EXPLANATORY STATEMENT
(Women with experiences of endometriosis and/or chronic pelvic pain)

Project ID: 37445
Project title: Endometriosis Management Plan (Endo-MP)

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You are invited to take part in a focus group as part of the consultation phase of the Endometriosis Management Plan (Endo-MP) project. The focus group, with a small group of women experiencing endometriosis and/or chronic pelvic pain, will seek to understand your experiences and views of current endometriosis management in primary care. We will also seek your input into how an endometriosis management plan might be used in Australian primary health care to improve endometriosis diagnosis and management. This research aims to reduce the delay between symptom onset and diagnosis, streamline referrals and transition between services, increase awareness of the impact of endometriosis, and increase efficiency in service delivery. The research is conducted through the SPHERE Centre of Research Excellence, Department of General Practice at Monash University. Please read this Explanatory Statement in full before deciding whether or not to participate in this research. If you would like further information, please contact a research team member via the contact information above or email: endo-mp@monash.edu or phone (03) 9902 4354.

What does the research involve?

The focus group aims to explore the experiences, perceptions and views of women with experiences of endometriosis and/or chronic pelvic pain. The study will strengthen our understanding of the needs of women with endometriosis and/or chronic pelvic pain, and determine how to develop an endometriosis management plan that can be successfully used in Australian primary care settings. Interested participants will be required to return a signed online consent form to the research team, prior to the focus group discussion. In addition, eligible participants will be invited to complete a brief, anonymous demographic questionnaire online to enable the research team to describe the participant sample.

De-identified, aggregate findings from the focus groups will be used to inform the development of an Endometriosis Management Plan prototype for piloting in Australian general practice settings. Participants are asked to join an online focus group (e.g. Zoom) for approximately 60-90 minutes with 5-8 women experiencing endometriosis and/or chronic pelvic pain and 1-2 researchers to discuss the abovementioned topics.

As part of the focus group, you will:

- Receive an overview of the Endo-MP project and the purpose of the focus group
- Provide feedback on your experiences of accessing care to diagnose and manage endometriosis and/or chronic pelvic pain in primary care.
- Provide feedback or suggestions on the need for a management plan in primary care to improve diagnosis and management for women experiencing endometriosis and/or chronic pelvic pain.
- Contribute to discussions to identify the needs of women experiencing endometriosis and/or chronic pelvic pain in primary care.

The focus group will be held online (e.g. Zoom) to be easily accessible and will be audio recorded to assist with transcription and analysis of the focus group findings.

Why were you chosen for this research?

We are sending you this Explanatory Statement because you have been identified: by SPHERE or partner organisations as someone who may have experience with or relevant insights into endometriosis or chronic pelvic pain, as a personal contact of the Endo-MP investigators, or as a participant in a previous research study who had indicated a willingness to be contacted about further research.

Source of funding

This project is funded by the Commonwealth of Australia, Department of Health and Aged Care, as part of the National Action Plan for Endometriosis. There are no declarable conflicts of interest.

Consenting to participate in the project and withdrawing from the research

You may express your interest in participating in this project or, if you have any questions, by emailing the Endo-MP team (endo-mp@monash.edu). Following this, a research team member will contact you via the details provided to confirm your eligibility, answer any questions, and send a link to an online, anonymous demographic survey before the focus group.

Participation in this study is completely voluntary. You are not under any obligation to participate. If you agree to participate, you can withdraw from the study at any time without adverse consequences. If you decide to withdraw from the study after the focus group has been completed, we will be able to delete your demographic information, but we will not be able to separate and delete your input from the focus group. There will be no negative consequences associated with refusal or withdrawal from participation.

Possible benefits and risks to participants

The focus group aims to understand the experiences of women with endometriosis and/or chronic pelvic pain, to facilitate the design of an endometriosis management plan prototype that aligns with the needs of patients and health professionals and has a high degree of utility in primary care. A management plan is expected to reduce the delay between symptom onset and diagnosis, streamline referrals and transition between services, increase awareness of the impact of endometriosis, and increase efficiency in service delivery.

The focus groups will explore the following topics:

- Participants' experiences of diagnosis and treatment of endometriosis and/or chronic pelvic pain in the primary care setting.
- Based on participants' experience, identifying the key areas of need for patients with endometriosis or pelvic pain, accessing the healthcare they need, and timely diagnosis and treatment in primary care settings. The key components that would be valuable in the development of an endometriosis management plan in general practice that would support the assessment, diagnosis and management of endometriosis and pelvic pain for patients.

We don't anticipate you will become distressed by participating in the study. To mitigate this risk, we have a distress protocol that we will follow. However, if you do experience any distress or discomfort from discussing your experience of endometriosis or chronic pelvic pain during the focus group, and wish to leave the discussion, you can exit the zoom meeting at any time. The focus group facilitator will contact you after the focus group ends (the same day, if possible) to ensure you are OK and to determine whether you require additional support.

If you experience any distress or discomfort from participating in the study, the following services can be contacted for support after the focus group:

- The researcher via email (endo-mp@monash.edu) or phone (03) 9902 4354 to discuss your concerns. If needed, the researcher will arrange for you to talk with a GP/researcher who collaborates with the Endo-MP team.
- Beyond Blue: https://www.beyondblue.org.au/ or https://online.beyondblue.org.au/#/chat/start
- Your local general practitioner or healthcare provider.

Remuneration

Focus group participants will be reimbursed $50 for their time. This will be provided after the session in the form of an e-gift card.

Confidentiality

All aspects of this study, including results, will be strictly confidential and only the principal researchers will have access to information provided by participants. No individual data will be disclosed, and all data will be de-identified upon analysis and reporting.

Storage of data

Any data collected will be stored on a secure drive on the Monash server. All electronic data (e.g. participant databases) will be password protected and only accessible to the researchers. Where non-Monash University parties require access (e.g., project investigators from other organisations), secure data exchange methods such as password-protected USB drives, encrypted files, or a secure cloud storage folder (e.g., Cloudstor, Onedrive) will be used. Any written data will be compiled into a MS Word document. Focus group activity sheets will be scanned along with all other documents stored on Monash University password-protected computers, and disposed of after five years in line with university protocol.

Use of data for other purposes

Secondary use of data increases the value of your data. The aggregated de-identified data collected may be used for purposes other than this study, where ethics approval has been granted.

Results

Data from the focus group will be utilised to design and identify the content for the Endo-MP prototype in a co-design workshop. We expect to present de-identified findings from the focus group, in addition to interviews with general practitioners and key stakeholders at conference(s) and publish our findings in a peer-reviewed journal. Abstracts of conference presentations relating to our study or links to journal publications can be directly shared via email or post. Participants can be provided with a report of findings from the research by the implementation team upon finalisation and publication of results. Participants can contact the Endo-MP team via email (endo-mp@monash.edu) or phone (03) 9902 4354 to request a copy of the published results.

Complaints

Should you have any concerns or complaints about the conduct of the project, you are welcome to contact the Executive Officer, Monash University Human Research Ethics Committee (MUHREC):

Executive Officer
Monash University Human Research Ethics Committee (MUHREC)
Room 111, Chancellery Building D, 26 Sports Walk, Clayton Campus
Research Office
Monash University VIC 3800

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Thank you,

Danielle Mazza

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in Women's Sexual and Reproductive Health in Primary Care