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Discontinuation of hormone replacement therapy: TAPER study

Submission date
06/11/2025

Recruitment status
Recruiting

Registration date
02/02/2026

Overall study status
Ongoing

Last Edited
02/02/2026

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Many women experience symptoms like hot flushes and joint pain during menopause. Hormone Replacement Therapy (HRT) is often used to help with these symptoms. However, some women stop taking HRT because of concerns about long-term risks, such as breast cancer. When they stop, symptoms can return, and some women decide to restart HRT. This study aims to understand why women stop HRT, what matters to them when thinking about restarting it, and how healthcare professionals support these decisions.

Who can participate?
Women who have used HRT and either stopped or restarted it, as well as healthcare professionals who support women through menopause, may be invited to take part.

What does the study involve?
Participants will be asked to take part in an interview to share their experiences and views. There will also be a survey to help researchers understand the reasons behind restarting HRT and how women make these decisions.

What are the possible benefits and risks of participating?
Taking part may help improve understanding and support for women going through menopause. There are no major risks, but some people may find it emotional to talk about their experiences. Support will be available if needed.

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
337336

Central Portfolio Management System (CPMS)
59760

National Institute for Health and Care Research (NIHR)
304353

Study information

Scientific Title

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

Acronym
TAPER

Study objectives
Aim:
Investigate why women stop Hormone Replacement Therapy (HRT) and what they value when considering restarting it.

Objectives:
1. Interview women and healthcare professionals about their experiences and views on stopping and restarting HRT.
2. Design a survey to understand why women restart HRT and their decision-making process.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/06/2025, North West - Liverpool Central Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; Liverpoolcentral.rec@hra.nhs.uk), ref: 25/NW/0168

Primary study design
Observational

Study design
Observational qualitative

Study type(s)
Other

Health condition(s) or problem(s) studied
Use of Hormone Replacement Therapy

Interventions
Project Plan
At the outset, I will establish three groups:
PPI Panel consisting of women (with experience of stopping HRT) from diverse backgrounds.
Project Research Group (PRG) consisting of women (from menopause charities/groups), GP, menopause specialists, clinical pharmacist, an expert in menopause trials, an expert in primary care trials, statistician, and a health economist.
Independent Project Steering Committee (PSG) consisting of an independent chair, two independent members of the public, an independent statistician, health economist, and expert in clinical trials. The PSG will meet every 10–12 months to provide independent oversight to the project's development and progression.

Qualitatively evaluate the experiences of women stopping HRT and the views of healthcare professionals (HCPs) caring for them.

Part 1: Designing the Interview Schedule
Using evidence from a scoping review examining the experiences and views of women stopping HRT and the HCPs advising them, and the experiences of the PPI panel and PRG, I will develop a semi-structured interview schedule to determine the experiences of women that have stopped or are stopping HRT.

The interview schedule for women will be developed as described but may include: why women chose to stop, how women stop, if they sought advice from an HCP and advice given, resurgent symptoms and whether they restarted HRT or other treatments, the impact of stopping on quality of life and responsibilities. Also, if women have equipoise around abrupt stopping vs tapering and willingness to take part in a clinical trial.

The interview schedule for HCPs will be informed as above but may include: establishing why HCPs advise women to stop, at what age and after what duration of HRT, how they advise women, if women re-consult with resurgent symptoms, if they re-prescribe HRT or other treatments, and if they have equipoise around abrupt stopping vs tapering and willingness to recruit to a future trial.

Part 2: Interviews with Women and HCPs
With a research fellow (RF), I will interview women who have discontinued HRT within three years or are currently tapering HRT (n=20–30). The total sample size will be guided by data saturation (no new themes emerging). Data analysis will run parallel to data collection. Women will be identified and recruited through general practice (where most HRT is prescribed and advice to start/stop is provided). I will employ purposive sampling, populating and monitoring a participant matrix to ensure participation from a diverse group, focusing efforts to include South Asian and Black women and those from low socioeconomic status. Translators will be provided for interviews when required.

We will interview HCPs involved in the care of women taking HRT (n=15, sample size guided as above). These may include GPs, advanced nurse practitioners, physician assistants, and clinical pharmacists. Purposive sampling will be employed to ensure we recruit a diverse range of practitioners including gender, year since qualification, job role, and interest in women's health. For both women and HCPs, interviews will be by telephone or virtually (Microsoft Teams).

Recruitment
Women will be recruited through general practices (through the primary care NIHR CRN). We will approach practices in the West Midlands serving a diverse population (by IMD quintile and ethnicity). Practices will act as Participant Identification Centres and will search for women that have discontinued HRT in the past three years (to limit recall bias). Women will be sent a text message or letter to direct them to study information and screening for eligibility. HCPs will also be recruited through GP practices.

In addition, I have established links with community organisations (South Asian Health Foundation, Cysters, and Black Women in Menopause) and they will recruit through these groups using their social media pages and WhatsApp groups to include seldom-heard women. To maximise recruitment, we will also employ a snowball sampling strategy and ask participants to share study information with other women from within their community they feel would be interested in taking part.

When women express an interest to be included in the study, they will be sent a copy of the PIS either via email or text message/WhatsApp. They will also be sent a copy of the consent form. Women will be sent a demographic form in order to purposively sample participants. Following

this, we will contact the participant by phone to arrange an interview date/time and check for eligibility using the inclusion and exclusion criteria. This phone call will happen at least 48 hours before the interview.

