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FULL/LONG TITLE OF THE STUDY

Feasibility testing of OurPERSPECTIVE: a co-designed survivorship intervention for women following endometrial cancer treatment.

SHORT STUDY TITLE / ACRONYM

OurPERSPECTIVE endometrial cancer survivorship study

PROTOCOL VERSION NUMBER AND DATE

V1.0_14/10/2025

IRAS number:	**363748**
Sponsor:	University of Leicester
Sponsor number:	1097
Funder(s) number:	
Study registration number:	

This protocol has regard for the HRA guidance and the University of Leicester Sponsor Standard Operating Procedures (SOPs)

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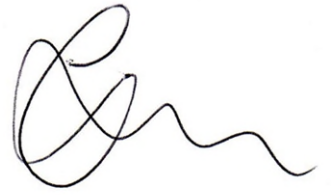
SIGNATURE PAGE

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, the UK Policy Framework for Health and Social Care Research, and other relevant regulatory requirements.

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 study 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. Any discrepancies and serious breaches of GCP from the study as planned in this protocol will be explained.

Chief Investigator:	
Name: (please print):	Dr Esther Moss
Signature:	
Date:	14/10/2025
Principal Investigator:	
Site:	University of Leicester
Name: (please print):	Dr Esther Moss
Signature:	
Date:	14/10/2025

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KEY STUDY CONTACTS AND INFORMATION

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Sponsor	Research Governance Office Research & Enterprise Division University of Leicester University Road Leicester LE1 7RH RGOsponsor@le.ac.uk 0116 3736508
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Funding start and end date(s)	01.06.2023- 30/06/2026
Key Protocol Contributors and Collaborators	Dr Esther Moss Associate Professor of Gynaecological Oncology University of Leicester University Road LE2 7LX em321@le.ac.uk +44 116 252 5827

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NIHR Portfolio adopted	No

ROLE OF THE STUDY SPONSOR

The Sponsor for this research project is the University of Leicester.

The University of Leicester is responsible for the design, management and outputs of the research. Participating research sites are responsible for the conduct of the study within their organisation.

The Research Governance Office review and approve all iterations of the protocol as part of the Sponsor review and amendment review processes. Further information is available from the Sponsor Standard Operating Procedures webpage.

CONTENTS

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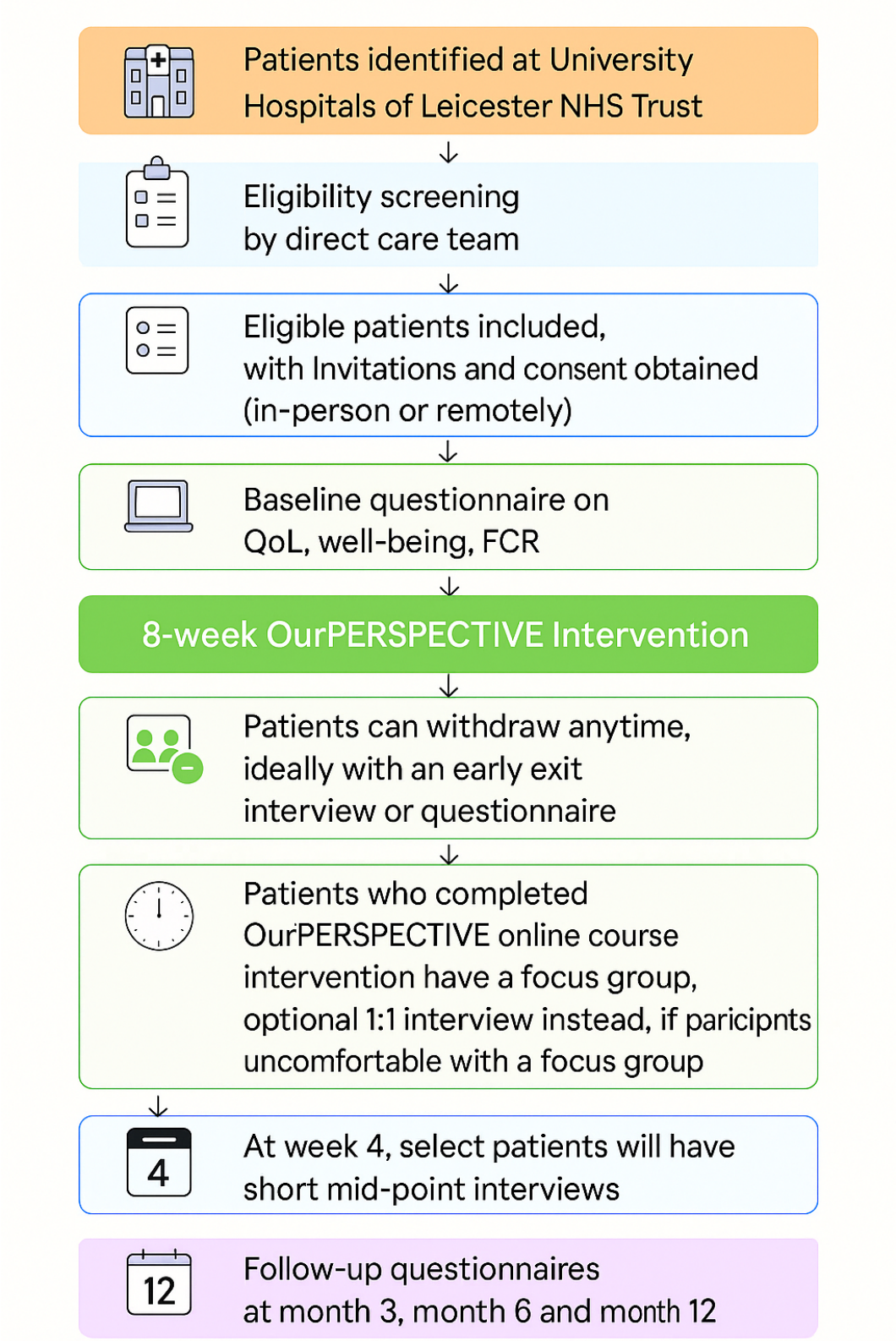
STUDY SUMMARY

