FULL/LONG TITLE OF THE STUDY

Understanding factors which affect willingness to self-manage a pessary for pelvic organ prolapse: A mixed methods study aiming to improve access to pessary self-management.

SHORT STUDY TITLE / ACRONYM

What affects willingness to self-manage a pessary?

PROTOCOL VERSION NUMBER AND DATE Version 1.10 04/08/22

IRAS Number: 304120

Sponsor's Number: B01328

Sponsor: Manchester University NHS Foundation Trust

Funder: Health Education England (HEE) / National Institute for Health Research (NIHR) NIHR300519

This project will be conducted in accordance with the study protocol and the ethical principles outlined by Good Clinical Practice (GCP) and the Declaration of Helsinki in its most current version

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), amended regulations (SI 2006/1928) and any subsequent amendments of the clinical trial regulations, GCP guidelines, the Sponsor's (and any other relevant) SOPs, and other regulatory requirements as amended.

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 clinical investigation without the prior written consent of the Sponsor

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

For and on behalf of the Trial Sponsor:

Signature: Date:

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

Name (please print):

Position:

Chief Investigator:

Signature: Date:

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

Name: Lucy Dwyer

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Funder(s)	Lucy Dwyer, Clinical Doctoral Research Fellow, NIHR300519 is funded by Health Education England (HEE) / National Institute for Health Research (NIHR) for this research project

i. LIST of CONTENTS

Contents

iii. TRIAL SUMMARY

Trial Title	Understanding factors which affect willingness to self-manage a pessary for pelvic organ prolapse: A mixed methods study aiming to improve access to pessary self-management.
Internal ref. no. (or short title)	B01328 What affects willingness to self-manage a pessary?
Trial Design	Mixed methods
Trial Participants	
Quantitative phase	Pessary using women at Manchester University NHS Foundation Trust
Qualitative phase	Pessary using women at Manchester University NHS Foundation Trust
Intervention development group	Pessary using women identified via the Royal College of Obstetricians and Gynaecologists (RCOG) Women's voices group Pessary practitioners
Expert review	Members of UK Clinical Guideline: for best practice in the use of vaginal pessaries for pelvic organ prolapse committee
Pilot	Pessary using women at Manchester University NHS Foundation Trust who do not have experience self-managing their pessary
Planned Sample Size	
Quantitative phase	90 pessary using women
Qualitative phase	10-15 pessary using women
Intervention development group	A combination of 10-17 pessary using women and pessary practitioners
Expert review	Sent to all UK pessary guidelines group committee members

Pilot	5-10 pessary using women
Duration	
18 months	
Research objectives	• To explore how the lived experience of being a woman affecting willingness to self-manage a pessary for pelvic organ prolapse • To co-create an intervention to better support women to feel willing and able to self-manage their pessary

iv. FUNDING AND SUPPORT IN KIND

FUNDER(S)	**FINANCIAL AND NON FINANCIAL SUPPORT GIVEN**
Health Education England (HEE) / National Institute for Health Research (NIHR)	Lucy Dwyer, Clinical Doctoral Research Fellow, NIHR300519 is funded by Health Education England (HEE) / National Institute for Health Research (NIHR) for this research project

v. ROLE OF TRIAL SPONSOR

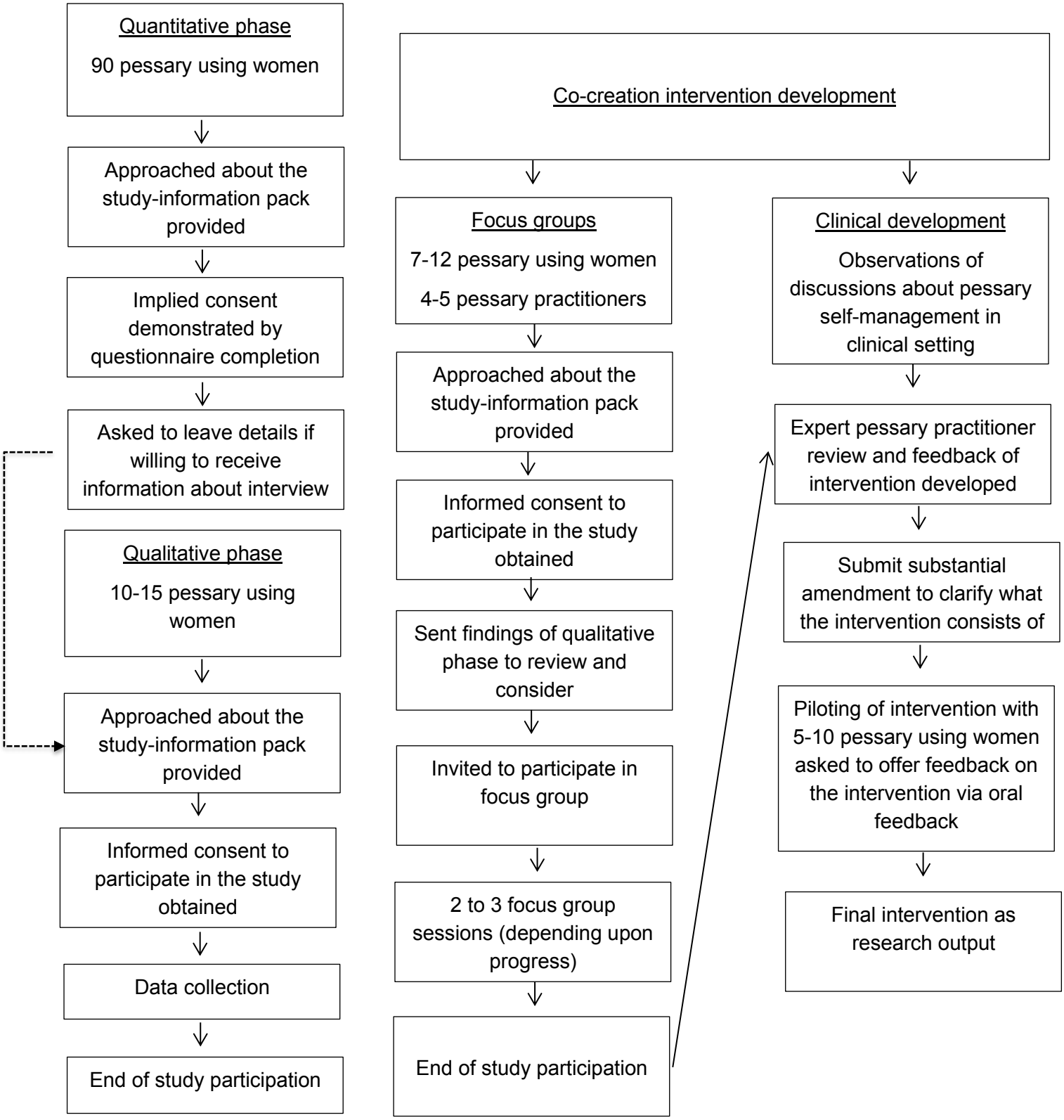
Manchester University NHS Foundation Trust are the sponsor and therefore assume overall responsibility for the initiation and management of the research. The sponsor will undertake this role through:

