

Early Menopause: Using the Experiences and Perspectives of Women and Health Professionals to Translate Evidence into Practice (Qualitative study & Consumer Online Resource)

EXPLANATORY STATEMENT

For women with experience of early or premature menopause

This project is being conducted by Professor Helena Teede (Monash University), Professor Renata Kokanovic (RMIT University), Associate Professor Amanda Vincent (Monash University), Professor Roger Hart (University of Western Australia), Dr Jacqueline Boyle (Monash University), and Professor Martha Hickey (University of Melbourne).

This research is a partnership between researchers from Monash University, RMIT University, University of Western Australia, University of Melbourne, the National Breast Cancer Foundation, Women's Health Victoria, Endocrine Society of Australia, Breast Cancer Network Australia, Australasian Menopause Society, Monash Health and Healthdirect Australia.

We will produce an online resource (hereafter 'website') detailing women's experiences of what it is like to go through early or premature menopause, including following cancer treatment. The website will also feature downloadable materials women can use to assist them in discussions with their health professionals.

Before you decide if you want to take part, we want to tell you why the research is being done, and what you can expect if you take part. After reading this, talk about it with friends, relatives and your health professional if you wish. Contact us if you have any other questions. Please take as much time as you need.

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You are invited to take part in this study. Please read this Explanatory Statement in full before deciding whether or not to participate in this research. If you would like further information regarding any aspect of this project, you are encouraged to contact the researchers via the phone numbers or email addresses listed above.

What is the purpose of this research?

This project examines the experiences and perspectives of women with early or premature menopause (menopause occurring before age 45 or 40 years respectively). This may be 'spontaneous' or following medical treatment (e.g. chemotherapy, radiotherapy or surgical removal of the ovaries). The stories collected in the research project (in video, audio (voice only) and / or written format) will be used to produce a Healthtalk Australia (healthtalkaustralia.org) website aimed at supporting and informing other women with early or premature menopause as well as their family members about what it is like to have this condition. The website also aims to inform health professionals, health service providers and policymakers about the experiences of and challenges faced by women with early menopause. The website will also feature downloadable materials such as factsheets and Question Prompt Lists (QPLs) which women can use to assist them in discussions with their health professionals.

We will collect video, audio and written interviews. With interviewees' permission, selected excerpts from these interviews will appear on the website. The interviews may also be used in the following ways:

- to develop support and information resources
- to train health and allied health professionals
- to write research papers and books

The idea is that our website will help:

- improve understanding of what it is like to experience early or premature menopause
- improve knowledge of what really matters to women when they experience early or premature menopause
- answer common questions and provide information
- women to have more informed discussions with health professionals about early or premature menopause
- health professionals to more effectively diagnose, manage and treat early and premature menopause and support women experiencing these conditions.

Women who are faced with difficult choices (e.g. which treatments to choose, what kind of health professional to consult) will be able to visit our website to find out how they can access help to make their decisions. Carers or partners of women experiencing early or premature menopause will be able to hear stories from others in a similar position. Health and allied health professionals, health service providers or health policymakers who want to understand what it is like for women to experience early or premature menopause can also visit the website.

What does participating in the research involve?

The study involves an interview with a researcher on our team about experiences of and views about early or premature menopause. It will be held at a time and place convenient for you. You can choose to have your interview either video or audio (voice only) recorded and you can choose whether you have excerpts from your interview presented on the website in written, audio or video format. There will also be a small amount of paperwork to do before and after the interview.

Before the interview:

If you were given / sent this **Explanatory Statement**, you will need to complete and send back the enclosed / attached **Expression of Interest** form to us, or email it to MCHRI-earlymenopause@monash.edu so that a researcher is able to contact you. A researcher will then ring or email you to arrange an interview at a time and place that suits you, and answer any questions you may have about the interview or the project. If the

location of the interview is not your home, you will be reimbursed for the cost of your public transport travel. A few days before the interview, the researcher will once again ring or email you to confirm the interview date, time and location.

On the day of the interview:

The researcher will show you an existing Healthtalk Australia (healthtalkaustralia.org) website which is similar to the one that will be produced for this project on a laptop computer. You can see how clips from other people's interviews look in video, audio and written formats. The researcher will then ask you if you are willing to have the interview video or audio recorded. You will be given a **Consent Form** – only sign this form if you agree to take part in the interview. You will be given a copy of your signed **Consent Form** to keep.

The researcher will also give you a **Participant Details Form** and go through this with you. The form will contain questions about some basic details (e.g. age, relationship status, children if any, occupation, education). This information is for our records and your 'Participant Profile' (see below). You will be asked if you would like to use a pseudonym (false name) on the website.