Short Study Title or Acronym	OurPERSPECTIVE endometrial cancer survivorship Study	
Study Design	Single arm feasibility study	
Study Participants	Women who have completed primary treatment for endometrial cancer within 36 months; no evidence of recurrence; able to provide consent; able to participate in English-language group sessions.	
Sample Size	Estimated 30 participants.	
Follow up duration	Follow up: 12 months	
Planned Study Period	February 2026 – January 2028	
	Objectives	**End Points / Outcome Measures**
Primary	Is the OurPERSPECTIVE course acceptable and useful for women who have completed treatment for endometrial cancer?	The primary outcome is the acceptability and feasibility of the OurPERSPECTIVE survivorship course. This will be assessed using: – Recruitment rates (proportion of eligible women approached who consent to take part). – Retention rates (proportion of participants completing the 8-week course). – Attendance and engagement (number of sessions attended). – Participant evaluation of the course (questionnaire ratings of usefulness and relevance, and qualitative feedback from focus groups). These measures will determine whether the intervention and study procedures are acceptable and feasible, and whether

		progression to a full randomised controlled trial is justified.
Secondary	– Can we recruit and retain women to take part in the OurPERSPECTIVE course? – Do women complete the questionnaires and engage with feedback assessments? – What changes or improvements to the course content or delivery are suggested by participants?	Secondary outcomes will focus on exploratory measures to inform the design of the subsequent randomised controlled trial. These include: – Recruitment feasibility, such as reasons for declining participation and the characteristics of those recruited versus not recruited. – Questionnaire completion rates and data quality, to assess the practicality of collecting patient-reported outcomes in this population. – Changes in patient-reported outcomes over the course of the study, including quality of life, wellbeing, and fear of recurrence, measured using validated questionnaires (e.g. SF-36, HADS, EQ-5D-5L). – Participant preferences regarding delivery mode (virtual group versus other formats) and suggestions for improvement. – Qualitative feedback on barriers and facilitators to participation, acceptability of study materials, and relevance of course content. These outcomes will provide information on which measures are most suitable and acceptable for inclusion in the future definitive RCT.

STUDY FLOW CHART



LIST OF ABBREVIATIONS

AE	Adverse Event
AR	Adverse Reaction
CI	Chief Investigator
CRF	Case Report Form
CTU	Clinical Trials Unit
GCP	Good Clinical Practice
ICF	Informed Consent Form
ISF	Investigator Site File
NHS R&D	National Health Service Research & Development
PI	Principal Investigator
PIC	Participant Identification Centre
PIS	Participant Information Sheet
QC	Quality Control
RCT	Randomised Control Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SOP	Standard Operating Procedure
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee

KEY WORDS

Feasibility study; endometrial cancer; survivorship intervention; patient education.

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PROTOCOL AMENDMENT HISTORY

Amendment Reference	Protocol version no.	Protocol Date	Author(s) of changes	Summary of changes made

1 Background and Rationale

Endometrial cancer is the most common gynaecological malignancy in high-income countries, and incidence is rising, largely due to obesity alongside population ageing and metabolic risk factors [1]. Although overall survival is favourable for many, women frequently report persistent problems after treatment, including fatigue, bladder and bowel dysfunction, sexual difficulties, sleep disturbance, and fear of recurrence; these symptoms reduce quality of life and are common in endometrial cancer survivorship [2–4]. Such sequelae are often under-recognised and under-addressed in routine follow-up [5].

Cancer survivorship refers to the phase beyond initial treatment and includes the physical, psychological, social, and functional consequences of cancer and its management, with a focus on living well with and beyond cancer and addressing late and long-term effects [6,7,8]. Survivorship courses are structured educational programmes to support this phase.

Current survivorship interventions for gynaecological cancers remain limited and are rarely co-designed with patients. Evidence from oncology indicates that group-based, peer-supported programmes can improve psychological wellbeing, self-efficacy, and quality of life [9, 10]. However, such approaches have not been systematically adapted or tested for women with endometrial cancer in the UK NHS context, despite documented unmet needs in gynaecological cancer survivorship [11]. Additionally, survivorship support shows inequitable reach, with ethnic minority groups and people living in socio-economic deprivation reporting poorer experience and access to cancer care, underscoring the importance of equitable design and delivery [12,13].

The OurPERSPECTIVE course was co-designed with women living after endometrial cancer and healthcare professionals to address these gaps. It is an 8-week structured, group-based intervention focused on physical, psychological, and lifestyle challenges after treatment. This feasibility study will establish whether recruitment, retention, delivery, and evaluation are practicable within the NHS, informing a future definitive trial.

2 Objectives and Outcome Measures/Endpoints

Objectives	Outcome Measures/Endpoints	Timepoint(s) of evaluation of this outcome measure
Primary Objective, Outcome, Timepoint(s)		
Is the OurPERSPECTIVE course acceptable and useful for women who have completed treatment for endometrial cancer?	The primary outcome is the acceptability and feasibility of the OurPERSPECTIVE survivorship course. This will be primarily assessed using: – Retention rates (proportion of participants completing the 8-week course). – Recruitment rates (proportion of eligible women approached who consent to take part). These measures will determine whether the intervention and study procedures are acceptable and feasible.	Data will be collected in three stages: Before the trial begins to collect baseline participant data. Participants will be asked to keep a diary of their experiences and views of the course and the different modules At week 4 of the 8-week intervention, representing mid-point data, with short interviews with individuals to assess usability and engagement with the intervention. Follow up period after the 8-week intervention at 3-months, 6-months and 12-months post-intervention.
Secondary Objective(s), Outcome(s), Timepoint(s)		
1. Can we recruit and retain women to take part in the OurPERSPECTIVE course within the NHS? 2. Do women complete the questionnaires and give feedback as expected? 3. What changes or improvements to the course content or delivery are suggested by participants?	Secondary outcomes will focus on exploratory measures to inform the design of the subsequent randomised controlled trial. These include: – Recruitment feasibility, such as reasons for declining participation and the characteristics of those recruited versus not recruited. – Attendance and engagement (number of sessions attended). – Participant evaluation of the course (questionnaire ratings of usefulness and relevance, and	Data will be collected in three stages: Before the trial begins to collect baseline participant data. Participant diaries At week 4 of the 8-week intervention, representing mid-point data, with short interviews with individuals to assess usability and engagement with the intervention. Follow up period after the 8-week intervention at 3-months,

Objectives	Outcome Measures/Endpoints	Timepoint(s) of evaluation of this outcome measure
	qualitative feedback from focus groups). – Questionnaire completion rates and data quality, to assess the practicality of collecting patient-reported outcomes in this population. – Changes in patient-reported outcomes over the course of the study, including quality of life, wellbeing, and fear of recurrence, measured using validated questionnaires (e.g. SF-36, HADS, EQ-5D-5L). – Participant preferences regarding delivery mode (virtual group versus other formats) and suggestions for improvement. – Qualitative feedback on barriers and facilitators to participation, acceptability of study materials, and relevance of course content. – Assessing how equity characteristics (PROGRESS-Plus) determine engagement and usability of the intervention. These outcomes will provide information on which measures are most suitable and acceptable for inclusion in the future definitive RCT.	6-months and 12-months post-intervention.
Exploratory Objective(s) Outcome(s), Timepoint(s)		
N/A	N/A	N/A

3 Study Design

This is a single-centre feasibility study based at the University Hospitals of Leicester NHS Trust. The study will recruit women who have recently completed treatment for endometrial cancer through NHS secondary care at University Hospitals of Leicester NHS Trust. The intervention, OurPERSPECTIVE, is delivered virtually as an online group course facilitated by a gynaecology nurse specialist: the structure of the module will follow the example showed in figure 2. The content of each module is summarised in figure 3. The online course will be complemented with an interactive workbook which will be supplied to participants.

All study activities (identification, recruitment, consent, delivery of the intervention, and follow-up) will be managed through this single NHS hospital site. No other types of sites (e.g. GP practices or community venues) are involved. There are no participant identification centres; recruitment will be undertaken directly by the clinical care team at Leicester Cancer Centre.

