Participant Information Sheet

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

Researcher: Sonia Tomescu-Stachie
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Ethics/ERGO number: 101967

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You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others, but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

What is the research about?

My name is Sonia Tomescu, and I am a PhD student at the University of Southampton. This project is being conducted as part of my doctoral research. It 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 by conducting this study, other than their normal salary/bursary as an employee/student at the University.

In this study, we want to understand if an online reading group is practical and acceptable for anyone affected by gynaecological cancers, and how it impacts your mental health, wellbeing, and quality of life. If you join us, you will be taking part in a 6-week programme where we 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.

Why have I been asked to participate?

You may have learned about this project via an online support group or social media, or via the oncology team at your local hospital. We have invited you to participate because you were assigned female at birth, are over 18 years old and have been diagnosed with a gynaecological cancer (either receiving treatment or now cancer-free).

To take part, it is important that you are able to fully understand the study, provide informed consent, and communicate in English during the reading sessions. We are excluding individuals who may have difficulty comprehending this information and giving informed consent (for example, due to a limited understanding of English without someone available to interpret for them), or those who have dementia or cognitive impairment.

What will happen to me if I take part?

If you agree to take part in this study, the first step will be to answer a short survey using an online platform called Qualtrics. This questionnaire will take up to 10 minutes and will help us make sure you're a good fit for the study. If you are eligible, we would love to invite you to join a new online reading group that I (Sonia Tomescu) will be leading. To maintain consistency, the reading group

will take place each week on the same day and time (to be arranged with all who join). This will happen online, via Zoom or Teams, for up to 60 minutes, once per week, for 6 weeks. Sessions ***will not*** be recorded.

You are welcome to but are not required to read aloud or speak; **simply listening is perfectly acceptable too**. The goal is to create an environment where you feel comfortable and relaxed. I may, from time to time, encourage you and others to share their feelings, thoughts, and memories related to the reading. Each person interprets the text uniquely, so all opinions are welcomed.

To help us evaluate the programme, we will ask you to complete some questionnaires about your general mental health, wellbeing, and quality of life. These will be short in nature, and they will be sent out 2 weeks and 1 week before, and once during the week the reading group starts. Three weeks into the programme and at the end of the 6 weeks, you will be asked to complete the same short surveys again and will be invited to an optional interview lasting up to 30 minutes to share your thoughts and experiences of the programme.

If at any point you do not wish to take part anymore, please let us know and we will not contact you again. However, because we hope our results will be used to review possible services for people affected by gynaecological cancer, it would be helpful for us to know why you are no longer taking part, therefore we will contact you up to 2 times, via email, to ask you a few short questions. If you do not wish to share your reasons, then you can indicate this, and we will not contact you again.

Are there any benefits in my taking part?
Participating in our research can also have some advantages or benefits. Firstly, sharing your experiences and insights could lead to improved support services and resources for you and other women affected by gynaecological cancers. Sharing your story may be also make you feel stronger and connected to others who have gone through similar experiences. Plus, your involvement will help us learn more about this topic and support more people in the future.

At the end of the study, participants who completed at least half of the oSR intervention will be given a **£50 Amazon voucher** as a token of gratitude for your time (e.g., this allows you to miss up to 3 sessions due to illness, unexpected appointments, or unforeseen circumstances).

Are there any risks involved?
You may find some texts upsetting or difficult to understand. If you can give our sessions a chance, you *may feel differently* after a short while. Of course, you may refuse to participate in this study, as it's entirely voluntary. If you find yourself feeling troubled during sessions, you also have the right to withdraw without providing a reason for doing so, or you may want to share with the researcher when a break would be needed.

What data will be collected?
In our research, we will talk to you and other biological women. We will collect information using the online demographic questionnaire on Qualtrics. This information will include your name/initials, age, gender, ethnicity, education level, employment status, cancer diagnosis/stage/date of the diagnosis, other health conditions you may have, previous participation in shared reading programmes and current psychological treatment, if any. This combined information will give us valuable insights into how to better support you and other people facing gynaecological cancers, and how to improve overall wellbeing.

Will my participation be confidential?
Your participation and the information we collect about you during the research will be kept strictly confidential. Only members of the research team and responsible members of the University of Southampton may be given access to data about you for monitoring purposes and/or to carry out an

audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

Only the interviews (**not the 6 reading sessions**) will be audio recorded to accurately document the discussions. These recordings will be securely stored on dedicated University computer systems or encrypted laptops, following strict confidentiality protocols. This method ensures that sensitive information is protected. Once the interviews are complete, the data will be transcribed using Clipto.ai, a secure AI programme which will allow the research team to quickly and accurately turn our audio interviews into written text. After transcription, the recordings will be deleted to further safeguard your confidentiality.