- Undertaking proportionate peer review of the proposed study
- Reviewing and ensuring all appropriate, valid supporting documentation is supplied to the necessary approval bodies at the point of application
- Ensuring the division of roles and responsibilities are clearly defined and signed off prior to the study commencing

- Undertaking the appropriate level of monitoring and audit proportionate to the study and ensuring the necessary level of oversight throughout the life cycle of the study
- Ensuring an agreed risk assessment process is in place to identify any potential risks to the organisation or the health, safety and well-being of researchers and research participants
- Ensuring that patients and/or public have been involved in study design
- Ensuring the CI has the relevant experience and appropriate training to fulfil their role
- Ensuring the study is registered on an accessible database
- Ensuring all findings are disseminated/published in an appropriate manner and intentions are made clear at the time of application

vi. KEY WORDS: Self-management, Self-care, Prolapse, Pessary, Willingness

vii. TRIAL FLOW CHART



1. BACKGROUND

There is a lack of evidence regarding factors which affect willingness to self-manage a pessary, including which are significant and whether this differs between women. Understanding these factors will enable development of resources to help women self-manage their care. Women should have the option of clinician-led care or self-management of their pessary. However, self-management of a pessary is discussed with women much less frequently in the UK than other countries, the reasons for this are unclear (Dwyer et al, 2022). Many factors which affect willingness to self-manage could potentially be overcome with tailored support, education and helping women to change perceptions. While patients should not be forced to self-manage, nurses have a duty to facilitate individuals to self-manage their health and enable this as far as possible (Nursing and Midwifery Council, 2018). Patients with other long-term health conditions such as diabetes or asthma receive support and education to ensure they are motivated and confident to take responsibility for their health (Barlow et al., 2002). This support is not currently available for pessary users.

Pelvic Organ Prolapse (POP) is downward displacement of the uterus, vaginal compartments and/or their neighbouring organs (Haylen et al., 2016). Pelvic organs are supported by pelvic floor muscles and weakness in these muscles may result in POP (Schaffer et al., 2005). While not life threatening, POP can severely impact upon a woman's quality of life through bowel or bladder symptoms, discomfort, impact upon self-image and sexual dysfunction (Haylen et al., 2016). The lifetime risk of a parous woman having POP surgery in the UK is 10% (Abdel-Fattah et al., 2011).

Surgical management of POP is an option, however some women wish to avoid or delay surgery and others may not be medically fit (Gorti et al., 2009). For these women, mechanical support of POP through by a vaginal pessary provides alternative, effective management (Cundiff, 2000). There are various types of pessaries available, with size and style being the main factors for the clinician to consider (Atnip, 2009). Pessaries can be categorised as a support pessary (ring) or a space filling pessary (Gellhorns or Cube) (Thakar and Stanton, 2002). Standard pessary follow-up tends to be biannual (Gorti et al., 2009), requiring significant healthcare resources as well as being burdensome

for women (Kearney and Brown, 2014). Regular long-term follow-up may be the reason some women opt for surgery (Kearney and Brown, 2014). Pessary follow-up entails removal of the pessary, and speculum examination of vaginal tissue to ensure the pessary has not caused damage.

Pessary self-management is the woman's ability to remove and reinsert their pessary. In addition to potentially reducing the burden of attending as many hospital appointments, self-management offers women autonomy regarding how to use a pessary.

Through in-depth interviews with pessary using women, this study aims to develop greater understanding of the lived experience of being a woman and how this may affect willingness to self-manage a pessary for prolapse. Utilising these findings, pessary using women and pessary practitioners will co-create an intervention to better support women to overcome barriers to pessary self-management.

2. RATIONALE

A scoping review undertaken by the chief investigator (Dwyer et al, 2022) suggests pessary self-management offers benefits to some women (Kearney and Brown, 2014, Hanson et al., 2006) with no increased risk of complications (Manchana, 2011, Lammers et al., 2019, Daneel et al., 2016, Morcuende et al., 2018, Holubyeva et al., 2021). It is clear some women do not feel willing or able to self-manage their pessary (Clemons et al., 2004a, Clemons et al., 2004b, Chen et al., 2020, Storey et al., 2009, Jacobs and Banks, 2010, Murray et al., 2017, Chan et al., 2019, Tam et al., 2019, Holubyeva et al., 2021, Wu et al., 1997, Ramsay et al., 2011, Manchana, 2011, Nemeth et al., 2013, Kearney and Brown, 2014, Pizarro-Berdichevsky et al., 2016, Daneel et al., 2016, Hooper et al., 2018, Thys et al., 2020, Lammers et al., 2019). However, it is uncertain whether increased support to help women overcome these issues or concerns may address this. The results of the scoping review have demonstrated that there is a lack of understanding about factors that affect willingness to self-manage a pessary other than brief references to physical inability, insufficient confidence and the intimate nature of pessary management requiring a woman to touch their genitals (Dwyer et al,

2022). The scoping review also confirmed there are certain factors which affect the likeliness of pessary self-management. However, it is currently not clear whether these factors increase willingness to self-manage a pessary or instead affect access or ability to self-manage a pessary. This gap in the evidence, and therefore our understanding of willingness to self-manage a pessary prevents pessary practitioners from better supporting women to overcome these barriers to self-management. Therefore, in-depth exploration of factors that affect willingness to self-manage a pessary is required. It may also be necessary to determine the barriers most frequently reported by women, in order to prioritise where to focus additional support or interventions to help women overcome perceived barriers, with the aim of increasing, and ensuring, equitable access to pessary self-management.

3. OBJECTIVES

3.1 Research aims

- 1. To gain a deeper understanding of factors affecting a woman's willingness to self-manage a pessary for POP
- 2. To explore how the lived experience of being a woman may impact willingness to self-manage a pessary for POP
- 3. To use these findings to better support women to self-manage a pessary for POP

3.2 Research objectives

- 1. To conduct in-depth interviews with pessary using women to gain a deeper understanding of factors which affect their willingness to self-manage a pessary for POP
- 2. To co-create an intervention to support self-management of a pessary for POP

3.3 Hypothesis

The lived experience of being a woman affects how willing women are to self-manage a pessary for pelvic organ prolapse.

