

TAPER DCE interview sub-study

Participant information leaflet

What is this study?

- The TAPER DCE interview study will explore what matters most to women and their doctors/nurses when women are considering stopping or restarting HRT. We hope that this information will help us to improve care for women in the future. (the **TAPER DCE sub-study**).
- *This study forms part of a larger programme of research called **DisconTinuAtion of hormone rePlacement thERapy (TAPER study); How and why do women decide and experience stopping HRT, why do women decide to restart and is a clinical trial comparing stopping methods feasible?***
- You can find out more information about the TAPER Study via this website or using the QR code: *website to be created*



Why should I get involved in this study?

- Stopping HRT often leads to menopausal symptoms returning. This can be problematic, and some women then choose to restart HRT. This can negatively affect women and also increase healthcare visits and healthcare costs.

Why is this study important?

- We will look at what matters most to women when women are considering stopping or restarting HRT. We have designed a decision making survey and we want to talk to you about the survey and will ask you to “think-aloud” while completing it. This will help us make the survey better and it will then be completed by more women.
- These results will show what women consider important when stopping/restarting HRT.

Why have I been invited to take part?

- You have been invited because you have (in the last 3 years) or are in the process of stopping your HRT, regardless of if you restarted or not.

What will I have to do to take part?

- You will be invited to take part in an online (e.g., via Zoom, Teams, WhatsApp) or phone interview with a member of the TAPER qualitative team.
- Interviews typically last for about under an hour, but this depends on how much you have to say.

- With your permission, the interview will be either video and/or audio recorded if done on remote platforms or audio recorded if done by phone to allow the researcher(s) to pay full attention to what you are saying and enable the research team to do further analysis later.
- If you agree to take part in an interview, the research team will ask you complete a consent form and a short background questionnaire, so we know a bit more about you (e.g., your age, ethnicity).
- Consent can be given in several ways, including written, electronic or verbally recorded.

What are the benefits of taking part?

- The research might not directly benefit you, but what you tell us may help us to improve care for women and the information available to HCPs who care for these women.
- At the end of the interview, you will be offered a £25 voucher to thank you for your time.

What are the risks of taking part?

- There are no physical risks to taking part in this study. However, conversations in the interview may be upsetting as they may relate to your personal experiences.
- If this happens, we will ask you if you want to stop and have a short break, or if you want to stop completely.

Do I have to take part?

- No. Taking part in this study is voluntary. If you decide to take part, you will be asked to complete a consent form. However, you will be free to withdraw at any time without giving us a reason.
- If you decide to withdraw within two weeks of your interview, then we will securely destroy your data wherever possible.
- If you withdraw more than two weeks after the interview, then we will continue to use your anonymised data as it will have been included in our ongoing analysis by that point.
- If you wish to withdraw, please contact the TAPER qualitative team using the information provided below.

Will my taking part be kept confidential?

- All the information collected as part of this study will be handled strictly in accordance with your consent, the Data Protection Act 2018 as part of the UK General Data Protection Regulations (GDPR).
- Very occasionally, interviews/discussions bring to light information about a participant that could affect their welfare or the welfare of others.
- If this happens during your interview/discussion group, then the researcher may need to disclose this information to the relevant authority/agency.

- Certain welfare concerns may override concerns about confidentiality. Where possible, the researcher will talk to you about this.

What will happen to any information that I give?

- The audio/video-recording of the interview may be transcribed by a specialist transcription company who will sign an agreement to keep your data confidential and stored securely. We will analyse the transcripts as part of our research.

What will happen to the results of the study?

- The results of this study will be used to develop a study looking at different methods of HRT discontinuation.
- The results may be published in academic journals, presented at conferences, and used to inform policy and practice.
- Please note that you will not be identifiable in any study related report.
- Results will be made available on the TAPER website – please scan the QR code or use the web address available at the end of this leaflet.

Who has funded and reviewed the research?

- This study has been funded by the National Institute for Health Research (Grant reference: NIHR 304353). It is organised managed and coordinated by the University of Birmingham where data will be securely stored.
- The study has been reviewed and had approval from the NHS research ethics committee
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What if there is a problem?

- If you are not satisfied with the way you have been approached or treated during this study, please speak to the researcher(s) first. Our contact details can be found below.
- You can also contact the lead researcher for the TAPER study, Dr Sarah Hillman (s.c.hillman@bham.ac.uk)
- If you wish to complain formally, you can contact the University of Birmingham Research Ethics team_researchgovernance@contacts.bham.ac.uk.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your name, age, language spoken, job, highest qualification, ethnicity, and contact details. People will use this information to do the research and make sure that the research is being done properly.

The University of Birmingham is the sponsor of this research.

University of Birmingham is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- A University approved transcription company

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

- All study data collected on paper will be held securely, in a locked room or locked cabinet that is accessible only to the research team and relevant regulatory authorities.
- All study data in electronic form will be held on secure networks/encrypted and password protected computers.
- Audio files will be transcribed by a specialist external company subject to a Confidentiality Agreement/Personal data transfer agreement to not disclose any information to third parties. Files will be transferred via a secure server with user identifiers and passwords.

Research team contact details

Email us via s.c.hillman@birmingham.ac.uk add RF email

Call on phone to be confirmed

Visit the TAPER study website: web address to be confirmed

Thank you for taking time to read this information leaflet and for considering taking part in the TAPER DCE interview sub-study