Figure 2: Structure of a module within the OurPERSPECTIVE Course.

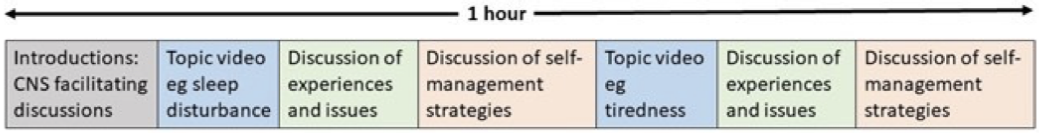


Figure 3: Topics for discussion in the OurPERSPECTIVE Modules.

4 Participant Eligibility Criteria

4.1 Inclusion criteria

– Women aged over 18 years.

– Completed primary treatment for endometrial cancer within the past 36 months.

– No evidence of recurrence.

– Able to provide informed consent.

– Sufficient English language skills to participate in the group sessions.

4.2 Exclusion criteria

– Second active primary malignancy.

– Significant comorbidity that would prevent participation.

– Inability to access or use the online course platform.

5 Study Schedule

5.1 Schedule of procedures

Procedures	Screening	Baseline	Week 4	Week 8-10	3-months	6-months
Visit window	± 4 weeks	± 4 weeks	± 8 weeks	± 12 weeks	± 24 weeks	± 36 weeks
Visit details	Face to face or Remote	Face to face or Remote	Remote	Remote	Remote	Remote
Invitation and expression of interest	X					
Telephone screening	X					
Informed consent	X					
Eligibility Assessment	X					
Demographics		X				
Medical history		X				
Questionnaires		X	X		X	X
Interview			X (For select participants only)	X		

5.2 Recruitment

The recruitment phase will commence as soon as all necessary approvals have been received. Potential participants will be identified and/or contacted through the approaches described below. In all instances participants will be provided with a copy of the Participant Information Sheet, confidentiality and privacy notice, and invitation letter.

5.2.1 Participant identification

Potential participants will be identified from patient records at the University Hospitals of Leicester NHS Trust (UHL). Screening for eligibility (date of treatment, diagnosis, recurrence status) will only be carried out by a member of the direct care team (gynae-oncologists or clinical nurse specialists), supported by Clinical Research Nurses. The clinical research fellow (JH) will not access patient records prior to consent. EM is a member of the direct clinical care team and leads the gynaecological cancer survivorship programme at UHL and therefore will have access to the patient records.

Once a potentially eligible patient has been identified, the care team or research nurses will approach them during routine follow-up clinic, or by sending written information through the post. Patients will be provided with an invitation letter, Participant Information Sheet (PIS) explaining the study, and given at least 24 hours to consider participation.

If a patient wishes to hear more, they may express interest directly to their care team or by contacting the research team, once they have agreed that their details can be shared. Alternatively, they may return a reply slip included in the invitation letter to indicate their willingness to be contacted.

Interested participants will then be contacted by the research team, who will answer any questions, confirm eligibility, and arrange the consent process.

5.2.2 Screening and eligibility assessment

Telephone pre-screening

Following a potential participant's expression of interest, a pre-screening telephone call will be arranged to provide further information about the study and to check their suitability to take part.

A pre-screening eligibility check will be conducted to confirm the following criteria:

- Age ≥18 years
- Completed primary treatment for endometrial cancer within the past 36 months
- No evidence of recurrence (as recorded at most recent clinical follow-up)
- Ability to provide informed consent

- Access to and ability to use an online platform for group sessions
- Sufficient English language skills to participate in the course

Where pre-screening eligibility is confirmed, the participant will be invited to proceed to full enrolment and baseline data collection.

Baseline screening / enrolment

There are no additional medical tests or procedures required beyond routine clinical care. Baseline eligibility confirmation will include:

- Review of recent clinic records by the direct care team to confirm no evidence of recurrence
- Confirmation of treatment completion date (within the past 36 months)
- Confirmation of that participant is able to attend the online course

Participants who meet all criteria will then provide written or electronic informed consent and be enrolled in the study.

5.2.3 Informed consent

Following the provision of the Participant Information Sheet, the potential participant will be given as much time as they need and at least 24 hours to decide whether or not they would like to take part.

The process of obtaining informed consent will include a discussion between the potential participant and a member of the research team, which will detail no less than: the exact nature of the study, the implications and requirements of the protocol, and any potential risks involved in taking part. It will be clearly explained that participation is voluntary and that the participant is free to withdraw from the study at any time, without giving a reason, without prejudice to their future care, and without their legal rights being affected. They will also be reminded that any data collected up to the point of withdrawal will be retained.

Potential participants will be given the opportunity to ask questions about taking part and withdrawing, and will have these answered before signing consent.

The person who obtains consent will be suitably qualified and experienced, and will have been authorised to do so by the Principal Investigator as detailed on the Delegation of Authority and Signature Log for the study.

All participants will be required to give written informed consent prior to any study activities taking place.

In-person consent

Written consent will be obtained by means of a participant's dated signature and the dated signature of the person who presents and obtains consent, using the latest approved version of the informed consent form. The original signed form will be retained within the Investigator Site File (ISF). A copy will be given to the participant, and another copy placed in the participant's NHS medical notes.

Remote consent

Where participants prefer, consent may also be obtained remotely. In such cases, the Participant Information Sheet and consent form will be sent electronically or by post in advance. The research team will arrange a remote consent discussion (telephone or video call) to review the information, answer questions, and confirm understanding. Participants will sign the consent form either electronically (via secure e-consent system) or by printing, signing, and returning by post. The research team member taking consent will then countersign the form. A fully signed copy will be provided to the participant and another copy will be retained in the ISF.

Language requirements

The study mandates English language proficiency due to the nature of the intervention, this is stated in our inclusion criteria. As such, Participant Information Sheets and consent forms will be written in plain language English.

5.3 Randomisation

Not Applicable.

5.3.1 Blinding and code breaking

Not Applicable.

5.4 Study assessments

Demographic and Clinical Data

Demographic information (age, sex, ethnicity, postcode) and relevant clinical details (date of completion of primary treatment, cancer and stage, and current disease status) will be obtained from routine NHS clinical records at the University Hospitals of Leicester NHS Trust. Specifically, the following information will be sought:

Anthropometric Data: Height and weight will be measured and used to calculate Body Mass Index (BMI).

Endometrial Cancer Data: Information will be collected on recurrence, definitive treatment undertaken, menopause status.

Medical History Data: Information on other medical conditions/medications will be collected, as well as smoking and alcohol intake questions.

Equity characteristics (modified PROGRESS-Plus): Information on equity characteristics and social circumstance will be collected, with the option of 'prefer not to say' provided for information deemed to be of a sensitive nature.

Baseline Questionnaires (Week 0)

At enrolment, participants will complete self-reported questionnaires delivered electronically or on paper (depending on participant preference). These will include:

- Quality of life: SF-36
- Psychological wellbeing: Hospital Anxiety and Depression Scale (HADS)
- Multi-dimensional health-related quality of life assessment: EQ-5D-5L
- Acceptability and usability questions tailored to the intervention

Midpoint Interview (Week 4)

At week 4, selected participants will be invited to take part in a short telephone interview to assess the feasibility and acceptability during the intervention. This will be with the research fellow. The interview will be recorded using Microsoft Teams.