4. METHODOLOGY

This study consists of three phases; firstly data gathering to explore the lived experience of pessary using women and how this may affect willingness to self-manage a pessary for POP; secondly co-creation of an intervention to support women to self-manage a pessary for POP and thirdly piloting the intervention to assess the clinical feasibility and utility of it. Women will be recruited from pessary clinics in the women's outpatient department at Manchester University NHS Foundation Trust for the first and third phase. For the co-creation phase, pessary using women and pessary practitioners will be identified by the Royal College of Obstetricians and Gynaecologists (RCOG) Women's Network Co-ordinator who will approach pessary using women who are members of the RCOG Women's Voice's Network. The RCOG Women's Voices Network is a group of over 600 women with personal experience of women's health issues who are willing to be approached about involvement in research. The maximum total sample size is 132 women though this may reduce depending upon data saturation.

4.1. Mixed methods methodology

Utilising a mixture of both qualitative and quantitative research through triangulation offers the opportunity to collaborate, elaborate or initiate findings (Rossman and Wilson, 1985). Collaboration refers to the convergence of findings collected via different methodological approaches to test reliability, elaboration is the generation of rich data to expand upon initial findings and initiation, the provocation of further thinking and questioning of findings (Rossman and Wilson, 1985). A mixed methods approach has been chosen to explore the factors which affect willingness to self-manage a pessary for POP with the aim of collecting rich accounts of women's lived experience of being a woman and how that affects their using a pessary for pelvic organ prolapse and their thoughts and experiences of pessary self-management. An explanatory mixed methods approach will enable the researcher to collect data from a large group of pessary using women which can be analysed to explore whether demographics, patient characteristics or self-image of the genitals is correlated with willingness to self-manage a pessary for prolapse. The findings of the quantitative phase will inform the qualitative phases by providing details about a group of women of varying characteristics and opinions about self-management who can then be sampled for the interviews to ensure stratified random sampling. Furthermore, findings of the quantitative phase which affect willingness to self-manage a pessary can be explored in greater detail during interviews as part of the qualitative phase. For example, if it is identified that

older women completing the questionnaire are less likely to be willing to self-manage their pessary, this will inform the questions to be asked. Moreover, offering women who may not feel comfortable being interviewed the opportunity to participate if they wish, by completing an anonymous questionnaire ensures different levels of involvement are possible. Furthermore, establishing whether female genital self-image, which can be reliably determined using a four-item questionnaire, is correlated with willingness to self-manage a pessary, may have clinical utility as it may help clinicians to target the intervention we plan to develop at those who are most likely to benefit from it.

4.1.1 Quantitative methodology

The Quantitative phase will be a simple cross-sectional descriptive design with the aim of collecting descriptive data about pessary using women's attitudes towards pessary self-management and establishing whether there appears to be a relationship between that and demographics, patient characteristics or self-image related specifically to their genitals (Gray and Grove, 2021).

4.1.2 Qualitative methodology

Qualitative methodology underpinned by phenomenology and an embodied enquiry approach to collect data will be used. Phenomenology offers a comprehensive insight into the nature, structures and meaning of the lived experience (Zeiler and Käll Folkmarson, 2014, Gray and Grove, 2021). A phenomenological approach takes into consideration environmental influences and the meaning which individuals have made from these external influences which have shaped our actions, beliefs and relationships (Gray and Grove, 2021). This research aims to generate rich accounts of the phenomenon of pessary self-management by developing understanding of the lived experiences of pessary using women and how past experiences have influenced their decision making about pessary self-management. Therefore, a phenomenological methodology is suitable for the purpose of this research (Smith and Shinebourne, 2012).

Philosophical approaches to the analysis of phenomenological research can be defined as either descriptive or interpretative (Matua and Van Der Wal, 2015). A descriptive phenomenological

approach aims to describe a phenomenon from the perspective of experts living it, avoiding any influence from the researcher who must disregard any prior opinions, views or experience (Matua and Van Der Wal, 2015). An interpretive approach to phenomenology aims to gain understanding or meaning from the experiences described my experts living the phenomenon (Matua and Van Der Wal, 2015). Interpretative phenomenologists acknowledge that the researcher's opinions and perspectives may influence interpretation of findings, but argue it is not possible to 'unknow'. Therefore, it is proposed instead that researchers record their opinions, views and perspectives and how these change during the course of data collection and analysis, via a reflexive diary (Engward and Goldspink, 2020). An interpretive phenomenological approach is suitable for this research proposal as it aims to develop an understanding of how the lived experience of being a woman influences willingness to self-manage a pessary, therefore requiring interpretation of the meaning of being a woman from the data collected in interviews (Matua and Van Der Wal, 2015).

A feminist approach to phenomenological research has previously been utilised to provide detailed description of uniquely female experiences (Zeiler and Käll Folkmarson, 2014). A feminist approach to phenomenological research ensures a focus on women's' perceptions and experiences of sexuality, power relations, privilege, social norms, cultural practices, bodies and desires in a society shaped by men (Zeiler and Käll Folkmarson, 2014). POP, pessary management and self-management of a pessary for POP are uniquely female experiences.

Embodied inquiry is a research approach which promotes the use of different and creative methods to gain greater insight into embodied, lived experience (Leigh and Brown, 2021). Embodied inquiry is suitable where the human body is central and integral to the research question, or where verbal communication may be insufficient to fully explore an issue (Leigh and Brown, 2021). An embodied inquiry approach facilitates the gathering of data which cannot be expressed using words using art-based, dramatic or physical methods (Leigh and Brown, 2021).

Therefore, a feminist phenomenological methodology with an embodied inquiry approach will consider sociological, cultural and historical influences upon women and how this influences willingness to self-manage a pessary. Feminist phenomenology will be used to ensure qualitative data collected provides in-depth understanding of the lived experience of women and how this may affect their willingness to self-manage a pessary.

4.2 Intervention development methodology

Following data collection, the project will proceed to the development of an intervention to meet the needs of pessary using women approached about self-management, to support them to overcome barriers they experience. A three stage intervention co-production framework (Hawkins et al., 2017), Medical Research Council (MRC) complex intervention development guidelines (Skivington et al., 2021) and Normalisation Process Theory (NPT) theory (Murray et al., 2010) will be utilised to inform and guide the process.

The first stage requires a review of relevant evidence and stakeholder consultation (Hawkins et al., 2017). Therefore, relevant literature and data collected in the qualitative phase will provide required evidence of the problem and target population. Depending on what the factors are that have been identified by women as potentially supporting or enabling them to self-manage their pessary, pessary using women will be asked to consider the types of intervention or support which may be most helpful. Furthermore, as advocated by Hawkins et al. (2017) observations of current practice in discussing pessary self-management will be undertaken to identify what support is currently being offered and how it is received and responded to by women.

In the second stage where the intervention will be co-created, an intervention development group will be established consisting of members of the research team and key stakeholders. Over a series of meetings the intervention development group will use an action research cycle approach of assessing the findings of stage one, asking members of the group to propose ideas of how pessary using women can be better supported to overcome barriers to willingness to self-manage, seeking feedback on

ideas, refining proposed ideas and gaining feedback again (Hawkins et al., 2017). Once the group are satisfied with the proposed support intervention, the development process will move to the final stage of prototyping (Hawkins et al., 2017). In this stage, expert pessary practitioners will be asked to review and provide feedback on the content and delivery of the proposed intervention as well as any associated documents. To test the intervention, it will be piloted amongst a small number of pessary using women to ensure usability, feasibility and obtain any further feedback about intervention delivery in a real world setting.

5. QUANTITATIVE PHASE STUDY DESIGN

5.1 Quantitative phase setting

Women will be recruited from the pessary clinic at Manchester University NHS Foundation Trust and if willing to participate will be asked to complete a short questionnaire either in the hospital waiting room, or at home to return via post if preferred.

5.2 Quantitative phase inclusion criteria

- Willing and able to give implied consent by completion of the questionnaire
- Female
- Over the age of 18 years
- Have retained a pessary for pelvic organ prolapse for a minimum of two weeks
- Able to speak and understand English
- Use a ring, shaatz, cube or inflatable pessary

5.3 Quantitative phase exclusion criteria

- Lacking capacity to give implied consent by completion of the questionnaire
- Has a first or preferred language that is not English
- Use a shelf, gell-horn or donut pessary

The convenience sample of women will be pessary using women who are attending a pessary clinic appointment in the women's outpatient department at Manchester University NHS Foundation Trust. While the limitations of a convenience sample are recognised, because such a large number of women attend the pessary clinic each week, it is anticipated that characteristics which may impact upon willingness to self-manage a pessary as identified in the scoping review such as pessary type, age, menopausal status, level of education, being sexually active, experience of pessary management and health status (Dwyer et al, 2022) will be represented within the sample (Gray and Grove, 2021).

5.4 Quantitative phase participant identification

The study will be introduced to women receiving pessary management for a prolapse in the women's outpatient department at Manchester University NHS Foundation Trust. Upon checking in for the clinic at the reception desk women will be given an information pack which explains the study.

5.5 Quantitative phase consent

For the quantitative phase, informed consent to participate will be indicated by completion of the questionnaire. The questionnaire does not require participants to provide any identifiable information unless they would be willing to receive further information about the qualitative phase. Should women wish to discuss any aspect of participation, before or after completing the questionnaire, they will be provided with the chief investigator's contact details or can speak with a member of the clinical team in the department. A participant information sheet reviewed by the Sponsor, REC and HRA will be given and read by all participants before they choose whether to complete the questionnaire.

5.6 Quantitative phase payment/reimbursement

There will be no payment or reimbursement for participation in the quantitative phase due to the short amount of time it is anticipated that completion of the questionnaire will take and the fact that it will be completed by women already attending the hospital. Therefore, no inconvenience will be experienced by the woman having to travel to the hospital. Should women wish to complete the

questionnaire at home and return it via post, they will be given a stamped addressed envelope to ensure they incur no costs as a result of study participation.

5.7 Quantitative baseline data

Descriptive data about the women who are participating in the research will be collected by the researcher from the woman and recorded on a paper case report form.

- Year of birth
- Length of time pessary used for
- Type and size of pessary in situ
- Comorbidities
- Self-management status
- Self-management experience
- Self-management willingness
- Ethnicity
- Post code
- Level of education
- Female Genital Self-Image Score (FGSIS)

5.8 Quantitative phase data collection

Data collection will be completion of a questionnaire which requests information about the woman's demographics, pessary use, self-management experience, willingness to self-manage and a free text box to express thoughts about pessary self-management. Women will also be asked to complete the Female Genital Self-Image Scale (FGSIS-4), a reliable and validated 4-item questionnaire which measures women's attitude and beliefs about their genitals (Herbenick and Reece, 2010).

5.9 Quantitative phase sample size

The distribution between willingness to self-manage a pessary and FGSIS-4 has not yet been established. Therefore, based upon statistical advice we have calculated the sample size for a medium effect size of 0.3, for a chi squared test on a two by two table (self-management vs FGSIS). With 5% significance level a sample of 90 will have 80% power to detect a medium effect size of 0.3 (Cohen, 1988). Therefore, based upon this, we aim to recruit 90 women to the quantitative phase.

5.10 Quantitative phase data analysis

Data collected in the questionnaires will be analysed to provide descriptive statistics about the women who have completed the questionnaire, their experience of self-management and willingness to be interviewed in the qualitative phase. Free text data will also be analysed for the emergence of themes and coded to explore whether there are any patterns that emerge between women of similar characteristics with regards to willingness, or not, to self-manage a pessary. Statistical analysis will be performed by a statistician to test for correlation between demographics, patient characteristics and FGSIS-4 scores and willingness to self-manage a pessary for prolapse. Scores in the FGSIS-4 range between 4-16, with a mean score of 12 in a nationally representative population of over 2000 American women (Herbenick et al., 2011). Herbenick et al. (2011) have not determined a binary score for high and low FGSIS, however for the purpose of this study, a score of eight or less will indicate low FGSI, whereas more than eight will indicate high FGSI. To score eight or less, a participant must disagree with all four statements describing genital self-image therefore this is deemed to accurately represent FGSIS-4.

5.11 Quantitative phase outputs

The output from the quantitative phase will be summary of the women who participated in the quantitative phase, their experience and opinions about pessary self-management and the results of the FGSIS. The findings will also inform sampling for the qualitative phase, as the chief investigator will ensure a stratified sample based upon characteristics, opinions and experience of pessary self-management as well as the FGSIS score. This will ensure the sample in the qualitative phase will be

representative and provide rich data. Collecting quantitative data from women who are not willing to be interviewed about their beliefs ensures these women have the opportunity to express their thoughts and opinions about pessary self-management.

6. QUALITATIVE PHASE STUDY DESIGN

6.1 Qualitative phase setting

Women will be recruited from the pessary clinic at Manchester University NHS Foundation Trust and interviewed in person either at the hospital or an alternative venue if preferred, or via video consultation using the 'Attend anywhere' secure technology utilised at Manchester University NHS Foundation Trust for clinical appointments.