The data, **when de-identified**, may be presented to others at academic conferences, or published as a project report, academic dissertation or in academic journals or books. The raw data, which would identify you, will **not** be passed to anyone outside the study team without your expressed written permission. Everything you say is confidential unless you tell us something that indicates you or someone else is at risk of harm. The exception to this will be any regulatory authority which has the legal right to access the data for the purposes of conducting an audit or enquiry, in exceptional cases. These agencies treat your personal data in confidence. We would discuss this with you before telling anyone else. Your personal data (e.g., email address, name) will be not be retained after finalising the research study. However, the raw data, such as the written transcripts, will be retained for a minimum of 10 years. When it is no longer required, the data will be disposed of securely (e.g. electronic media and paper records/images) and destroyed.

Do I have to take part?
No, it is entirely up to you to decide whether or not to take part. We will describe the study as best as possible in this information sheet, but you can always ask me (Sonia Tomescu) for further information. If you agree to take part, we will then ask you to digitally sign our consent form dated April 28th, version number 2.

What happens if I change my mind?
You have the right to change your mind and withdraw at any time by emailing sts1e22@soton.ac.uk without giving a reason and without your participant rights or routine care being affected. The consent form includes a statement that requests your permission to retain and analyse your anonymised study data, even if you choose to withdraw from the study. This means that if you withdraw from the study, we will keep the information about you that we have already obtained for the purposes of achieving the objectives of the study only. It is important to clarify any questions or concerns you may have about this statement with the research team.

What will happen to the results of the research?
Your personal details will remain strictly confidential and will be deleted after the study has ended. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent. The information collected will be analysed and written up as part of my PhD thesis and will be published in a journal or presented at a conference. The final research report will include direct quotes from the transcribed recordings; however, these will be anonymised as participants will be assigned a pseudonym. The final write-up for this paper is expected to be completed by the end of 2026, and any consenting participants will be provided with a copy of the results.

Where can I get more information?
After reading this information sheet, you can take your time to consider whether you want to be a part of the research. If you would like to take part, please contact me directly using the details below.

Chief Investigator (CI) –Sonia Tomescu, Psychology PhD student and Trainee Health Psychologist, University of Southampton: sts1e22@soton.ac.uk

What happens if there is a problem?
If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions.

If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Head Research Ethics and Governance (023 8059 5058, rgoinfo@soton.ac.uk).

Name and Contact Details of Researcher:

Sonia Tomescu-Stachie (sts1e22@soton.ac.uk)

Name and Contact Details of Researcher Supervisor(s):

Dr. Miznah Al-Abbadey (miznah.al-abbadey@port.ac.uk)
Dr. Andrew Merwood (andrew.merwood@porthosp.nhs.uk)
Dr. Katy Sivyer (k.a.j.sivyer@soton.ac.uk)
Dr. Sarah Kirby (Sarah.Kirby@soton.ac.uk)

Data Protection Privacy Notice

How will we use information about you?
For the purposes of data protection law, the University of Southampton is the 'Data Controller' for this study, we will need to use information from you for this research project. This information will include your:

- Name/Initials
- Email address
- Age
- Gender
- Ethnicity
- Education level
- Employment status
- Cancer diagnosis/stage/date of the diagnosis
- Any other health conditions you may have
- Previous participation in shared reading programmes
- Current psychological treatment

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. The University of Southampton is the sponsor of this research and is responsible for looking after your information.

We will keep all information about you safe and secure by:

- Handling data in accordance with the General Data Protection Regulations (GDPR) conditions, which came into force in May 2018 (e.g., audio recordings of the interviews will be saved with a participant number rather than your name or other identifiable information). Once transcribed into written text, the audio recordings will be deleted. Any specific medical details that arise during the interviews will be considered carefully to ensure they do not lead to identifying a specific participant.
- Having the collected data collected stored in a secure University of Southampton One Drive server with appropriate backup systems, anti-virus software and security protocols also compliant with NHS information governance standards.
- Having the data as only accessible by members of the researcher team, listed in the delegation log of the trial master file.

We have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep all pseudonymised information about you that we already have.
- You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this

Where can you find out more about how your information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK.

- Human Regulatory Authority (HRA) protects and promotes the interests of patients and the public in health and social care research, More information can be found at www.hra.nhs.uk/information-about-patients/
- the leaflet available from [www.hra.nhs.uk/patientdataandresearch]
- by sending an email to University's Data Protection Officer (data.protection@soton.ac.uk).
- by asking one of the research team or from our general privacy policy.
- by sending an email to sts1e22@soton.ac.uk, or by ringing us on 023 8059 5000

Thank you
Thank you for taking the time to read the information sheet and considering taking part in the research. Do not hesitate to ask me (sts1e22@soton.ac.uk) any questions if you are unsure about any aspect of the study.

If you are distressed before, during or after the study, please find some useful links to help guide you:

Talking Therapies Portsmouth – NHS Solent

Mental Health Guidance – NHS
Portsmouth Gynae Cancer Support Group – Macmillan Cancer Support
Samaritans any time at 116 123, or email jo@samaritans.org