

DisconTinuation of hormone re Placement thERapy (TAPER study); How and why do women decide and experience stopping HRT, why do women decide to restart?

TAPER qualitative sub-study

Participant information leaflet: Women

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 qualitative 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:*
<https://www.birmingham.ac.uk/research/projects/taper-study>



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 and their doctors/nurses when women are considering stopping or restarting HRT. We will interview women and healthcare professionals to hear their views. Next, we will use this information to design a special type of survey to find out why women decide to restart HRT and how they weigh up the pros and cons of doing this. 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?

- We want to make sure that in this research we speak to a wide range of women. To make sure we do, we will ask some quick questions about you and your treatment for menopause. This information will be used to decide who we need to speak to (for example if we have not spoken to any women over the age of 55 we may prioritise this age group).
- Once we have this information we will organise (by text, whats app or email) a telephone call with you so that we can set up an interview time and run though some questions to make sure you are eligible to take part (i.e. that you are over 45 years old and tried or have stopped your HRT in the last three years)
- Once your eligibility is confirmed we will take your consent
- Consent can be given in several ways, including written, form sent via email or verbally recorded.
- 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.
- 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).
- 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.
- You do not have to answer all questions, should you choose not to.
- If needed you can stop the interview and restart at a different time/date.
- The interview will normally take between 30minutes and 1 hour
- You will be asked for a backup telephone number in case the connection is lost during your interview. This number will be destroyed at the end of the interview.
- The study will end once data has been collected from the last participant.

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 £10 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 you become upset, 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, 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?

- Interviews will be recorded and kept safe on a secure password protected network drive at the University on a password protected device
- 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.
- The recordings will be transcribed within 12 months and once the transcription is received and checked by the researcher, will be deleted

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 North West - Liverpool Central Research Ethics Committee

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 patient advice and liaison service (PALS) <https://www.nhs.uk/nhs-services/hospitals/what-is-pals-patient-advice-and-liaison-service/> for NHS patients or contact the sponsor's office as an independent University of Birmingham representative using 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
- contact details.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

The University of Birmingham is the sponsor of this research.

The 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:

- University approved transcribing services

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.

International transfers

- Your data will not be shared outside the UK.

How will we use information about you after the study ends?

- 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.
- We will keep your study data for a maximum of 10 years. The study data will then be fully anonymised and securely archived or destroyed.

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 information about you that we already have
- you have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. 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
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

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

You can find out more about how we use your information:

- by asking one of the research team
- by sending an email to taper@contacts.bham.ac.uk, or
- by ringing us on 07717 444813.
- Our leaflet (URL to add)
- Visit the TAPER study website: [web address to be confirmed](http://www.taperstudy.com)
- By contacting our UK representative at researchgovernance@contacts.bham.ac.uk

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