Post-Intervention Questionnaires (3 months)

After completing the OurPERSPECTIVE course, participants will be asked to complete the same set of questionnaires as at baseline to assess feasibility of data collection and exploratory changes in quality of life, psychological wellbeing, and fear of recurrence. It is anticipated that this data collection will be approximately 3-months since recruitment. Additional acceptability and usability questions will capture participant feedback on the intervention as a whole. Further follow up questionnaires will be sent at the 6-month and 12-month point, respectively.

OurPERSPECTIVE Course Attendance

Attendance at each of the 8 weekly online group sessions will be recorded in the case report form. Sessions will last approximately 60 minutes and will be facilitated by a gynaecology nurse specialist. Group rules will be set at the start, and each session will end with a short debrief, and mood self-rating in the accompanying guided workbook provided to patients. Participants will be given a workbook to support their attendance on the course and a separate reflective diary where they can document their thoughts, experiences and feedback of the different modules. The diary will be returned to the research team at the end of the course; however, the participants will be able to keep the course workbook.

Focus Group

Within 4 weeks of course completion, participants will be invited to take part in a virtual focus group to provide qualitative feedback on their experience, the data collection from each participant will conclude at 3-months. Discussions will explore perceived benefits, challenges, and suggestions for improvement. Sessions will be audio recorded, transcribed, and anonymised for analysis. The number of participants in each focus group will be 4-6 in order give participants time and opportunity to share their experiences. For individuals who do not wish to discuss their experiences openly, the option of a one-one virtual or telephone interview with the research fellow will be offered.

Withdrawal or Early Exit

If a participant withdraws before completing the course, the reason (if provided) will be recorded. Participants will be asked if they are willing to complete an early-exit telephone interview in order to explore their reasons and what could be done to improve the course to reduce future withdrawals.

Mode of Delivery

All questionnaires will be completed remotely (online or postal). The OurPERSPECTIVE intervention and focus groups will be delivered virtually (videoconferencing platform). No face-to-face study visits are required.

5.4.1 Long term follow-up assessments

This is a feasibility study and long-term follow-up beyond the 8-week intervention period includes the 3-month, 6-month and 12-month questionnaires to investigate the longer-term impact of the course.

Frequency and duration of follow-up

Participants will be sent questionnaires approximately 2 weeks after completion of the 8-week OurPERSPECTIVE course (3 month); and will be invited to participate in focus group or interviews to approximately 4 weeks after completing of intervention completion. Further long-term follow up will be completed at 6-month and 12-month of intervention completion with the included questionnaires to compare to baseline symptom burden.

Assessments

Post-intervention assessments will include the same questionnaires completed at baseline (SF-36, HADS, EQ-5D-5L, acceptability/usability questions) and an optional focus group.

These measures will capture short-term changes in wellbeing and evaluate the acceptability of the intervention.

Differences from standard care

The course and the assessments are additional to standard NHS follow-up, which typically focuses on clinical surveillance for recurrence and does not include a structured survivorship course, questionnaires or peer-support evaluation.

Retention strategies

Retention will be supported through flexible scheduling of questionnaires (online or postal completion), reminder emails/telephone calls, and provision of modest shopping vouchers as a token of thanks. The focus on short-term follow-up reduces risk of attrition.

Identification of lost to follow-up

Participants will be considered lost to follow-up if they do not return post-intervention questionnaires and cannot be contacted after three attempts (e.g. email, phone, postal reminder).

Handling missed data

If questionnaire time-points are missed, participants will still be invited to complete subsequent assessments where possible. Early-exit data will be recorded if participants withdraw before completing the study.

Data from non-adherers

For participants who discontinue the intervention but do not withdraw consent, available outcome data (e.g. questionnaires completed up to that point) will still be retained and included in feasibility analysis.

5.5 Study intervention(s) and comparator(s)

5.5.1 Description of study intervention

The study intervention is OurPERSPECTIVE, a virtual, group-based survivorship course co-designed with women who have experienced endometrial cancer.

The course will be facilitated by a gynaecology clinical nurse specialist who is part of the UHL direct clinical care team and will be known to the participants. The course will be delivered online via a secure videoconferencing platform (Microsoft Teams). The course will run for 6-8 consecutive weeks, with one session each week lasting approximately 60 minutes. There are 6 core modules for all participants and 2 additional modules (menopause and sexual function) that participants can chose to attend if they wish. Each session combines education, discussion, workbook activities and peer support, and covers the following modules: physical activity, sleep disturbance, body changes, tiredness, fear of recurrence, tiredness, menopause, and sexual disturbance.

At the start of the course, group rules will be established to create a safe and respectful environment. Each session will conclude with a short debrief to check wellbeing and provide closure. The specialist nurse who will be facilitating the course will be able to provide additional support to participants who become distressed or indicate that they need additional support during a session.

Attendance at each session will be recorded in the attendance log. The courses will aim to have 10 women per cohort, with 3 cohorts planned for the feasibility study.

5.5.2 Description of comparator

Not Applicable.

5.6 Expenses and benefits

Participants will not be asked to attend any face-to-face visits outside of routine NHS care. All questionnaires, intervention sessions, and focus groups will be delivered remotely.

To recognise the time and effort required to take part, participants will be offered a shopping voucher (£20 in value) after completion of the study assessments. The voucher may be for a supermarket, high-street store, or coffee shop, according to participant preference, and will be issued once all post-intervention activities are completed.

This is not intended as payment but as a token of appreciation. No reimbursement of travel expenses is required as all activities are virtual.

5.7 Early discontinuation/withdrawal of participants

Participants may withdraw from the study at any point, without giving a reason and without any prejudice to their current or future NHS care.

Withdrawal can take different forms:

- A participant may choose to stop attending the OurPERSPECTIVE course but remain in the study to complete questionnaires and/or the focus group.
- A participant may withdraw fully from all aspects of the study.
- The Principal Investigator may withdraw a participant if it is judged that continued participation would not be in their best interests or exclusionary criteria is later met (e.g. recurrence of cancer, significant health deterioration, or safeguarding concerns).

If a participant withdraws or loses capacity to consent for themselves, data collected up to the point of withdrawal will be retained and included in the study analysis.

No specific safety follow-up procedures are required for participants who withdraw, as this is a low-risk, non-CTIMP feasibility study. However, participants will be asked (where possible) whether they are willing to complete an early-exit questionnaire to capture partial outcome data. The specialist nurses will be aware of the participant's withdrawal and can follow-up if clinical concerns.

The type of withdrawal and reason for withdrawal will be recorded in the CRF and on the subject enrolment log.

5.8 Definition of end of study

For the purposes of this protocol, the end of the study will be taken as the point at which the final participant has completed all study-related activities. In practical terms, this will be the return of the post-intervention questionnaires at the 12-month mark and completion of sample analysis. The study will formally close once the last element of data collection has been completed for the last participant.

6 Sample Handling

Not Applicable.

6.1 Arrangements for sample storage

Not Applicable.

6.2 Arrangements for sample destruction

Not Applicable.

7 Safety Reporting

7.1 Definitions

Term	Definition
Adverse Event (AE)	Any untoward and unintended medical occurrence (including an abnormal laboratory finding), symptom or disease in a participant, **whether or not it is considered related** to the study.
Adverse Reaction (AR)	Any untoward and unintended medical occurrence (including an abnormal laboratory finding), symptom or disease in a participant **which is considered related** to the study. The assessment of expectedness **must be** undertaken by a delegated medically qualified professional. Where an event could be considered possibly, probably or unlikely related to the study, for the avoidance of doubt, this should be considered related.
Serious Adverse Event (SAE)	Any untoward and unintended medical occurrence that meets the following serious criteria, **whether or not it is considered related** to the study: • results in death • is life-threatening^ • requires inpatient* hospitalisation or prolongation of existing hospitalisation • results in persistent or significant disability/incapacity, or • is a congenital anomaly/birth defect • Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences. NOTE: ^The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.
Serious Adverse Reaction (SAR)	Any untoward and unintended medical occurrence that meets the above referenced serious criteria and, in the opinion of the delegated medically qualified professional, is believed to be **related (possibly, probably, unlikely)** to the study intervention.
Suspected Unexpected Serious Adverse Reaction (SUSAR)	Any untoward and unintended medical occurrence that meets the above referenced serious criteria and, in the opinion of the delegated medically qualified professional, is believed to be **related** to the study intervention but is not listed within the anticipated events section below. Any untoward and unintended medical occurrence that meets the above referenced serious criteria and, in the opinion of the delegated medically qualified professional, is believed to be **related** to the study intervention. There are **no anticipated**

	events for this study therefore, any events which are considered related will be considered unexpected.

NB: to avoid confusion or misunderstanding of the difference between the terms "serious" and "severe", the following note of clarification is provided: "Severe" is often used to describe intensity of a specific event, which may be of relatively minor medical significance. "Seriousness" is the regulatory definition supplied above.

7.2 Expected Adverse Events/Reactions and Serious Adverse Events/Reactions

Expected events are medical occurrences which are known to occur based on the population/disease being studied. **Expected reactions** are medical occurrences which are known to occur as a result of the intervention being tested.

7.2.1 Expected Adverse Events/Reactions

There are no anticipated adverse events in the population being studied.

7.2.2 Expected Serious Adverse Events

There are no anticipated SAEs in the population being studied.

7.3 Reporting procedures for All Adverse Events/Reactions

All non-serious Adverse Events/Adverse Reactions occurring from the time of start of study intervention until the end of the participants involvement in the study, observed by the investigator or reported by the participant, will be recorded.

The following information will be captured on the adverse event log;

- Description of the event
- Date of onset
- End date
- Severity*
- Assessment of relatedness to study (not related or related; possibly, probably unlikely)
- Action taken

Follow-up information will be provided as necessary.

The relationship of the event to the study will be assessed and signed off by a medically qualified individual listed on the Delegation of Authority and Signature Log.

Events will be followed-up until resolution or the event is considered stable.

It will be left to the investigator's clinical judgment whether or not an AE is of sufficient severity to require the participant's removal from the study (or the study intervention/procedures). A participant may also voluntarily withdraw from treatment/the study due to what he or she perceives as an intolerable AE. If either of these occurs, the participant must undergo an end of study assessment and be given appropriate care under medical supervision until symptoms cease or the condition becomes stable.

*The severity of events will be assessed on the following scale: 1 = mild, 2 = moderate, 3 = severe.

7.4 Reporting Procedures for Serious Adverse Events/Reactions (SAE/R)

The Sponsor, the CI or the local PI at a research site may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health or safety. If any urgent safety measures are taken, the CI/Sponsor shall be notified immediately, and in any event no later than 3 days from the date the measures are taken, give written notice to the Sponsor and the relevant REC of: the measures taken; reason these measures were taken; the circumstances giving rise to those measures and the plan for further actions.

7.5 Reporting Urgent Safety Measures

The Sponsor, the CI or the local PI at a research site may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health or safety. If any urgent safety measures are taken, the CI/Sponsor shall be notified immediately, and in any event no later than 3 days from the date the measures are taken. Written notice must be provided to the Sponsor and the relevant REC of:

- the measures taken
- reason these measures were taken
- the circumstances giving rise to those measures
- plan for further actions.

8 Statistics and Analysis

8.1 Sample size calculation

The sample size for this feasibility study is pragmatic and based on the anticipated recruitment rate within University Hospitals of Leicester NHS Trust. Approximately 30 participants will be enrolled.

8.2 Planned recruitment rate

It is anticipated that 100% of the recruitments will be through the University Hospitals of Leicester.

8.3 Statistical analysis plan

8.3.1 Summary of baseline data and flow of patients

Data will be collected from all the participants using the CRFs and baseline questionnaires (EQ-5D-5L, HADS, SF-36).

8.3.2 Primary outcome analysis

Primary outcomes will relate to feasibility, including recruitment, retention, attendance and acceptability of the OurPERSPECTIVE programme.

Data will be collected using study Case Report Forms (CRFs) and participant feedback questionnaires. Descriptive statistics will be undertaken to report:

- the proportion of eligible participants who consent to participate;
- the proportion completing the 8-week programme;
- attendance across the six core sessions and 2 optional sessions; and
- acceptability ratings following each session and at study completion.

Quantitative outcomes will be summarised using frequencies and percentages for categorical data and means, standard deviations, medians and interquartile ranges for continuous data as appropriate. No formal hypothesis testing will be undertaken.

Qualitative data generated from the post-intervention focus group will be analysed using Reflexive Thematic Analysis as described by Braun & Clarke (2006). Audio recordings will be transcribed verbatim, anonymised and imported into suitable, confidential software (Microsoft Teams). Data familiarisation, coding, theme development, and refinement will be undertaken iteratively. Two researchers will code independently and discuss discrepancies to ensure credibility. A reflexive log will be maintained to document analytic decisions. Themes will capture participants' perceptions of programme acceptability, perceived benefits and barriers to participation. These qualitative findings will complement the quantitative data to provide a comprehensive assessment of feasibility and acceptability.

8.3.3 Secondary outcome analysis

Secondary outcomes will assess change in participant-reported quality of life and psychological well-being. Data will be collected using the SF-36, Hospital Anxiety and Depression Scale (HADS), and EQ-5D-5L at baseline, post-intervention, and 3-, 6- and 12-month follow-ups. Descriptive statistics will summarise scores at each timepoint. Mean within-participant changes from baseline will be presented with 95 % confidence intervals and standardised effect estimates.

Qualitative data from midpoint interviews (week 4) and the post-intervention focus groups/interviews will also be analysed using Reflexive Thematic Analysis.

8.4 Subgroup analyses

Feasibility outcomes and participant-reported changes will be examined by baseline characteristics such as ethnicity, deprivation quintile, time since treatment completion, and menopause status.

8.5 Adjusted analysis

Not applicable.

8.6 Interim analysis and criteria for the premature termination of the study

No interim efficacy analysis is planned. Feasibility progress will be reviewed periodically by the Chief Investigator and Sponsor.

8.7 Participant population

Analyses will include:

- Enrolled set: all participants who consent;
- Intervention set: all participants who attend at least one session;
- Feasibility analysis set: all participants providing evaluable data at each timepoint.

Given the single-arm design, all available data will be included in descriptive analyses, with adherence and withdrawals reported.

8.8 Procedure(s) to account for missing or spurious data

Not applicable

8.9 Other statistical considerations.

Not applicable

8.10 Economic evaluation

Not applicable

9 Data Management

Not applicable

9.1 Data flow diagram (this is a mandatory requirement)

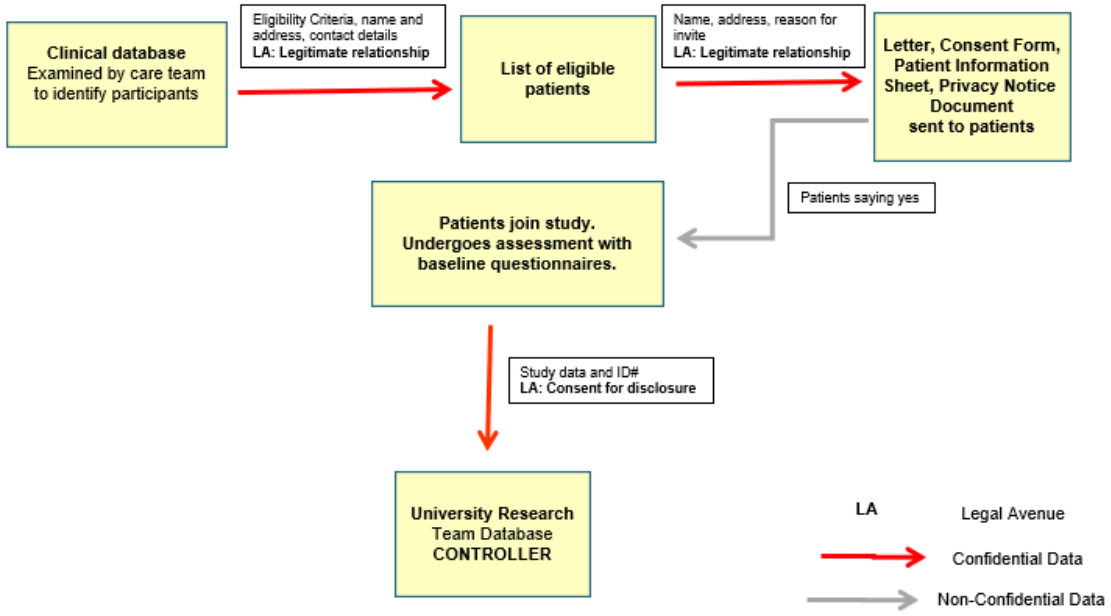
Data Flow Diagram (Example)

Project Name: OurPERSPECTIVE endometrial cancer survivorship Study

Date: 12/10/2025

Chief Investigator: Dr Esther Moss

IRAS ID: 363748



9.2 National data opt-out (this section is mandatory)

The national data opt-out was introduced on 25th May 2018 enabling patients to opt out from the use of their data for research or planning purposes in line with the recommendations of the National Data Guardian in their review of Data Security, Consent and Opt-outs. As from 1st August 2022, all NHS Trusts are now compliant with the national data opt-out operational policy guidance document; for further information please visit https://digital.nhs.uk/services/national-data-opt-out/operational-policy-guidance-document.
The NHS Trust's R&I SOP for the national opt-out will be adhered to before patients are approached/invited and before any data processing takes place.

9.3 Source data

Source documents are defined as the first place where study data are recorded, from which entries into the case report forms (CRFs) are derived. For this study, source documents will include:

- Hospital records (used to confirm eligibility, diagnosis, and treatment completion date)

- Signed informed consent forms
- Participant-reported questionnaire responses (completed electronically or on paper)
- Participant reflective diaries
- Attendance logs for the OurPERSPECTIVE sessions
- Audio recordings and anonymised transcripts of focus groups

CRF entries will themselves constitute source data when they are the original record, for example, attendance records or direct questionnaire data entered electronically.

All documents will be stored securely and under confidential conditions. On all study-specific documents, other than the signed consent form, participants will be identified only by their unique study ID number rather than by name.

9.4 Data collection tools, handling and record keeping

Each participant will be assigned a unique study identification number upon consent. This identifier will be used on all study-specific documentation and data collection tools in place of the participant's name.

Study data will be collected primarily through participant-completed questionnaires (baseline, midpoint, post-intervention) and attendance logs for the OurPERSPECTIVE course. Data will first be captured in paper case report forms (CRFs) or electronic questionnaire booklets and subsequently entered into a secure University of Leicester research database. The database will be hosted on encrypted University servers located within the UK. Access will be limited to authorised members of the research team using individual usernames and passwords.

Signed informed consent forms will be retained in the Site File (SF) with the clinical research team (located in the Gynaecology Research Office at Leicester General Hospital), with a copy also placed in each participant's NHS medical notes. All SF documents will be stored securely in a locked cabinet within a locked office within University Hospitals of Leicester NHS Trust.

To maximise completeness of data, reminders will be sent to participants who do not return questionnaires within the expected timeframe. These reminders will be issued by email or telephone, with follow-up by post if required. Participants who withdraw will be asked whether they are willing to complete an early-exit questionnaire, and partial data collected prior to withdrawal will be retained with consent.

Participant contact details will be held separately from research data in a password-protected file accessible only to the research team. This contacts database will be stored on the University of Leicester secure server, in compliance with GDPR and NHS data protection requirements.

All electronic systems will comply with Good Clinical Practice (GCP) standards:

- The database will maintain an audit trail of data changes, with no capacity for deletion of original entries.
- Data entry rights will be restricted to authorised study personnel.
- Regular backups will be performed in line with University IT policies.
- An unambiguous participant identification code will allow linkage of all data collected for each participant.
- Pseudonymisation will be maintained at all stages, and only anonymised data will be shared outside the Sponsor institution.

All study documentation containing identifiable data will be managed in accordance with ICH-GCP, the UK Policy Framework for Health and Social Care Research, GDPR, and the Data Protection Act. Documents will be retained securely for at least six years after study closure, after which secure destruction will be arranged.

9.5 Access to data

The Chief Investigator and authorised members of the study team will have access to data collected as part of this research. Access to the study database will be restricted through role-based permissions, ensuring that only personnel with appropriate responsibilities can view or edit data. All members of the study team will be suitably trained prior to being granted access. Individual user accounts will be password-protected and will not be shared between members of the team.

Direct access to source data and study documentation will also be granted to authorised representatives from the Sponsor (University of Leicester), the host institution (University Hospitals of Leicester NHS Trust), and regulatory authorities, for the purposes of monitoring, audit, and inspection. Such access will be in line with participant consent and applicable data protection regulations.

