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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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
311041

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Other

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(s)
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

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
45 years

Upper age limit
69 years

Sex
Female

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
United Kingdom

England

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

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Research council

Funder Name
Economic and Social Research Council

Alternative Name(s)
Economic and Social Research Council (ESRC), 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, Biotechnology and Biological Sciences Research Council (BBSRC), BBSRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes