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Menopause care and shared decision-making after breast cancer

Submission date
04/07/2023

Recruitment status
No longer recruiting

Registration date
14/07/2023

Overall study status
Completed

Last Edited
10/01/2024

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Breast cancer affects 1 in 9 UK women. Breast cancer treatment can trigger early menopause and /or more severe menopause symptoms compared with natural menopause. Hormone replacement therapy (HRT) effectively treats menopausal symptoms but is not recommended for breast cancer survivors due to recurrence concerns. Non-hormonal treatments target specific symptoms but do not improve the overall quality of life or reduce long-term health risks as HRT does. The risk of recurrence with HRT is uncertain, but many women would still consider it for symptom relief and improved quality of life. Patient dissatisfaction with menopause care after breast cancer is high, and HRT is currently limited to exceptional cases. This study aims to assess the needs and experiences of UK breast cancer survivors to inform clinicians, and policymakers, and raise awareness.

Who can participate?
Women aged 18 to 70 years with a history of breast cancer and resident in the UK

What does the study involve?
Women will be invited to complete a survey that will be advertised on menopause and breast cancer charity social media sites. The survey is anonymous and takes around 20 minutes to complete. Women will be asked about their experience of menopause care since their breast cancer diagnosis. If women change their minds and wish to withdraw consent, they can simply close the survey without submitting their completed responses.

What are the possible benefits and risks of participating?
Breast cancer is an upsetting experience. Not being listened to is also upsetting. We hope that participating patients who may be struggling with menopause symptoms and/or having difficulty accessing menopause care will be given a voice and feel able to air their views and concerns. If found to be lacking, it is hoped that the survey results can be used to raise awareness about the unmet needs of breast cancer survivors and improve menopause care in this patient group. This will benefit all breast cancer survivors. There are no risks to patients who consent to participate.

The survey will be hosted on the secure and GDPR-approved University College London Qualtrics Survey Platform. This means that the survey is anonymous and the results can only be seen by the researchers.

Where is the study run from?
Newson Health Ltd (UK)

When is the study starting and how long is it expected to run for?
January 2023 to January 2024. The survey will launch in August 2023 and will be open for two months.

Who is funding the study?
Newson Health Ltd (UK)

Who is the main contact?
Dr Sarah Glynne, Sarah.glynne@newsonhealth.co.uk

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-how-women-receive-information-make-decision-about-their-menopause-care-after-breast-cancer#undefined

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Menopause care and shared decision-making after breast cancer: a UK-based cross-sectional study

Study objectives
Breast cancer patients are more likely to struggle with menopause symptoms and have fewer treatment options compared with cancer-free women. Very limited evidence suggests that many breast cancer survivors suffer from debilitating symptoms but struggle to access menopause care and support. We wish to explore the scale of the problem and the types of issues that breast cancer survivors face. We hope that this will inform higher quality menopause care for women after breast cancer in the future.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 13/06/2023, UCL Research Ethics Committee (Office of the Vice Provost (Research), University College London, 2 Taviton Street, London, WC1E 6BT, United Kingdom; +44 (0)20 7679 8717; ethics@ucl.ac.uk), ref: 9093/005

Study design
Observational cross-sectional survey study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Community, Internet/virtual

Study type(s)
Quality of life, Treatment

Participant information sheet
The participant information sheet is accessible by clicking the link to the online survey. Women are automatically directed to the information sheet and consent form, and can't proceed to the survey until they have ticked that they understand the information and consent to participate.

Health condition(s) or problem(s) studied
Menopause care in breast cancer survivors

Interventions
Breast cancer survivors will be invited to participate in an on-line survey that will be advertised on various breast cancer and menopause social media sites.
The survey includes questions about symptoms, quality of life, menopause care including shared decision making (using the validated 9-item Shared Decision-Making Questionnaire (SDM-Q-9), and patient views and attitudes.
The survey is anonymous and takes 15-20 minutes to complete.
The survey will be hosted on the secure and GDPR-approved UCL Quailtrics Survey Platform.

Intervention Type
Other

Primary outcome measure
Patient involvement in menopause treatment shared decision-making after breast cancer measured using the Shared Decision-Making Questionnaire (SDM-Q-9) at one timepoint

Secondary outcome measures
1. The nature and severity of unmet needs in breast cancer survivors
2. Breast cancer survivor's views and attitudes about HRT after breast cancer
3. Breast cancer survivor's experience of menopause care in the UK
All secondary outcome measures will be assessed using survey questions designed by the research team at one timepoint.

Overall study start date

01/01/2023

Completion date
01/01/2024

Eligibility

Key inclusion criteria
Women with a history of breast cancer aged 18-70 years and resident in the UK

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Female

Target number of participants
500 to 1000

Total final enrolment
1718

Key exclusion criteria
1. Women without breast cancer
2. Women aged <18 or >70 years
3. Men
4. Non-UK resident

Date of first enrolment
01/08/2023

Date of final enrolment
01/10/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newson Health Ltd
Winton House
Church St
Stratford-upon-Avon
United Kingdom
CV37 6HB

Sponsor information

Organisation
University College London

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Sponsor type
University/education

Website
https://www.ucl.ac.uk/womens-health/institute-womens-health

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Industry

Funder Name
Newson Health Ltd

Results and Publications

Publication and dissemination plan

This is an anonymous survey so there we will have no way to disseminate the results of the study with participants directly. However, we will share the results on Newson Health's social media as well as via our breast cancer charity partners. In turn, they will publicise the findings.
Data collected will be submitted for peer review and if published, a link to the published results will be also shared with participants via the same channels that were used during recruitment.

Intention to publish date

01/08/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository. Data will be stored securely on password-protected UCL N hard drives during the period of the project for the purposes of data analysis. Computer storage will be in G12, Paul O'Gorman Building, Huntley Street, WC1EE 6BT. Any excess data not required for publication will be deleted. Project data will be kept for purposes of verification/peer review /further analysis as required, for a maximum of 10 years, after which it will be deleted.

IPD sharing plan summary

Stored in non-publicly available repository