9.6 Archiving

All study data and essential documents will be archived for a minimum of six years after study closure, in line with University of Leicester and NHS Trust policy. Paper records will be stored securely on site, and electronic data will be retained on encrypted University servers with restricted access. Archiving will follow the University of Leicester Archiving SOP (https://le.ac.uk/research/regi/standard-operating-procedures). Destruction of documents will require formal Sponsor authorisation.

10 Quality Assurance Procedures

The study will be conducted in accordance with the current approved protocol, ICH-GCP, the principles of the Declaration of Helsinki, and all relevant regulations and standard operating procedures (SOPs). The Principal Investigator, or their delegate,

will be responsible for maintaining the Investigator Site File and ensuring it is kept "inspection ready" at all times.

10.1 Monitoring, audit and inspection

The University of Leicester as Sponsor operates a risk-based monitoring programme which this study will be subject to.

11 Protocol Compliance

11.1 Protocol deviations

A study related deviation is a departure from the ethically approved study protocol or other study document or process (e.g. consent process or administration of study intervention) or from Good Clinical Practice (GCP) or any applicable regulatory requirements. Planned deviations or waivers are not allowed however it is acknowledged that accidental protocol deviations may occur. Any deviations from the protocol will be documented in a protocol deviation form and filed in the Trial Master File/Investigator Site File as applicable.

If a protocol deviation occurs, then the CI (or delegate) will document this in accordance with the University's Standard Operational Procedure (SOP) Identifying and Reporting Deviations and Serious Breaches of GCP and/or the Protocol.

Deviations from the protocol which are found to frequently recur will be explored and where necessary an amendment to the protocol will be made.

11.2 Serious breaches

A "serious breach" is a breach of the protocol or of the conditions or principles of Good Clinical Practice which is likely to affect to a significant degree –

(a) the safety or physical or mental integrity of the trial subjects; or

(b) the scientific value of the research.

In the event that a serious breach is suspected the Sponsor will be contacted within one working day. In collaboration with the CI, the serious breach will be reviewed by the Sponsor and, if appropriate, the Sponsor will report it to the approving REC committee and the relevant NHS host organisation within seven calendar days.

12 Ethical and Regulatory Considerations

12.1 Research ethics committee (REC) and regulatory review, approvals/permission/support, compliance and reports

Once the Sponsor Review process is complete, authorisation from the University of Leicester's Research Governance Office will be issued to book further regulatory review of the proposed research. The University of Leicester's Ethics Committee will then review the proposal. Agreement in principle is subject to the research receiving all relevant regulatory permissions. Submission for regulatory approvals will occur via the Integrated Research Application System (IRAS). The Chief Investigator will ensure that all regulatory approvals,

confirmation of capacity and capability from NHS sites and sponsor green light are in place before participants are approached.

For any required amendment(s) to the study, amendment will be submitted to the sponsor in the first instance for review and approval to submit the amendment for external regulatory approval. Amendments must be implemented following all required ethical, competent authority, site and Sponsor approvals and in line with Sponsor Standard Operating Procedures.

The Research Governance Office's Standard Operating Procedures will be followed for the duration of the study.

The Chief Investigator will notify the REC when the study has ended by completing the end of study notification form and will submit a final report of the results within one year after notifying REC.

A Trial Master File and an Investigator Site File (per site) will be maintained for the duration of the study and will be stored for a minimum of 6 years after the study has ended. The only time this could be exceeded, is if samples are being retained beyond the scope of the original study i.e. there is consent for future research. In this circumstance ICFs may be retained for as long as the samples are in existence, as we have a legal requirement to prove the samples were obtained with consent.

12.2 Peer review

This study has undergone peer review by senior oncology and gynaecology specialist nurses who are leading such survivorship initiatives and are experts in gynaecological cancers. The review was proportionate to the size and complexity of the study, which is a single-centre, low-risk feasibility study.

The review process considered the clinical relevance, feasibility of recruitment and delivery within the NHS, and the methodological appropriateness of the design. Feedback was incorporated into the final version of the protocol to ensure clarity, feasibility, and compliance with NHS research governance standards.

As this is a small-scale feasibility study and not seeking adoption onto the NIHR CRN Portfolio at this stage, peer review by expert nurses who would be delivering or overseeing such an intervention was deemed sufficient. The review is consistent with the requirement for proportionality in peer review standards, ensuring the protocol is appropriate for submission and delivery within the host institution.

12.3 Patient and public involvement

Who was involved?	The intervention course content was co-designed with a patient advocacy group for endometrial cancer: Peaches Womb Cancer Trust to ensure course modules were relevant and sensitive.
How and when have they been involved?	The PPI group have supported the need for the study and the development of a survivorship programme for patients diagnosed with endometrial cancer. The PPI community were engaged through online discussions and dialogue.
How has the input of the people you involved made the study ethically acceptable?	The study has taken direct views from patients with lived experience of endometrial cancer and the long-term survivorship implications, this has allowed sensitivity tailoring of the intervention to the appropriate cohort of patients.

12.4 Assessment and management of risk

This study is considered to be low risk. The intervention under investigation is a structured survivorship programme, delivered in a group format, which does not involve any invasive procedures, drug treatments, or collection of biological samples. The main potential risks are psychosocial rather than physical.

The anticipated risks are:

- Emotional distress: Discussion of survivorship experiences may be sensitive or upsetting. This will be managed by establishing ground rules at the start of sessions,

ensuring a safe environment, and providing opportunities for protected debriefs at the end of each session. Participants experiencing distress will be signposted to appropriate NHS support services.

- Confidentiality risks: As group sessions are conducted in a shared environment, there is a risk of inadvertent disclosure of personal information. Participants will be reminded of confidentiality expectations at the outset, and study materials will reinforce this. Data will be pseudonymised and stored securely in line with University of Leicester and NHS data governance policies.
- Data handling risks: Risks related to loss or breach of personal data will be mitigated by strict adherence to GDPR, secure storage on University servers, and password-protected access restricted to authorised personnel.

The researchers have extensive experience of undertaking such interviews, supporting participants, and signposting to additional support in order to minimise any distress, including clinical nurse specialists and cancer charity support. The distress protocol will be followed (Appendix 1) in such circumstances.

12.5 Data protection and patient confidentiality

The Chief Investigator will act as the data custodian for this study. All information collected will be kept strictly confidential.

The Chief Investigator and members of the research team will comply fully with the requirements of the Data Protection Act 2018, the UK General Data Protection Regulation (UK GDPR), and all applicable NHS and University of Leicester policies relating to the collection, storage, processing, and disclosure of personal data. The core principles of the legislation will be upheld at all times.

Analysis of pseudonymised data will be undertaken by the Chief Investigator (or delegate) on secure University of Leicester servers. Identifiable data (e.g. consent forms, contact details) will remain within the NHS site and will not be shared outside of the clinical care setting.

All research data will be pseudonymised at the point of collection and fully anonymised before analysis or dissemination. Pseudonymised research data will be stored for six years after study completion. Consent forms, enrolment logs, and participant identification records will also be retained for this period to permit verification of data integrity should it be challenged. At the end of this retention period, destruction of data will require Sponsor authorisation.

While participants are enrolled in the study, their contact details will be available to the research team for the purpose of scheduling research activities and sending reminders.

These details will be deleted once they have fulfilled their purpose, except where participants have explicitly consented to receive a copy of study findings. In such cases, contact details will be securely retained until dissemination is complete.

The Site File (SF) will be kept at the University Hospitals of Leicester NHS Trust in a locked cabinet within a secure office. All electronic records will be stored on password-protected servers with restricted access.

Archiving and long-term storage will comply with the University of Leicester Archiving Standard Operating Procedure.

12.6 Access to the final trial dataset

The Chief Investigator and their appointed deputies will have access to the analysed trial dataset following completion of data analysis and preparation of the End of Study Report.

13 Finance and Insurance

13.1 Funding

Funding has been received from Leicester, Leicestershire and Rutland Integrated Care Board (LLR ICB) in order to develop the OurPERSPECTIVE course. The funding is covering Dr Hayre's salary and has funded the creation of the course materials. The specialist nurse input of the course is through the University Hospitals of Leicester and additional expenses eg patient thank you vouchers and questionnaire licences, will be covered from the UHL gynaecological cancer research fund (U16).

13.2 Indemnity

Sponsorship and insurance for study design and management will be provided by the University of Leicester.

If a participant is harmed due to negligence and/or the conduct of the study, this will be covered by the local NHS Trust(s) indemnity arrangements for all participants in clinical studies. If a study participant wishes to make a complaint about any aspects of the way they have been treated or approached during the research project, the standard National Health Service complaint system will be available to them. Details of this are made available to participants in the PIS.

13.3 Contractual arrangements

No third-party contractual arrangements are required for this study.

14 Dissemination

14.1 Dissemination Policy

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by Leicester, Leicestershire and Rutland Integrated Care Board funding. .

14.2 Authorship eligibility guidelines and any intended use of professional writers

Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

Research participants will have the opportunity to receive a summary of the study findings. If they wish to receive a copy, this will be indicated on their consent form.

15 References

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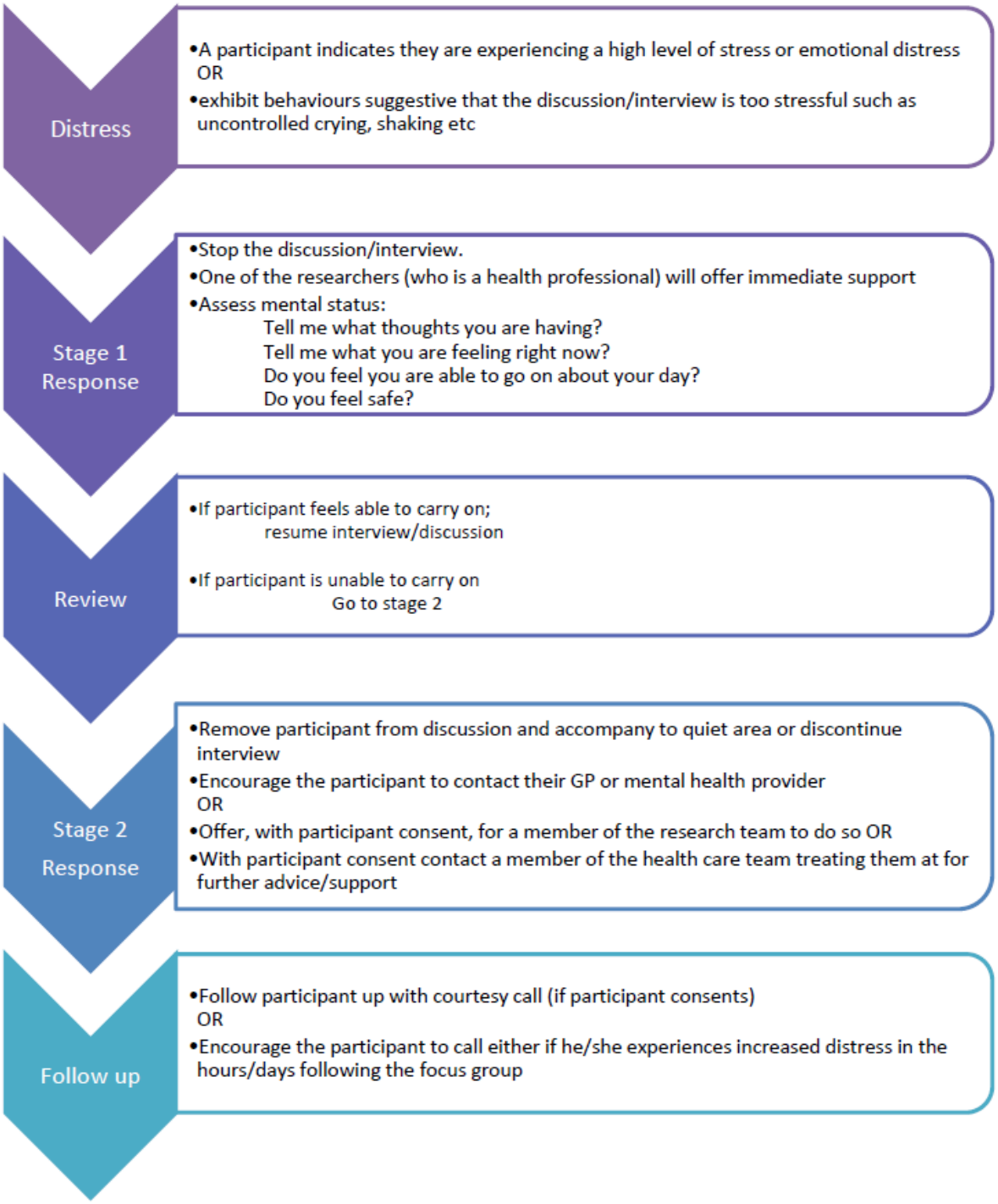
APPENDIX 1:

Distress Protocol 1:The protocol for managing distress in the context of a research focus group /interview
(Modified from : Draucker C B, Martsolf D S and Poole C (2009) Developing Distress Protocols for research on Sensitive Topics. *Archives of Psychiatric Nursing* 23 (5) pp 343-350)


Distress
•A participant indicates they are experiencing a high level of stress or emotional distress OR
•exhibit behaviours suggestive that the discussion/interview is too stressful such as uncontrolled crying, shaking etc
Stage 1 Response
•Stop the discussion/interview.
•One of the researchers (who is a health professional) will offer immediate support
•Assess mental status:
Tell me what thoughts you are having?
Tell me what you are feeling right now?
Do you feel you are able to go on about your day?
Do you feel safe?
Review
•If participant feels able to carry on;
resume interview/discussion
•If participant is unable to carry on
Go to stage 2
Stage 2 Response
•Remove participant from discussion and accompany to quiet area or discontinue interview
•Encourage the participant to contact their GP or mental health provider OR
•Offer, with participant consent, for a member of the research team to do so OR
•With participant consent contact a member of the health care team treating them at for further advice/support
Follow up
•Follow participant up with courtesy call (if participant consents) OR
•Encourage the participant to call either if he/she experiences increased distress in the hours/days following the focus group