6.2 Qualitative phase inclusion criteria

- Willing and able to give informed consent
- Female
- Over the age of 18 years
- Have retained a pessary for pelvic organ prolapse for a minimum of two weeks
- Able to speak and understand English or, for those whose first or preferred language is a language other than English, speak a language with an available interpreter

6.3 Qualitative phase exclusion criteria

- Lacking capacity to give informed consent
- Has a first or preferred language that is not English, or a language without an available interpreter

The criterion sample of women will be pessary using women who receive pessary care at the women's outpatient department at Manchester University NHS Foundation Trust. In order to ensure a rigorous approach to sampling, criterion sampling will be used whereby all women will have a shared experience of the phenomena of using a pessary (Gray and Grove, 2021). However, to ensure

a stratified sample, women who have certain characteristics of interest identified during the quantitative phase (for example age, high or low FGSIS scores) and indicated a willingness to receive information about the qualitative interviews will be sent information about the qualitative phase to consider.

6.4 Qualitative phase participant identification

The study will be introduced to women receiving pessary management for a prolapse in the women's outpatient department at Manchester University NHS Foundation Trust. If identified while attending the hospital, a clinician will approach the woman and give them an information pack. The CI will also identify women for study participation by screening MFT pessary clinic lists or who have expressed willingness to receive information about the qualitative phase when participating in the quantitative phase. In this instance the study information pack will be posted out to these women by the chief investigator. Following receipt of the information, the woman will be asked to confirm willingness to be interviewed by the investigator by completing and returning an expression of interest form. The investigator will then arrange an appointment for the woman at a convenient time. For women who require a language interpreter, the interview will need to be conducted at MFT to ensure access to the hospital interpretation service, or via video consultation.

6.5 Qualitative phase consent

For the qualitative phase, informed consent will be obtained by the chief investigator. The chief investigator will have completed recent Good Clinical Practice training as per the Sponsor's requirements. During the informed consent process, a discussion will take place between the potential participant and the chief investigator about the research, the nature and objectives of the study and possible risks associated with their participation. Potential participants will also be given the opportunity to ask any questions they have. A participant information sheet reviewed by the Sponsor, REC and HRA will be given and read by all participants before written informed consent is obtained. Capacity to give informed consent will be assessed by a member of the research team in accordance with training to assess capacity provided by the sponsor. For women who choose to have

a face to face interview, informed consent will be obtained via a paper consent form. For women who prefer to have their interview conducted remotely via 'attend anywhere', the informed consent process and verbal consent will be video recorded following permission from the woman prior to the call. The consent to record will be confirmed before and after pressing Record. The video recording will be stored securely on the chief investigator's password protected account on the MFT NHS hospital server. The chief investigator will obtain recorded verbal agreement to each point on the consent form. Remote participation in the interview also acts as confirmation that the participant is willing to continue in this way. Following the informed consent process, the video recording will be stopped and the audio recording commenced. The video recording of confirmation will be emailed securely to each participant. If the recording is lost or fails, the woman will be contacted again and asked to sign a paper consent form either in person (if preferred), or via post, in which case a consent form will be posted to her with a stamped, addressed envelope. If returned via post, the consent form will be signed by the researcher upon receiving the consent form signed by the woman. The consent date for the researcher will be the date the form is received in the post. The consent process, whether face to face or during video consultation as well as any need to re-consent will be documented in the woman's hospital records.

6.6 Qualitative phase payment/reimbursement

- £10 shopping voucher following interview
- £10 shopping voucher upon receipt of a photograph or presentation of participant's identity box

  Maximum total £20

6.7 Baseline data

Descriptive data about the women who are participating in the research will be collected by the researcher from the woman or medical records if necessary (for example if a woman isn't sure of the type or size of her pessary) and recorded on a paper case report form). Should the woman have

previously completed a questionnaire in the quantitative phase, this data will be verified with the woman, but will not need to be collected again if still correct.

- Year of birth
- Length of time pessary used for
- Type and size of pessary in situ
- Comorbidities
- Self-management status
- Self-management experience
- Self-management willingness
- Ethnicity
- Post code
- Level of education
- Female Genital Self-Image Score (FGSIS)

6.8 Qualitative phase data collection

Data collection will be via semi-structured interviews. An interview guide will be used to structure the interviews. This guide has been developed based upon findings of a scoping review and systematic review undertaken by the chief investigator in addition to wider reading of similar studies exploring the lived experience of being a woman from a feminist perspective. The interviews will be conducted by the chief investigator either in person or via video consultation depending upon the participants' preference. The interviews will be audio recorded, anonymised and transferred to a professional transcription service by their encrypted file transfer page. Upon receipt by the professional transcription service, the audio recording will be transcribed verbatim then returned to the researcher for coding. The chief investigator will also make field notes recording observations, emerging themes and concepts, methodological issues and a summary of the data collected and how this contributes towards research findings (Groenewald, 2004).

An embodied enquiry approach will also be utilised whereby data will also be gathered by asking participants to collect an identity box prior to the interview which reflects their physical, psychological and emotional experiences of having prolapse, using a pessary or self-management of a pessary. Women will be asked not to include any items which would identify themselves or anyone else for, example by including personal photos or using names. The women will be asked to take a photograph of the identity box or bring the identity box to the interview if preferable and convenient in which case the researcher will take a photograph of the identity box. The researcher will engage the woman in discussion about the contents of their identity box to ensure understanding of how the items reflect their lived experience. Photographs of the identity boxes will be used in the dissemination of findings to further illustrate women's physical, psychological and emotional experiences which cannot be explained using spoken word.

6.9 Qualitative phase sample size

Phenomenological research typically requires a sample size of less than ten prior to data saturation (Moser and Korstjens, 2018). Therefore, a provisional sample size of 10-15 women has been established with awareness that this may be reduced or increased depending upon informational redundancy. Consensus will be sought from the supervisory team and pessary user members of the project management group to ensure all agree saturation of data has occurred and that the themes identified accurately reflect the lived experience of pessary users.

