the researchers thinking. There has been very little exploratory work done in this field so ascertaining a non-professional perspective was invaluable. The biggest impacts are hard to quantify but we attempt to describe them here.

Firstly, all members agreed that there was a need for further understanding of male sexual health in inflammatory bowel disease - although arguably this was to be expected as this was probably a driving factor for them to become members in the first place. They also all agreed that qualitative exploration was appropriate and needed. Three members expressed concern that recruitment of participants may be challenging. This led to several suggestions of how to overcome this (skype interviews, diary collection, photographs, use of novel technologies) and a slight but important semantic shift within our patient facing documentation from 'sex' to sexual well-being and identity. Members were able to even provide personal experiences and accounts that shaped the research teams' ideas (quotes given here are paraphrased from memory as meetings were not recorded).

'Have you heard of the men in sheds concept? It's almost like you need a way to gain interest without being too in your face 'let's talk about sex'.

Food for thought on how to engage participants, wording of documentation, setting of interviews etc.

'When I was at the shop, I thought what will my wife think if she sees this (information leaflet)?'

This raised consideration of whether participants may not want to receive post about the study and reiterated the need for privacy and sensitivity to be respected. This also raised discussion of the potential input from partners.

'What I like is that you make it easy for me to meet you, I hope you'll do that for your participants'

Highlighting the importance of making the study accessible to participants.

'But sex isn't important to everyone, so what you first have to find out is 'it a problem' - if it's not a problem don't create one'

This contributed to the rephrasing of the primary research question from 'what is the impact of IBD on male sexual health' to 'how to men with IBD experience and perceive their sexual health'.

'When I had surgery, I was really lucky, I had 6 months paid off work and they said I could come back whenever I was ready'

This was part of a discussion about gender identify and masculinity as part of sexual health and that employment is an important part of masculine identity in this context and thus strengthening the concept that sexual health is more than function.

A summary of contributions is provided here;

Section	Contributions made
Research ideas/aims/questions	<p>We received very detailed feedback on the overarching ideas of the project. This included:</p> <ul style="list-style-type: none"> - Making a distinction between altered sexual function and dysfunction. The difference between true dysfunction and anxiety of dysfunction which leads to altered function. - Consideration of the impact of the disease on physique and male stature. - Not for the researcher to project ideals about relationships but understand what is important to individuals. - To be open to the idea that 'a problem' may not exist. - Explore the scope of a nurse – need to be consider when a sex therapist or relationship counsellor is more important. - To avoid emotive language that presumes chronic illness is problematic. - The feeling that nurse training in this matter is important. - 'Sexual health'/'Sexuality' should also include other forms of sexual expression such as enjoyment of masturbation and not to exclude people not currently in sexual relationships.
Study design	<p>Members agreed that a large cohort studies was not currently appropriate. One member suggested a three-part study with pilot, intervention and then large cohort study. Although the research time did not feel that aligned well with the question or aims, the idea of a pilot was well received.</p> <p>Members felt semi-structured interviews are appropriate and sensitive. Some members did not quite understand the concept of photo-elicitation and this idea</p>

	<p>will need much more discussion and refinement before ethical approval is sought.</p> <p>One member felt that providing a range of different methods of which participants could select which suited them would encourage more people to participate.</p> <p>Members felt participants may need to be prompted about diary keeping and there were concerns over whether study participants would want to keep them stored at home while they were filling them in. Two members separately suggestion whether an electronic (audio or written) version should be considered.</p> <p>All members recognised the barriers in regards to data projection and ethical approval of using more novel forms of data collection yet felt these could be of real value if managed appropriately and sensitively.</p>
Interview specifics	<p>Meeting near a toilet.</p> <p>Provide a taxi if possible/needed.</p> <p>Limit to 60min maximum.</p> <p>Provide option of skype or text-chat.</p> <p>Second interview should be 6 months after first not 12.</p> <p>Conversely to the research team, members felt that the nurse-researcher should wear a uniform during the interview. They felt that the uniform symbolised trust, confidentiality and professionalism.</p>
Ethical considerations	<p>Make it explicit that participants can be referred to clinical psychology if needed.</p> <p>The security of personal diaries, how long voice recordings will be kept for.</p>
PI information sheet and strategy	<p>Members provided detail feedback including asking for clarification of sentences, identifying inconsistencies with some terms and grammar changes etc.</p>
Public facing research documents	<p>Modifications to some terminology (eg research team to study team).</p> <p>One member was pleased it did not contain difficult medical terminology.</p> <p>One member asked for the documents to be converted into active voice with easier to digest verbs.</p> <p>Note to make it clear about how long recordings will be kept.</p> <p>Detailed feedback on consent forms – including to add more explicit sections on voice recordings, why study participants may be contacted in the future and data retention periods. Amendments suggested were made to the document.</p>
Future PI	<p>Introduced confidentiality agreement for PI members.</p> <p>Feeling that one or two meetings per year the study is running is enough although willing to stay in touch via email and telephone if other assistance in the interim was needed.</p> <p>Choice of vouchers was requested (not just Amazon).</p>
CCUK application	<p>Members were overall very happy with the proposal and application. There were several amendments to make sure sentences were clearer.</p> <p>One member provided a letter of support to go with the application.</p>
Other funds	<p>Suggestion of application to a local charity.</p>

