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Accelerating adoption of group information sessions for menopause in the United Kingdom

Submission date	**Recruitment status**	[X] Prospectively registered
20/03/2024	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/03/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
26/03/2024	Other	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
High-quality care is scarce for many non-urgent conditions worldwide, including for a wide variety of chronic diseases and life stages such as pregnancy and menopause. Healthcare delivery innovation can result in more effective and efficient ways to see patients. The typical way for a patient to meet a clinician for non-urgent care is via a one-on-one appointment. In an alternative care delivery model, known as a “group clinic”, 5-15 patients with the same underlying concerns meet with a clinician at once, and each receives one-on-one attention while the others listen in. Patients get to spend more time (although not one-on-one) with the clinician, are exposed to more information both from the clinician and from their peers and may feel a sense of community. In addition, the clinician save time due to not having to repeat common advice. Despite these potential benefits, the uptake of group clinics has been slow. The aim of this study is to examine ways to improve recruitment into group clinics. The researchers will specifically focus on recruitment into group clinics for menopause, in which women can learn more about menopause and the options available to manage it.

Who can participate?
All women aged 45-60 years who live in the UK can participate, except those who have engaged in the researchers' prior survey on menopause

What does the study involve?
The researchers will recruit women via an online survey platform and ask them some questions about themselves. Then they will be asked to choose between attending a 90-minute online group clinic with 5-10 other women their age and a menopause expert, a 20-minute online one-on-one appointment with a menopause expert, or neither, varying the amount and type of information that they receive about the group clinic.

What are the possible benefits and risks of participating?
Participants may be given the opportunity to attend a menopause information appointment of their choice (a group clinic or a one-on-one) if they wish to. There are no risks involved in this study that they would not encounter in daily life.

Where is the study run from?
This is an online study run from London Business School, by researchers from the University of Edinburgh Oxford University, University College London, and London Business School (UK)

When is the study starting and how long is it expected to run for?
January 2024 to September 2024

Who is funding the study?
Research England (UK)

Who is the main contact?
Prof. Kamalini Ramdas, reachable at womens_health@london.edu

Contact information

Type(s)
Public, Scientific, Principal Investigator

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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

Accelerating the adoption of group clinics in the United Kingdom

Acronym
AdoptGroupClinics

Study objectives
The researchers propose four main hypotheses related to the effect of random assignment to information treatment on our two primary outcomes:
1. It is expected that respondents invited to attend a group clinic via a standard text message invite plus statements reflecting peers' experience of a group clinic are more likely to say they want to attend the group clinic than not attend one if offered a choice among a group clinic, a one-on-one appointment offered on the same date and none, and also conditional on their having chosen to attend an appointment.
2. It is expected that respondents invited to attend a group clinic via a standard text message invite plus statements reflecting an expert's description of what goes on in a group clinic and behavioral nudges to attend are more likely to say they want to attend the group clinic than not attend one if offered a choice among a group clinic and a one-on-one appointment offered on the same date, and none, and also conditional on their having chosen to attend an appointment.
3. It is expected that decisional conflict will be lower for participants who were randomly allocated to the two information treatment arms than for those randomly allocated to the control arm.
4. It is expected that the no-show rate among those who were offered and booked an appointment slot for group clinics will be lower for respondents who were randomly allocated to the two information treatment arms than for those randomly allocated to the control arm.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/03/2024, London Business School Research Ethics Committee (Sussex Place, Regent's Park, London, NW1 4SA, United Kingdom; +44 (0)2070008638; ethics@london.edu), ref: REC928-23022027

Study design
Online interventional unmasked randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Impartation of knowledge about menopause symptoms and options available to manage menopause

Interventions
1. Control arm: Respondents receive a standard text message invitation to attend a group clinic.
2. Treatment arm 1 (peer group information): Respondents receive a standard text message invitation plus statements reflecting peers' experience of a group clinic.
3. Treatment arm 2 (expert information): Respondents receive a standard text message invitation plus statements reflecting an expert's description of what goes on in a group clinic and behavioral nudges to attend.

Randomization is computerized.

Intervention Type
Behavioural

Primary outcome measure
1. Selection of a group clinic, a one-on-one, or neither, measured using 0-1 survey responses in Survey 1 at baseline
2. Extent of decisional conflict experienced in selecting, measured using 0-1 survey responses in Survey 1 at baseline
3. Attendance of a one-on-one appointment or a group clinic measured using a 0-1 variable by implementation partner ELC works during the 10-week intervention period between baseline and endline

Secondary outcome measures
1. Duration of each appointment measured using a watch by implementation partner ELC works
2. Time spent by the menopause expert in each appointment, measured using a watch by ELC Works during the 10-week intervention period between baseline and endline
3. Satisfaction with the appointment, measured using 1-7 Likert Scale variables in online Survey 2 at endline
4. Knowledge of menopause symptoms measured using 0-1 variables in online Surveys 1 and 2 at baseline and endline
5. Knowledge of menopause management options measured using 0-1 variables in online Surveys 1 and 2 at baseline and endline
6. Channels through which respondents obtain information about menopause measured using 0-1 variables in online Surveys 1 and 2 at baseline and endline
7. Demographic variables measured using survey responses in online Survey 1 at baseline
8. Life stage (pre-menopause, menopause, post-menopause) measured using survey responses in online Survey 1 at baseline
9. Severity of menopause symptoms measured using 0-3 Likert scale variables in Survey 1 at baseline
10. The number of patients in each group clinic appointment measured by counting by ELC Works during the 10-week intervention period between baseline and endline

Overall study start date
15/01/2024

Completion date

15/09/2024

Eligibility

Key inclusion criteria
1. Should not have participated in the pretest survey for this project
2. Female
3. Aged 45-60 years

Participant type(s)
Other

Age group
Mixed

Lower age limit
45 Years

Upper age limit
60 Years

Sex
Female

Target number of participants
The target number of participants is a minimum of 3939 participants and the number of participants the researchers can recruit by 31/03/2024. The researchers will continue recruitment until 31/03/2024.

Key exclusion criteria
1. Participated in the pretest survey for this project
2. Not female
3. Aged under 45 or over 60 years

Date of first enrolment
22/03/2024

Date of final enrolment
31/03/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

London Business School
Sussex PLACE
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/001c2sn75

Funder(s)

Funder type
Government

Funder Name
Research England (Funder Type: Regional Innovation Fund 2023 to 2025)

Alternative Name(s)
ResEngland, UKRI-Research England, Research England - UK Research & Innovation

Funding Body Type
Government organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The researchers intend to publish this research in leading medical journals, health economics journals and academic business journals.

Intention to publish date
30/05/2025

Individual participant data (IPD) sharing plan
The researchers will share the data on the publication of a peer-reviewed publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			26/03/2024	No	No