6.10 Qualitative phase data analysis

The process of making field notes represents the commencement of data analysis, as reflecting upon the data collected, the meaning derived from this, how it directs future data collection and fits with previous data collected is analysis (Groenewald, 2004). Formal analysis of the collected data will be undertaken using an interpretive phenomenological approach described by Smith and Shinebourne (2012). The first step is becoming immersed in the interview transcript to ensure familiarity with the findings, making notes and annotations as required (Smith and Shinebourne, 2012). After this, the transcript will be re-read and emerging themes noted (Smith and Shinebourne, 2012). The next stage

is to look for connections between the themes identified within the transcript and create clusters while constantly referring to the original transcript to verify interpretations being made (Smith and Shinebourne, 2012). The final stage of transcript analysis is to create a table of themes, structured to prioritise themes rich in evidence and which accurately reflect the interview (Smith and Shinebourne, 2012). Clusters will be renamed to reflect the superordinate and subordinate themes recorded within them (Smith and Shinebourne, 2012). The step by step process will be utilised for the analysis of further transcripts, however the researcher will use the analysis of prior transcripts to examine whether there are similarities and differences in the data gathered from women (Smith and Shinebourne, 2012). Once each transcript has been analysed, a master table of superordinate and subordinate themes identified within the whole data set will be created (Smith and Shinebourne, 2012). Smith and Shinebourne (2012) clarify that themes should be included and prioritised within the table based upon the richness of data supporting the theme and how accurately it reflects the accounts given by participants rather than the frequency of which they are identified. In accordance with the feminist approach the chief investigator will consider whether the themes identified represent gender differences or power imbalances acknowledging the structural implications of society, culture and politics for being a woman (Clifford et al., 2019).

6.11 Qualitative phase outputs

The output from the qualitative phase will be rich accounts of the lived experience of being a woman and how this has influenced willingness to self-manage a pessary for POP, a list of factors that affect willingness to self-manage a pessary identified within the rich data and photograph images of the identity boxes with a text description of the items included and the meaning placed upon these items by women.

7. INTERVENTION DEVELOPMENT PHASE STUDY DESIGN

7.1 Intervention development phase setting

The intervention will be co-created by pessary using women and pessary practitioners. Intervention development meetings will be held virtually to facilitate attendance without travel, minimising inconvenience to attendees.

7.2 Intervention development phase inclusion criteria

Pessary using women

- Willing and able to give informed consent
- Female
- Over the age of 18 years
- Have retained a pessary for pelvic organ prolapse for a minimum of two weeks
- Able to speak and understand English

Pessary practitioners

- Willing and able to give informed consent
- Provide regular pessary care as part of clinical role (defined as insertion or removal of a woman's pessary on a minimum of a monthly basis)
- Able to speak and understand English

7.3 Intervention development phase exclusion criteria

Pessary using women

- Lacking capacity to give informed consent
- Does not speak or understand English

Pessary practitioners

- Lacking capacity to give informed consent
- Does not speak or understand English

- Does not provide pessary care at a minimum of a monthly basis

A purposive sample of pessary practitioners will be identified by the chief investigator taking into account different professions, pessary practitioner experience, different types of care settings and other factors which may influence their opinions of pessary practice and pessary self-management.

7.4 Intervention development phase participant identification

The RCOG's Women's Network have agreed to support identification of pessary using women from members of their organisation using their social media accounts on Instagram, Facebook, Twitter, in addition to email contacts of women who have previously expressed an interest in being informed of involvement opportunities and given permission to be contacted with information about upcoming projects. Standard text which has been developed by the chief investigator and the RCOG Patient and Public Involvement manager will be shared via email distribution to the Women's network members who have previously consented to receiving such communications. The standard text will also be shared via posts on the RCOG's Instagram, Facebook, Twitter accounts.

Potential pessary practitioner participants will be identified by asking specialist organisations in Urogynaecology such as the RCOG and British Society of Urogynaecology to share an invitation letter via email with their members.

7.5 Intervention development phase payment/reimbursement for pessary using women

- £110 per meeting attended (costed at half a day in accordance with INVOLVE guidelines to allow for time to prepare for the meeting)
  Maximum total £330 per pessary using woman participant

7.6 Intervention development phase consent

For the intervention development phase, prior to the first meeting, all potential participants will be provided with an information sheet containing details of the co-creation process to ensure they are

able to make an informed decision. The chief investigator's contact details will be included to enable potential participants to ask any questions they might have. Before the first intervention development meeting, the chief investigator will arrange to conduct a video consultation with each participant using 'attend anywhere' to obtain informed consent. Following discussion of the study and the opportunity to ask any questions, the participant will be asked to confirm verbal consent which will be video recorded following permission from the participant at the start of the call. The video recording will be stored securely on the chief investigator's password protected account on the MFT NHS hospital server. Following the informed consent process, the video recording will be stopped. If the recording is lost or fails, the woman will be contacted again and asked to sign a paper consent form and return it via the post in the a stamped, addressed envelope provided. The consent form will be signed by the researcher upon receiving the consent form signed by the woman. The consent date for the researcher will be the date the form is received in the post. It is not deemed necessary to reobtain consent prior to each subsequent meeting as the consent will cover research participation in its entirety. However, at the start of each meeting, the facilitator will remind attendees of important aspects of the meeting such as confidentiality and anonymity, as well as the importance of respecting and valuing everyone's contributions to the meeting to ensure enduring consent.

7.7 Intervention development phase data collection

Descriptive data about the pessary using women and pessary practitioners who are participating in the research will be collected from the woman or pessary practitioner by the chief investigator completing a short questionnaire during the pre-meeting video consultation following informed consent being obtained.

Data which will be collected from participants via the questionnaire includes the following information:

Pessary using women

- Year of birth
- Length of time pessary used for
- Type and size of pessary used (if known)

- Self-management status
- Ethnicity
- First or preferred language
- Post code
- Level of education

Pessary practitioners

- Year of birth
- Ethnicity
- Profession
- Grade
- Length of time providing pessary care
- Experience providing pessary self-management support

The intervention development meetings will be audio recorded and field notes taken as required. The audio recording will be transferred to a professional transcription service by uploading the file on to their encrypted file transfer page. Upon receipt by the professional transcription service, the audio recording will be transcribed verbatim then returned to the researcher for analysis.

7.8 Intervention development sample size

A sample size of between five and ten pessary using women, two additional pessary using women who are members of the project steering committee and three to five pessary practitioners has been decided upon based upon an informal review of similar intervention development processes. To ensure there are a sufficient number of attendees at each meeting, the required number of participants has been increased to create a range of participants. By approaching more potential participants than required, it is hoped that even with attrition, there will be a large enough number of attendees at each meeting.

7.9 Intervention development data analysis

Baseline data of the pessary using women and pessary practitioners co-creating the intervention will be analysed to provide descriptive statistics of the population. The transcript of the intervention development meetings will be reviewed and reported to describe the iterative process of intervention development. Field notes made while observing discussions about pessary self-management in clinical practice will also be analysed thematically to identify recurring themes in the way pessary self-management is discussed.

7.10 Intervention development observation

To develop an understanding of conversations between pessary using women and pessary practitioners, the chief investigator will observe several pessary clinics in the women's outpatient department at Manchester University NHS Foundation Trust. While the chief investigator is a member of the clinical team who delivers pessary care here, due to her interest in pessary self-management she recognises that her clinical experience may not accurately reflect pessary using women and pessary practitioners typical conversations. Therefore, in order to bring this experience to the co-creation process the chief investigator will observe pessary clinics with the agreement of pessary using women and the pessary practitioner providing care, making non-identifiable notes until she deems she has gained sufficient understanding and no further points of interest arise. The types of questions or concerns pessary using women express and the ways these are discussed by pessary practitioners will be relayed during the intervention development meetings to ensure the process is informed by real world data. In the instance of observing any poor practice, the chief investigator will use her nursing experience including being a qualified mentor, to address the situation appropriately, either immediately or following the consultation depending upon the urgency of the issue. Should the practice be sufficiently concerning, the practitioner's line manager will be informed in accordance with the MFT 'Raising Concerns at Work and Whistleblowing Policy'.

8. INTERVENTION PILOT PHASE STUDY DESIGN

8.1 Intervention pilot phase setting

Women will be recruited from the pessary clinic at Manchester University NHS Foundation Trust and if willing to participate, following their appointment would be asked to review the intervention and provide feedback via questionnaire or verbally at that time, or an appointment can be made for a later date if preferable.

8.2 Pilot phase inclusion criteria

- Willing and able to give informed consent, review the intervention and provide written and/or verbal feedback.
- Female
- Over the age of 18 years
- Have retained a pessary for pelvic organ prolapse for a minimum of two weeks
- Able to speak and understand English
- Have no previous experience self-managing a pessary (defined as never having removed or inserted their pessary, or received any pessary self-management teaching or support from a healthcare professional)

8.3 Intervention pilot exclusion criteria

- Lacking capacity to give informed consent, review the intervention and provide written and/or verbal feedback.
- Does not speak or understand English
- Have prior experience self-managing a pessary (defined as previously removing or inserting their pessary, or receiving any pessary self-management teaching or support from a healthcare professional)

For the intervention pilot, potentially eligible women will be given an information sheet explaining what participation in piloting the intervention entails. Informed consent will be obtained face to face

by the chief investigator who will ask participants to sign a written consent form to indicate their willingness to participate in the pilot study.

8.4 Intervention pilot phase data collection

Descriptive data about the women who are participating in the research will be collected by the researcher from the woman or medical records if necessary (for example if a woman isn't sure of the type or size of her pessary).

- Year of birth
- Length of time pessary used for
- Type and size of pessary used (if known)
- Ethnicity
- First or preferred language
- Post code
- Level of education

Once baseline information has been collected from the woman by the chief investigator, the intervention will be provided to the woman and a timer started to record the length of time the intervention is utilised. The woman will be asked to identify any aspects of the intervention which were unclear or confusing (Gray and Grove, 2021). Any additional feedback about the intervention will be recorded in note form by the researcher on the paper case report form.

8.5 Intervention pilot sample size

Five to ten pessary using women identified via the pessary service at MFT will be recruited. Piloting the intervention tool aims to test the feasibility of the intervention, rather than measuring the outcome of it within a generalisable population. Therefore a sample size of five to ten is deemed to be sufficient (Gray and Grove, 2021).

8.6 Intervention pilot data analysis

Baseline data of the group of women in the pilot study will be analysed to provide descriptive statistics of the population. The length of time it took the woman to utilise the intervention will be analysed and provided via descriptive statistics. Notes made about the women's responses regarding whether the intervention was unclear or confusing and any additional feedback will be analysed for recurring themes and presented in text.

9. END OF STUDY

The end of the study is defined as the date the last participant recruited to the intervention pilot phase provides feedback on the intervention.

10. DATA MANAGEMENT

10.1 Data collection tools and source document identification

All members of the research team will comply with the requirements of the Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

- Hard copies of data will be held within a locked cupboard and locked office used by clinical members of the urogynaecology clinical team within Saint Mary's Hospital. Electronic data will be held on the Chief Investigator's personal drive on the secure MFT NHS hospital server.
- Baseline data will be inputted in anonymised format on Excel.
- Interview data will be audio recorded and anonymised with a linked participant identification number prior to transfer to a professional transcription service. The audio file will be saved electronically on the Chief Investigator's personal drive on the secure MFT NHS hospital server. A log containing the linked participant identification number and name will be held on the Chief Investigator's personal drive on the secure MFT NHS hospital server. The audio files will be transferred via upload to the encrypted file transfer

page of a professional transcription service who will be required to sign a confidentiality agreement prior to transfer of data.

- The intervention development meetings will be audio recorded. During the meetings it is likely that the first names of attendees will be used when addressing individuals as part of conversations and discussions. The first name alone will not enable identification of attendees. The audio files will be transferred via upload to the encrypted file transfer page of a professional transcription service who will be required to sign a confidentiality agreement prior to transfer of data. Once the audio recording has been transcribed, names will be removed and replaced with a pseudonym chosen by each participant.
- The transcription service will hold the audio recordings on a secure encrypted database. All recordings and transcriptions will be deleted two weeks after receipt.
- Once the audio recording has been transcribed, names will be removed and replaced with a pseudonym chosen by each participant.
- Access to data will be restricted to the minimum number of individuals necessary for quality control, audit, and analysis as detailed in section 9.2.
- The study data will remain the property of MFT. A complete copy of the study data will be kept on the MFT secure IT server at the end of the study. At the end of the study all documents and data relating to this project will be stored securely at MFT for 5 years following completion of the project, or in line with MFT policies and in accordance with ICH GCP.
- The Chief Investigator will be the custodian for data generated by the study.

10.2 Access to Data

Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections in line with participant consent.

10.3 Archiving

The study data will remain the property of MFT. A complete copy of the study data will be kept on the MFT secure IT server at the end of the study. At the end of the study all documents and data relating to this project will be stored securely at MFT for 5 years following completion of the project, or in line with MFT policies and in accordance with ICH GCP.

11. MONITORING, AUDIT & INSPECTION

The study will be subject to the audit and monitoring regime of Manchester University NHS Foundation Trust in line with applicable MFT SOPs and policies. The study will have, as a minimum, an annual survey sent out for completion by a member of the research team.

12. ETHICAL AND REGULATORY CONSIDERATIONS

12.1 Study approval

NHS Research Ethics Committee (REC) and Health Research Authority (HRA) approval will be obtained prior to the study commencing. As it is unclear what the intervention will consist of, while overarching REC and HRA approval for the pilot phase is being applied for as part of the whole study, a substantial amendment will be submitted once the intervention has been developed but before the pilot phase to enable the REC and HRA teams to review the intervention and understand exactly what participants in the pilot phase are being asked.

All correspondence with the REC and HRA will be retained in the site file. An annual report will be submitted to the REC by the chief investigator until the formal end of the study upon which the Chief investigator will notify the REC accordingly. Within a year of the study ending, the Chief investigator will ensure a final study report is submitted to the REC.

Before the start of the study, a favourable opinion will be sought from an NHS REC for the study and all the supporting documents including the protocol, information sheets, informed consent forms and other

relevant documents. The study team will be responsible for the maintenance of a study site file, in which all current and superseded study documents will be retained. Also contained in the site file will be the approval documentation including correspondence with relevant authorities such as the HRA and REC.

The study team are responsible for producing progress reports throughout the study, including annual reporting (APR) to REC as required. The Chief Investigator will notify the REC of the end of the study, and will submit a final report with the results, including any publications/abstracts, to the REC within 12 months of the end of the study. If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.

No participants will be enrolled into this research study prior to the study being reviewed by the relevant regulatory authorities and receiving HRA and REC approvals, as well as approval from the R&D office at Manchester University NHS Foundation Trust.

12.2 Amendments to the Protocol

Any amendments to the to the study shall be reviewed by the sponsorship team prior to submission. Any non-substantial amendments shall be notified to the HRA and any substantial amendments, along with amended documentation, shall be approved by the REC, and HRA, prior to implementation as per nationally agreed guidelines. The Chief Investigator or designee will work with the R&I department to put the necessary arrangements in place to implement the amendment and to confirm their support for the study as amended.

12.3 Burden

To minimise the burden of study participation, visits will be arranged at the woman's convenience as far as possible. Participation in the qualitative and intervention development phases can be undertaken remotely via video call if preferred by the participant.

12.4 Potential for distress

Due to the topic of the qualitative interviews there is potential for discussions related to body image, touching own genitals and other sensitive issues. This may distress participants. A study distress policy has been developed. The applicant has 11 years' experience working within gynaecology including prior situations where disclosures related to abuse and other sensitive issues have arisen. Using this experience as well as skills and knowledge from relevant training, the applicant will be able to halt an interview if necessary and provide appropriate support or referral as indicated.

12.5 Non coercive recruitment strategy

It is an important principle of Good Clinical Practice that recruitment to research is non-coercive. Participants in the qualitative phase will be recruited from MFT and may have received clinical care from the applicant. It will therefore be clearly explained to potential participants that future clinical care will not be affected by study participation.

12.6 Confidentiality

Potential participants for the qualitative and pilot phases will be identified and approached by members of the direct clinical care team at MFT. If willing to discuss research participation, a member of the research team will provide written information and further details of the research. No participants will be identifiable in any data presented. During pessary clinic observations, should poor practice be observed which requires reporting, the identity of the pessary using woman will only be shared with the pessary practitioner's line manager if required to enable investigation of the specific circumstance of the incident.

12.7 Lone working

Lone working policies from The University of Manchester and MFT will be followed including completion of a risk assessment to ensure appropriate controls are in place for the qualitative phase which involves interviewing participants at a location convenient and preferable to them

12.8 Peer review

This study has been reviewed by the NIHR as part of the funding application, therefore further peer review is not deemed necessary.

12.9 Financial and other competing interests

This study is fully funded as part of the investigator's HEE-NIHR Integrated Clinical Academic Programme Clinical Doctoral Research Fellowship. Lucy Dwyer and Rohna Kearney are co-applicants on the NIHR HTA TOPSY grant. There are no other competing interests.

12.10 Indemnity

The NHS indemnity scheme will apply to this study to ensure it meets the potential legal liability of the sponsor, equipment, employer and investigators/collaborators for harm to participants arising from the management, design and conduct of the research. No arrangements will be made for the payment of compensation in the unlikely event of harm.

12.11 Access to the final study dataset

The final anonymised electronic data set will be accessible to the investigator, academic and clinical supervisory team and statistician as required and stored on the chief investigator's personal drive on the secure MFT NHS hospital server.

13. PUBLIC AND PATIENT INVOLVEMENT

The need for research exploring pessary self-management was highlighted by The James Lind Alliance (JLA) Priority Setting Partnership for pessary and prolapse (Lough et al, 2018). A number of women with experience of pessaries participated in this partnership either as members of the steering group, by attending the consensus workshop or completing questionnaires. Understanding more about self-management including who can self-manage was ranked third out of 20 priorities by the JLA Priority

Setting Partnership. The research question has therefore been identified and prioritised by patients and members of the public.

The proposal has been reviewed by the Urogynaecology user group at Saint Mary's Hospital. Feedback provided confirmed that the research question was perceived to be of value and interest to the service users as well as acceptable in terms of study participation. The service user group agreed to provide further feedback upon the proposed research.

The research proposal has also been reviewed by the Royal College of Obstetricians and Gynaecologist's (RCOG's) Women's Network who supported funding of the project. This demonstrates that women support the research question, are in agreement with the methods proposed and are willing to participate in patient and public involvement for the study.

A pessary using woman from The RCOG Women's Network has reviewed and provided feedback on the study protocol, approval applications and study documents to ensure the research plan is ethical and answers the research question, that study documents are written clearly and to inform creation of the interview guide.

Once recruitment commences, public members of the project steering group will be asked to contribute to discussions regarding the progress of the project and the course it is taking. This is particularly important for this research as it aims to understand the lived experience of pessary using women, therefore it is essential that the steering committee members with this lived experience are in agreement with the coding and themes developed by the researcher.

The public members of the steering group will be asked to contribute to the writing up and dissemination of study findings. Public members will be asked to review manuscript drafts to ensure they are in agreement with the interpretation of study findings. Findings will be submitted for presentation at both a national and international conference. Funding has been requested for a public member of the project

steering group to attend the national conference and co-present study findings. Study findings will also be disseminated with assistance of the RCOG Women's Network Co-ordinator via Facebook support groups for women with prolapse as well as being shared via the RCOG twitter account and inclusion in an RCOG e-newsletter to The Women's Voices Involvement Panel (over 500 members throughout UK).

14. DISSEMINATION POLICY

- Data arising from the study will be owned by Manchester University NHS Foundation Trust.
- On completion of each research phase, the data will be analysed and published in scientific journals. Following completion of the research, the findings will be submitted for presentation at a national and international conference.
- Study participants can opt to receive a summary of the research findings following completion of the study on the consent form.

Authorship eligibility guidelines and any intended use of professional writers

In accordance with guidelines created by The International Committee of Medical Journal Editors, all authors will meet the following criteria and will have:

- made substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work;
- performed drafting of the work or revised it critically for important intellectual content;
- approved the final version of the article prior to publication;
- agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

15. EQUALITY AND DIVERSITY STATEMENT

All individuals will be considered for inclusion in this study regardless of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion and belief, sex, and sexual orientation except where the study inclusion and exclusion criteria explicitly state otherwise.

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