If you agree to have your interview video-recorded, the researcher will need to choose a suitable location for the interview (within your home or the place the interview is being conducted) and set up the equipment. Once they are ready, they will then offer to record you for less than a minute before the interview begins, talking about a general topic of interest. You can then view the recording (on the camera screen) to ensure you are comfortable with how you appear in the video recording.

During the interview, which will be like a conversation, the researcher will ask you to talk about your experiences of early or premature menopause. They will ask you questions about when you first noticed symptoms, what it was like seeking help and being diagnosed, how you made / make decisions about treatment, your experiences with health professionals, how early or premature menopause has impacted on your lifestyle, general wellbeing, relationships and sense of self, how you think and feel about early or premature menopause in relation to your experience of cancer if you have had cancer, how you would like to be best supported, and what other services or information you think should be available to women experiencing premature or early menopause.

After the interview, the researcher will also give you a **Copyright Form** to read, and talk you through the implications of signing this and the process of reviewing your transcript (written record of the interview). Should you agree to granting copyright of your interview after the interview, you will need to sign the **Copyright Form**. This means that you give copyright of the interview to Monash University to use your interview audio and / or video recording or the written form of your interview (N.B. written interviews and audio recordings can be de-identified) for broadcasting, research and teaching. It is very important that you take time to think about and discuss the **Copyright Form** before you sign it. If you like, you can also sign it later when you review and return your transcript. Once signed, you will be sent a copy of your signed form to keep.

Your interview will be used along with interviews from around 40 other women who will also be talking with us about their experiences of early or premature menopause. Summaries of the topics covered in these interviews ('Talking Points') will be prepared for the website. People who use the site will be able to see the Talking Points as well as read extracts from the interviews, view video clips and listen to audio clips from interviews with people who agree to such use of their interviews. The interviews we collect will contribute to the information presented on the site, and extracts will be used to highlight some points.

The interviews will not be used for profit or commercial gain. As well as the website, we may use the interviews to help create other information and support resources, such as DVDs or short films, and extracts from the interviews (video, audio or written) may be shared on social media through pages such as DIPEX International on Facebook or Twitter, or appear on other women's health websites. These may be shown to people by health professionals as part of their training. All the interviews we collect will be included in our analysis for preparing research articles and papers.

In the weeks / months following the interview:

We will send you a copy of your interview transcript via post or email (according to your preference) and ask you to read over it. If there are any parts you wish to be removed, we will ask you to mark these and send the transcript back to us. Along with the transcript, we will also send you your 'Participant Profile' – a 500 word summary of your story that will appear on the website for you to check and approve. We will ask you to return all these documents by email or reply paid envelope (including your signed copyright form if you did not sign this straight after the interview). Finally, once the website is ready to go live, we will invite you to the website launch and send you the website address.

How much time will the research take?

The time it will take for the interview varies, depending on how much you would like to share, but most interviews last between one and two hours. Remember, if you want to stop the interview at any time, you can do so without giving any reason at all. Communicating with us before and after the interview (setting up an interview date and time checking the transcript and your 'Participant Profile') will take up to two hours, and potential travel to the interview location up to one hour.

Inconvenience/discomfort

Participation in the study is not expected to have any particular risks for interviewees. While people sometimes find it helpful to talk about their story with researchers, it is important to remember that research is not the same thing as counselling. If you become upset or distressed during the interview, you may take a break from the interview or we can visit you another time to finish the interview. We will also provide you with a list of organisations that offer counselling or other support that you may contact for further support as needed. You are also free to withdraw from the study at any time.

Why were you chosen for this research?

We would like to interview women between the age of 20 and 45 with experience of early or premature menopause (EM / PM), including spontaneous EM/PM, or EM/PM due to medical treatment (medically-induced) including breast cancer, ovarian cancer or uterine cancer, surgical removal of ovaries, or chemotherapy for non-cancer cause. If we have your contact details, you will have learnt about this study from an advertisement or information provided in a service you access.

Who can participate?

Women aged 20-45 years living in Victoria with either spontaneous or medically-induced early or premature menopause. Early menopause is defined as no menstrual periods for 12 months (amenorrhoea) before age 45; premature menopause is defined as 12 months amenorrhoea before age 40. Medically induced early or premature menopause can follow oophorectomy (removal of the ovaries), chemotherapy or radiotherapy.

Source of funding

Funding for this research has been provided by the National Health and Medical Research Council (NHMRC Partnership Project APP1116008), National Breast Cancer Foundation, Women's Health Victoria, Endocrine Society of Australia, Breast Cancer Network Australia, Australasian Menopause Society, Monash Health and Healthdirect Australia.

Consenting to participate in the project and withdrawing from the research

Being in this study is voluntary and, if you decide to participate, you are free to leave the study at any time. The process for consenting to participation is described on page 2 of this **Explanatory Statement** ('On the day of the interview'). If you decide to leave the study after your interview has taken place, all video / audio files, transcripts and notes associated with your interview would be destroyed. If you decide to leave after the website or other audio-visual resources have been finished, we would remove your contribution from all later versions, but we would not be able to destroy existing material, which other people could already have accessed or copied. Please note that if you agree to be on the website in video format, and then change your mind after the website has been produced, it is not possible to change the presentation of your material to audio or written – if you were unhappy with video format, the only option would be to have your material completely removed from the website.

Possible benefits and risks to participants

We cannot guarantee that you will receive any direct benefit from this project other than the opportunity to talk with a researcher about your experiences of and views about early or premature menopause. Your input will enable us to contribute valuable information to the website which will be of benefit to others going through similar difficulties, as well as their partners or family members, health professionals, and policymakers.

Participation in the study is not expected to have any particular risks for interviewees. While people sometimes find it helpful to talk about their story with researchers, you may become upset or distressed during the interview, so please take a break from the interview if required or we can visit you another time to finish the interview. We will provide you with a list of organisations that offer support that you may contact as needed. You are also free to withdraw from the study at any time. See also 'Confidentiality' below.

Services on offer if adversely affected

The researcher will provide you with a list of services and associated contact details who can support you and who are not related to the researchers/research team.

Payment

There will be no payment offered for participation in this research. After the interview, a small gift voucher will be offered in appreciation of your contribution and assistance.

Confidentiality

The main uses of the information you provide in the interviews will be to produce a website, and to write research articles and book chapters. In research articles and book chapters, your information will not be identifiable – pseudonyms will be used and other identifying information will be removed. On the website, you will have a choice about whether a video, audio or written version of your interview is used and whether or not you use a pseudonym.

If you choose to have your video recording used, you will be potentially identifiable on the website, however you can still use a pseudonym for yourself and other people and places you mention, and you can keep out of the interview anything which might identify you.

You may wish to discuss this with members of your family, since they might possibly be connected to your appearance on the screen. If you are recognised on a website or a DVD, this would be a little like appearing on TV.

If you choose to have your audio recording used, and you use a pseudonym for yourself and others and keep anything that might identify you out of the interview, it is less likely you will be identifiable. If you use only a text version and pseudonym, it is even less likely you will be identifiable. The material on the website is protected by copyright and people are not allowed to copy or record what they find there, but it is possible that they could. If you have any doubts about how you want the interview to be included on the website, please talk to the researchers.

Storage of data

Electronic data: All audio and video files, transcripts, 'Participant Profiles,' and scanned copies of forms (participant details / consent / copyright) will be stored in password-protected files on Monash University's School of Social Sciences computer system for five years after data collection is complete. After this time, original transcripts and 'Participant Profiles' will be deleted, but with your consent, the remaining data (audio and video files, de-identified transcripts, and scanned copies of participant details / consent / copyright forms) will be retained indefinitely in password-protected files on the Monash University School of Social Sciences computer system for secondary data analysis on related future research projects for which ethics approval is obtained. During this time only researchers named on the approved ethics application will have access to this information, and selected staff from the organisation responsible for production of the website, which has undertaken to comply with privacy legislation.

Physical data: Hard copies of documents (participant details forms, copyright forms, consent forms, returned copies of transcripts, returned copies of 'Participant Profiles') will be kept in a locked filing cabinet in the Research Fellow's office until three months after the website launch. During this time only researchers named on the approved ethics application will have access to this information. Three months after the website launch these documents will be destroyed by shredding.

Website data: The website will remain live indefinitely and will be updated every two years. You may request your data be removed from website at any time, even after the website is published. The researchers cannot guarantee however that your information from previous versions of the website has not been copied and disseminated elsewhere.

Use of data for other purposes

In addition to your data being used for secondary analysis or future research as described above, your de-identified data may be used for other purposes. Because it is de-identified data, you will not be named or identified in any way. Aggregate de-identified data may only be used for other projects where ethics approval has been granted.

Results

The project findings will be published via the website, academic journal articles, a report to the funding body as well as possible educational materials such as DVDs or other resources aimed at people who have received a diagnosis of early or premature menopause, their family, health service providers and practitioners, and policymakers. If you would like to be informed of the aggregate research findings, please contact Professor Renata Kokanovic (details on page 1). The findings are accessible for five years from the date the website goes live.

Complaints

This study has obtained ethics approval from the Monash University Human Research Ethics Committee (MUHREC) (2016-1429). Should you have any concerns or complaints about the conduct of the project, you are welcome to contact the Executive Officer, MUHREC (details over the page):

Executive Officer
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Thank you,

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