At the start of the interview or focus group, the interviewer will go through the information sheet and reiterate the information from the sheet, specifically that participants can ask questions and withdraw from the study at any point without providing a reason. Participants who want to proceed will then be asked to consent to taking part.

For face-to-face interviews or focus groups, consent will be obtained by ticking all boxes on the consent form and signing the consent form. For telephone or remote video interviews, participants will be asked all questions on the consent form and for their name. Only if the participant answers all questions with 'yes' and provides their name will consent be obtained. Oral consent will be audio-recorded.

Analysis
All interviews will be transcribed verbatim by a University-approved transcription service. Transcripts will be checked for accuracy and anonymised. Qualitative data from interviews will be analysed by two researchers (SH and an RF). Taking an iterative approach, we will start data analysis simultaneously with data collection using framework analysis to compare experiences. Thematic analysis will accommodate the inductive nature of the topic and allow themes (unexpected and expected) to be identified. A matrix will be created, with 'cases' against 'codes'. Nvivo software will be used to support this process.

Use a Discrete Choice Experiment (DCE) to establish what women value most when deciding to restart HRT
A key outcome measure for successfully stopping HRT is not restarting. Little is known about why women choose to restart. A DCE experiment will allow understanding of the importance that women place on attributes to restart. In a DCE, participants are presented with hypothetical scenarios (choice sets). Each choice set is made up of several options. Each option consists of several attributes and each attribute has one or more levels measuring a different aspect of the outcome of interest. Understanding how women value these choices will allow quantification of the trade-offs individuals make.

I will conduct a 4-stage process to establish the DCE:
Stage 1: A scoping review (completed 2025) allowing me to create a "long list" of potential attributes (variables) that women consider when deciding to restart HRT (examples include resurgent VMS, cancer risk, vaginal bleeding). I will include the views of our PPI participants and project research group.
Stage 2: Qualitative development of the DCE tool (survey) using data gathered in WP1 from women and HCPs regarding attributes women consider when restarting HRT and a systematic review and meta-analysis of qualitative studies will allow me to refine the attribute list.
Stage 3: Attribute and level selection. The PRG/PPIE panel will meet independently virtually to reduce the attributes list to a manageable number. Too many attributes increase the complexity of individual tasks resulting in attribute non-attendance (not all attributes are considered equally, resulting in biases). Most studies limit attributes to six. Criteria such as context, correlation between attributes, relevance, and capability of being traded will be used as part of the assessment. The DCE instrument will be designed in light of best practice, will use a fractional factorial design, and have oversight from a health economist.
Stage 4: Piloting
I will interview ten participants (see recruitment below) using a think-aloud approach whilst participants complete the questionnaire. Understandability of attribute definitions/levels,

survey length, and ability to complete independently will be iteratively evaluated. Participants will verbalise their thought process when completing the DCE, giving insight for tool refinement. The PRG/PPIE panel will meet a second time to review the results and make refinements.

Recruitment
We will use the same eligibility criteria as for qualitative interviews. Women participating in the qualitative interviews will be invited to take part. Further recruitment will be via the Primary Care CRN team (West Midlands), social media, and community organisations using the methodology described above.

Sample Size
Sample size calculation using modelling method is challenging as the use of DCE in this area is limited. We therefore used the rule of thumb method for sample size calculation: a sample of 100 respondents is needed, assuming two subgroups (restart HRT or no medication), four maximum attribute levels, and ten tasks.

Analysis
Descriptive statistics will be used to summarise responses. A mixed (regression) modelling approach will be undertaken to estimate potential value sets for the different health states. The method will use a combined Maximum Likelihood Estimation approach to synthesise responses. I will evaluate model performance by checking consistency of parameters and goodness of fit. The preferences will be transformed to represent a utility score.

Intervention Type
Other

Primary outcome(s)
WP1. Experiences of women discontinuing HRT and their experiences of re-starting HRT, through qualitative interviews. WP1 also uses qualitative interviews to explore the experiences of HCP when they advise women to discontinue HRT. Data will be analysed using framework analysis
WP2. Successfully stopping HRT measured using patient records at the end of the study

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
01/03/2031

Eligibility

Key inclusion criteria
Women:
1. Aged over 45 years
2. Recent experience of discontinuing or attempting to discontinue HRT (in the last 3 years)

For HCPs:
1. Working in NHS and delivering menopause care

Participant type(s)
Health professional, Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
45 Years

Upper age limit
99 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
For women:
Severe mental health or learning difficulties meaning they cannot give informed consent. This will be at the discretion of the GP screening for potential participants or the researcher taking informed consent

Date of first enrolment
19/08/2025

Date of final enrolment
01/10/2030

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Birmingham
186 Mill Lane
Birmingham
England
B93 8NU

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from
(Sarah Hillman – s.c.hillman@bham.ac.uk, qualitative data from interview transcripts and results for DCE, data will be available after publication and available up to 12 months after the end of study date (01/03/2032), data will be shared upon request as part of a data sharing agreement as laid out by University of Birmingham guidelines, people requesting data would have to be affiliated with a higher education institute, for secondary analysis, data will be shared via secure transfer per the data sharing agreement, only data relating to participants who have given prior agreement for secondary analysis will be part of any data set available for sharing, all data will be fully anonymised prior to data sharing)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Interview version 1.0		12/11/2025	No	Yes
Participant information sheet	Survey version 1.0		12/11/2025	No	Yes
Participant information sheet	WP 1 for Health care professionals version 6.0	18/06/2025	12/11/2025	No	Yes
Participant information sheet	WP1 for Women version 6.0	18/06/2025	12/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes