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Chronic pain during menopause

Submission date 11/08/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 12/08/2022	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 12/08/2022	**Condition category** Signs and Symptoms	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to understand the experiences of women with chronic/persistent pain conditions during the perimenopause – the period preceding and immediately after the final menstrual period. The perimenopause is a sensitive period for women, characterized by both physical and social changes that may predispose them to pain.
Through the use of in-depth interviews and other qualitative activities, the study will expose the narratives by which women make sense of pain and gynaecological events throughout their life as well as their interpretation of the variety of symptoms experienced during the perimenopause – and how pain and perimenopause symptoms may overlap or interact.

Who can participate?
Women aged 45-69 years of peri-menopausal age with a chronic/persistent pain diagnosis at an NHS secondary care pain management service

What does the study involve?
The research activities will be:
1. A first semi-structured interview with a life mapping exercise conducted by the researcher at participants' homes
2. A second semi-structured interview conducted by the researcher at the participants' homes
3. A go-along interview conducted by the researcher at the participants' homes or communities, in which the participant carries out a daily-life activity (eg. shopping, cooking, etc)

What are the possible benefits and risks of participating?
While there is no direct benefit in participating in this study, participating in research can be rewarding as the participants contribute to the furthering of knowledge that might one day result in enhanced experiences for people with similar conditions. There are no direct risks in participating in this study, but taking part in interviews can sometimes be distressing so the researchers will take care to monitor participants' well-being. Participants also have the right to withdraw from the study at any point.

Where is the study run from?
University College London (UK)

When is the study starting and how long is it expected to run for?
September 2021 to June 2023

Who is funding the study?
1. Economic and Social Research Council (ESRC) (UK)
2. Biotechnology and Biological Sciences Research Council (BBSRC) (UK)

Who is the main contact?
Prof. Sahra Gibbon, s.gibbon@ucl.ac.uk.

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
311041

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 311041

Study information

Scientific Title

The emergence of chronic pain during perimenopause: an ethnographic study of women attending a secondary care pain management service

Study objectives
This study will investigate the experiences of chronic pain in women during perimenopause, since there is an unequal distribution of chronic pain during adulthood between men and women. This study will investigate if and how the intersection of pain and menopause affect women.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Medical anthropological study using interviews (semi-structured and go-along) and participant observation

Primary study design
Observational

Secondary study design
Ethnographic study

Study setting(s)
Home

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request participant information sheet

Health condition(s) or problem(s) studied
Chronic pain, menopause

Interventions
This study will collect data through three interviews - two semi-structured interviews with a life-mapping exercise, and one go-along interview - and participant observation.

Intervention Type
Other

Primary outcome measure
1. Participant experiences measured using a semi-structured interview and life map at week 1
2. Participant experiences measured using a semi-structured interview at week 2
3. Participant experiences of activities and pain measured using a go-along interview at week 3

Secondary outcome measures

Participant experiences and contextual information measured using field notes from participant observation at weeks 1-3. A sub-sample of participants had measurements taken at additional monthly sessions over a period of 5 months.

Overall study start date
01/09/2021

Completion date
30/06/2023

Eligibility

Key inclusion criteria
1. Cis-gender women (females at birth who self-identify as women)
2. Aged 45-69 years
3. Pain symptom onset age 40-55 years
4. Have had the final menstrual period (FMP)
5. English-speaking
6. Formal diagnosis of chronic pain (CP)
7. Able to understand the study processes

Participant type(s)
Patient

Age group
Adult

Lower age limit
45 Years

Upper age limit
69 Years

Sex
Female

Target number of participants
10

Key exclusion criteria
1. Awaiting further investigations to confirm diagnosis
2. Significant comorbidities which may affect CP and perimenopause symptoms (e.g. cancer, diabetes, neuropathy)
3. Unable to comply with study processes
4. Lack of capacity to give consent

Date of first enrolment
01/12/2022

Date of final enrolment

01/06/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UCLH Pain Management Centre at NHNN
National Hospital for Neurology and Neurosurgery at Cleveland Street
25 Cleveland Street
London
United Kingdom
W1T 4AJ

Study participating centre
Royal Free Hospital Pain Management Service
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Sponsor information

Organisation
University College London

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Sponsor type
University/education

Website

http://www.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Research council

Funder Name
Economic and Social Research Council

Alternative Name(s)
ESRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Biotechnology and Biological Sciences Research Council

Alternative Name(s)
UKRI - Biotechnology And Biological Sciences Research Council, BBSRC UK, BBSRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

This study's participants are patients of a clinical pain management service, and as such a report will be disseminated to the clinical team in the form of a final report at the conclusion of the research.

Results will inform part of Catherine Borra's PhD, funded by the Economic and Social Research Council (ESRC) and Biological and Biotechnology Research Council (BBSRC), and will be included in her final thesis.

Results will be communicated to the wider research community by:
1. Publications in peer-reviewed journals
2. Presentations at scientific meetings and conferences

Funders will be acknowledged within the publications and other final reports of the study.

Results will be communicated to participants who have expressed this wish in their ICF, in the form of a condensed report written in layman's terms, and making the final scientific publication accessible to them upon request. The resulting publications and/or abstracts will be emailed to the JRO.

Further dissemination will be done through patient support networks, and charities and will be circulated to general media – as part of the education of the general public which was identified as a priority in the PPI activities. PPI members also identified the need for sharing findings with primary care health professionals– this will be done by disseminating results in a condensed report form to relevant professional bodies. In all cases participants will remain anonymous.

The primary author of any reports and studies utilising the primary data will be Catherine Borra (CB) – who will also be listed as the last author in any secondary publications using this data. All study team members who make a substantive contribution to reading and writing the final report will be granted authorship on the final study report. Substantive contributions will be defined by satisfying the following points, in line with the International Committee of Medical Journal Editors guidelines:
1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or revising it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Intention to publish date
30/12/2023

Individual participant data (IPD) sharing plan
The data will not be made available since ethnographic data is context-specific. It will be held in the UCL Data Safe Haven for 10 years upon study completion.

IPD sharing plan summary
Not expected to be made available