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The feasibility of online Shared Reading for gynaecological cancers

Submission date 06/10/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol
Registration date 14/10/2025	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 14/10/2025	**Condition category** Cancer	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to understand if an online reading group is practical and acceptable for anyone affected by gynaecological cancers, and how it impacts their mental health, wellbeing, and quality of life. Participants will be taking part in a 6-week programme where they will read literature together as a group, for approximately 60 minutes, once per week, online. The reading will happen at the same time each week, and a calendar invite will be sent in advance.

Who can participate?
Patients aged 18 years old and over assigned female at birth who have been diagnosed with a gynaecological cancer (either receiving treatment or now cancer-free).

What does the study involve?
Participants may hear about the study through an online support group, social media, or their hospital's oncology team. To take part, individuals must be able to understand the study information, give informed consent, and communicate in English during the reading sessions. People who may struggle to understand the study or provide informed consent, such as those with limited English and no interpreter, or those with dementia or cognitive impairment, will not be included.

The first step for those who agree to take part is to complete a short online survey using a platform called Qualtrics. This questionnaire takes up to 10 minutes and helps determine eligibility. Eligible participants will be invited to join an online reading group led by Sonia Tomescu. The group will meet once a week for six weeks, at the same time and day each week, which will be arranged with participants. Sessions will last up to 60 minutes and take place via Zoom or Teams. They will not be recorded. Participants may choose to read aloud or speak, but simply listening is also welcome. The aim is to create a relaxed and comfortable environment. Occasionally, participants may be encouraged to share thoughts, feelings, or memories related to the reading, and all interpretations are valued.

To help evaluate the programme, participants will be asked to complete short questionnaires about their mental health, wellbeing, and quality of life. These will be sent two weeks and one week before the reading group starts, once during the first week, again at the three-week mark,

and at the end of the six weeks. Participants will also be invited to take part in an optional 30-minute interview to share their experiences.
Anyone who decides to stop taking part can let the team know, and they will not be contacted again. However, because the study aims to inform future services for people affected by gynaecological cancer, the team may follow up by email up to two times to ask a few short questions about the decision to withdraw. If participants prefer not to share their reasons, they can say so, and no further contact will be made.

What are the possible benefits and risks of participating?
Taking part in this research may offer several benefits. By sharing their experiences and insights, participants could help improve support services and resources for women affected by gynaecological cancers. Telling their story may also help them feel stronger and more connected to others with similar experiences. Their involvement will contribute to a better understanding of the topic and may help support more people in the future. As a thank you, participants who complete at least half of the oSR intervention will receive a £50 Amazon voucher (for example, this allows up to three missed sessions due to illness, appointments, or other unforeseen circumstances).

There are also some risks to consider. Some of the reading materials may be upsetting or difficult to understand. However, participants may feel differently after attending a few sessions. Participation is entirely voluntary, and individuals can choose not to take part or to withdraw at any time without giving a reason. If someone feels distressed during a session, they are encouraged to let the researcher know if a break is needed.

Where is the study run from?
The study will be run online, for convenience, via Zoom or Microsoft Teams. This means that the location within the UK or internationally will not affect the ability to participate.

When is the study starting and how long is it expected to run for?
January 2025 to June 2026. The recruitment for the study will begin in November 2025, but the literature reading will not start until January 2026. It is expected that the study will end around June 2026, but involvement will last 6 weeks.

Who is funding the study?
The study is funded by the South Coast Doctoral Training Partnership (SCDTP) and is sponsored by the University of Southampton, Department of Psychology. None of the researchers or study staff will receive any financial reward for conducting this study, other than their normal salary /bursary as an employee/student at the University.

Who is the main contact?
Sonia Tomescu, Psychology PhD student and Trainee Health Psychologist, University of Southampton, sts1e22@soton.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
348294

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 69110, Economic and Social Research Council Grant Codes ES/P000673/1

Study information

Scientific Title
Turning the Page: Evaluating the feasibility of online Shared Reading (oSR) for gynaecological cancers

Study objectives
Primary Objective: to assess the feasibility and acceptability of oSR for women affected by gynaecological cancers.

Secondary Objective: to explore preliminary individual-level outcomes of oSR on psychological wellbeing, distress, and quality of life (QoL).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 24/06/2025, HRA and Health and Care Research Wales (HCRW) (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; HCRW.approvals@wales.nhs.uk), ref: 25/PR/0739

Study design
Non-randomized study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Gynaecological cancer

Interventions
Recruitment
Following ERGO (University of Southampton) and NHS/REC approval, patients who attend their appointments at sites within the South-Central RRDN may be approached and informed about the study by a member of the clinical team, or they may see the research poster in the oncology waiting room (containing the research team details).

If needing to boost recruitment, the CI (ST) will promote the research project via the community (e.g., relevant charities such as Maggie's Centre, Macmillan and social media platforms such as LinkedIn, X, and Facebook support groups).

The contact information for the research team will be included in all invitation emails, posters, and the PIS to facilitate participant engagement.