Evaluation

Three members completed the 'Quality Involvement Questionnaire' (Morrow et al. 2010) and all members completed the NIHR feedback questionnaire. Feedback was positive:

'Sara has made my involvement with the project very easy; providing print-outs of the documents she wants comments for as well as one-to-one meetings for training and information dissemination.'

'Experience has been and continues to be excellent.'

Two of the three responders rated all areas of the QIQ highly. The third member gave good ratings in the domains of research relationships, ways of doing research and research structures but expressed they did not feel involvement had enabled them to make decisions about how to do the research, taking on new research challenges and identifying research priorities. Interestingly, this member was also new to participation in a public panels and steering groups and demonstrates the importance of working closely with members that may be new to such processes. This was reflected in their contribution to the project in that while they provided comprehensive feedback on research documents, they gave less direct feedback on the research ideas themselves. This member may really have benefited from participation in a group that met as a group rather than individually with the researcher, as they would have been able to listen to and observe the kind of input had by the other members. It is also something for the research team to be aware of and ensure they enable members to be empowered to bring their own ideas to the table.

Moving forward

Funds for continued PI will be sought as part of a Crohns and Colitis funding application and include costs for travel to meetings, lunch and refreshments and a gift in kind for participation. The group did not identify any further requirement for training and decided that five meetings over a three-year study period would be suitable. The PI group will be involved in the following as the project evolves:

- Review/participation in ethics application.
- Review and comment on study progress reports.
- Devising interview guides and helping to pilot interviews.
- Reviewing findings and data analysis.

Difficulties

The biggest difficulty we encountered was finding a time suitable for the group to meet. As previously noted, due to time constraints we decided to proceed using on-to-one meetings at locations and times convenient to the individual members. All members responded positively to this and felt that it was of benefit to them. However, this put an unexpected time demand on the lead researcher who then proceeded to organise several separate meetings and receive feedback individually rather than from the group.

One strength of the PI proposal was the provision of a training day. Although several dates were offered to participants a date could not be found where more than one person could attend at once. A pragmatic approach was taken to deliver the training individually. This meant that the training could be tailored to individual needs which was required as there was a range of experience from 'never participated in a group like this' to 'experienced retired researcher'. All members contributed ideas, and we do not know whether these would have been better developed as a group. However, we also recognise that as this is a sensitive matter group work could have also inhibited open expression of ideas and opinions.

One member expressed their disappointment at receiving an Amazon voucher as they did not feel that the company aligned with their social ideologies. In future, we will offer options for vouchers to overcome this. Members were encouraged to claim for travel but often chose not to. All welcomed refreshments and food although there did appear to be some awkwardness at receiving the vouchers. I interpreted this as undoing the feeling that they were contributing because they wanted to/believed in the project. Conversely, I noted all members were very busy and fitting this activity into busy schedules. When I presented the idea that this was a small gift for the time given, they agreed that I should apply for further funds for continued involvement but would be happy to accept less or no gift. The provision of food/refreshments was gratefully received, and I personally

felt that the idea of 'sharing of a meal' made members feel more relaxed particularly around this sensitive area.

Three members were very actively engaged in the project and very responsive. One member was less active and did not complete all the requested activities.

Outcome of award

We are one of 6 applicants to be shortlisted during the first stage of the selection process. The second stage involved an interview in London on the 25th of March 2020 and we expect to hear the outcome by April 2020.

Costs/Spend

Item	Budget	Actual spend
Amazon vouchers (£65 in total per participant)	£260	£260
Food and refreshments	£160	£143.3
Travel	£80	£16
Total	£500	£419.30