Next steps
1. Initial contact
Patients who express interest in the study via Qualtrics or direct contact with the CI (ST) will be contacted via email by the CI (ST). The PIS will be shared via Qualtrics, and participants will have the opportunity to ask questions or express concerns before providing consent

2. Consent process
-Consent forms will also be accessed via Qualtrics (directly after the PIS) and will require the participant's digital signature. Qualtrics automatically allows participants to save a copy of their consent following the submission of their response. On request, the CI (ST) can also provide a copy to participants via email
-After consent, participants will be asked to complete screening questionnaires to ensure their eligibility.
-Participants who wish to take part in oSR sessions will add their email addresses to be contacted.
-Before the oSR intervention begins, the CI (ST) will confirm consent has been received and documented via email.

3. Participation in the Study
-To identify a suitable time for the oSR group, the CI (ST) will utilise an appointment scheduling software (e.g., Bookwhen, a UK-founded and NHS-approved encrypted scheduling tool that automates the process of booking meetings and appointments); this will provide some time options for participants to indicate their availability. The contact information for the group will not be visible to other members.
-The researcher will meet with the oSR group via an online platform (e.g., Zoom or Teams).
-Participants will be reminded of their right to withdraw at any time and will have an opportunity to ask final questions before the study begins.
-oSR sessions will not be recorded to maintain privacy.

Data collection
1. Screening Questionnaire

-Participants will complete a screening questionnaire via Qualtrics to assess their eligibility. Recruitment will be closed after 10 eligible participants have consented.
2. Demographics Questionnaire
-At baseline, participants will complete a demographics questionnaire along with the baseline measures, 3 times (-2 weeks, -1 week, and week 0 of the intervention), to establish stability in key measures before the intervention.
-Data will also be collected mid-intervention (week 3) and at the end of the intervention (week 6).

3. Optional qualitative interviews (post-intervention)
-Post 6-week oSR intervention, participants will be invited to an optional online interview via Zoom/Teams.
-The interview will last up to 30 minutes and will be conducted using a semi-structured interview guide. Interviews will be audio-recorded and transcribed. Audio recordings will be deleted after transcription.

4. Debriefing and Incentives
-As a token of appreciation, upon completion of at least half of the oSR sessions, participants will receive a £50 Amazon voucher as a token of gratitude for their time.

Intervention Type
Behavioural

Primary outcome(s)
Primary outcome measures (feasibility)
1. Recruitment demand will be measured by the number of eligible participants who express interest versus the required sample size, recorded continuously throughout the recruitment period.
2. Recruitment efficiency will be measured by the total time taken to recruit the target sample, recorded continuously throughout the recruitment period.
3. Reasons for declining participation will be measured through documentation of participant-reported reasons at the point of initial contact.
4. Retention rates will be measured by the percentage of enrolled participants who complete the intervention, calculated at week 6 (post-intervention).
5. Session attendance is measured by the number of oSR sessions attended per participant (out of 6 total sessions), recorded continuously from baseline (week 0) to week 6.
6. Intervention completion rate is measured by the percentage of participants who attend all 6 oSR sessions, calculated at week 6 (post-intervention).
7. Acceptability and satisfaction with the online Shared Reading (oSR) intervention will be measured using qualitative individual semi-structured interviews lasting up to 30 minutes, conducted at week 6 (post-intervention).
8. Reasons for dropout are measured through a brief exit survey administered at the point of participant withdrawal.

Key secondary outcome(s))
The following secondary outcome measures (preliminary individual-level outcomes) are assessed at baseline 1 (week -2), baseline 2 (week -1), baseline 3 (week 0), mid-intervention (week 3), and post-intervention (week 6):
1. Psychological distress will be measured using the Kessler-10 (K10)
2. Psychological wellbeing will be measured using the Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS)

3. Social quality of life will be measured using the World Health Organization Quality of Life Social Domain Subscale (WHOQOL-Social)
4. Global health and quality of life will be measured using the 2 global items from the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-30)

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Biological women aged 18 years or older
2. Diagnosed with a form of gynaecological cancer (e.g., cervical, ovarian, uterine, vaginal, vulvar or fallopian tube) as a primary diagnosis
3. Either in active treatment or remission

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Attending or previous attendance of SR groups, specifically
2. Women with cancer of unknown primary, or gynaecological cancer as secondary
3. Currently receiving other psychological interventions (e.g., counselling, CBT)
4. Unable to comprehend the study and/or provide informed consent (e.g., insufficient command of English in the absence of someone who can adequately interpret)

Date of first enrolment
01/11/2025

Date of final enrolment
31/01/2026

Locations

Countries of recruitment
United Kingdom

Study participating centre
-
United Kingdom
-

Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Research council

Funder Name
Economic and Social Research Council

Alternative Name(s)
Economic and Social Research Council (ESRC), ESRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	28/04/2025	13/10/2025	No	Yes
Participant information sheet	version 2	28/04/2025	13/10/2025	No	Yes
Participant information sheet	version 1	12/03/2025	13/10/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes