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Usability and accuracy of the Hormona at-home perimenopause test kit and mobile app

Submission date 08/01/2026	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 13/01/2026	**Overall study status** Ongoing	
Last Edited 04/02/2026	**Condition category** Other	

Plain English summary of protocol
Background and study aims
This observational study is being conducted to understand how well women can use the Hormona Perimenopause test kit and mobile app at home, and how the system can measure natural changes in hormones during the perimenopausal transition. The purpose of this study is to evaluate the usability of the Hormona system (how easy it is to use, understand, and interpret) and its clinical performance (the device's ability to provide results that correlate with a specific health condition or biological process) in women aged 40–55 years.

Who can participate?
Women aged 40–55 years.

What does the study involve?
The study is observational and non-interventional, meaning that participants will perform the tests themselves at home and record their experiences. No medical treatment or clinical procedures are involved, and the results are for informational purposes only.

Participants will log symptoms daily in the Hormona app, complete a few short questionnaires, and perform several at-home urine tests according to their individual cycle schedule. All data will be anonymised and used solely for research purposes.

What are the possible benefits and risks of participating?
Findings will be used to refine Hormona’s technology and support its continued development as a regulated tool to help women better understand their hormonal health during perimenopause.

Participants might feel a little frustrated when using the app or trying to understand the test results; that’s understandable and completely normal. It’s important to note that the hormone test results provided during this study are for informational purposes only and are not diagnostic. They do not replace professional medical advice. If there are any concerns about participants’ health during the study, they should contact their doctor for support.

Participants' personal and health information will be kept secure. While there is always a remote risk to privacy, the company follows strict data protection rules under our Privacy Policy, which

fully complies with UK GDPR. To help keep participants' information even safer, it is recommended that participant secure their phones with Face ID or a passcode in their device settings to protect against unauthorized access to the Hormona App and the data logged there.

Where is the study run from?
Wlness Science Ltd (trading as Hormona)

When is the study starting and how long is it expected to run for?
January 2026 to April 2026.

Who is funding the study?
Wlness Science Ltd (trading as Hormona)

Who is the main contact?
Anna Targonskaya, anna@hormona.io

Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Integrated Research Application System (IRAS)
365049

Protocol number
HPERI-CPS001

Study information

Scientific Title
Clinical performance and usability assessment of hormona perimenopause

Study objectives
The main purpose of this study is to understand how women experience and use the Hormona Perimenopause at-home hormone test and app, and how well the system tracks hormone changes during the perimenopause transition.

The study aims to:
- Observe changes in hormones related to fertility function during perimenopause.
- Assess how easy the Hormona Perimenopause system is to use at home.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 18/12/2025, Health and Social Care Research Ethics Committee A (HSC REC A) (Lissue Industrial Estate West, 5 Rathdown Walk, Lisburn, BT28 2RF, United Kingdom; +44 (028) 95 361400; info.orecni@hscni.net), ref: 25/NI/0156

Primary study design
Observational

Secondary study design
Cross sectional study

Study type(s)

Health condition(s) or problem(s) studied
Perimenopause and menopause

Interventions
The study is designed to assess the performance of the Hormona Perimenopause self-test system, as well as the usability and comprehension of the test kit and mobile app among a representative group of women with diverse backgrounds and demographics. Importantly, this is a non-interventional (observational) study. Participants will not receive any medical advice, diagnosis, or treatment based on their test results. The study will not influence or alter participants' usual healthcare, medication, or lifestyle decisions in any way. Data are collected solely to evaluate the device's performance and user experience under normal conditions of use.

Participants will be women aged 40 to 55, living in Great Britain (excluding Wales). Recruitment will take place via email invitation. Interested individuals will complete an eligibility questionnaire, and inclusion will be determined by the Principal Investigator based on predefined criteria. Eligible participants will then be invited by email to confirm their willingness to take part and provided with a Participant Information Sheet and Informed Consent Form to review and sign before enrolment. Once consent is received, participants will be sent an onboarding email and Participant Protocol containing detailed study information.

Following enrolment, participants will receive their Hormona Perimenopause test kit, which includes printed Instructions for Use and a reusable urine collection cup. At the end of the study, participants will receive an end-of-study email with a link to complete the post-study questionnaire.

Participants will be instructed to:
- Perform hormone self-testing at home using first-morning urine, according to their personalised schedule in the app.
- Log daily symptoms in the Hormona app.
- Complete short user diaries after each testing day.
- Fill out a post-study questionnaire to provide feedback on usability and comprehension.

No biological samples will be sent to a laboratory, and no medical or clinical decisions will be based on test results. The results displayed in the app are for informational purposes only and are not a substitute for medical advice.

This study design enables a comprehensive evaluation of both the clinical performance and usability of the device in a natural, real-world setting, while maintaining an entirely observational nature. The study is conducted fully remotely, without any clinical visits, direct contact with healthcare professionals, or deviation from participants' usual behaviour or medical care, allowing participants to complete all activities comfortably from home.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Hormona Perimenopause

Primary outcome(s)
1. Quantitative urinary hormone values for FSH, E1G, and PdG measured using the Hormona Perimenopause self-test system lateral flow immunoassay at 15 mintues

2. Assessment of test usability based on participant-reported ease of use, adherence to instructions, and scanning success rates measured using a survey and backend metadata tracking at study duration

3. Symptom segmentation in two main age groups (40-45 and 46-55) measured using the symptom logs from participants at study duration

Key secondary outcome(s))

Completion date
12/04/2026

Eligibility

Key inclusion criteria
1. Age between 40 and 55 years.
2. Own a compatible smartphone (Android 6.0 or later, or iOS 13.4 or later)
3. Located in England and Scotland

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
40 years

Upper age limit
55 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Currently pregnant
2. Currently breastfeeding
3. Using hormonal contraceptives (including oral, implant, patch, or IUD)
4. Receiving hormone replacement therapy (HRT)
5. Diagnosed with any of the following conditions: Hormone-related disorders (e.g. PCOS, thyroid dysfunction), mood disorders (e.g. depression, bipolar disorder), dementia or significant cognitive impairment, kidney, liver, or cardiovascular disease

Date of first enrolment
01/01/2026

Date of final enrolment
28/02/2026

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
Remote [at-home study]
Remote [at-home study]
London
England
W1W5PF

Sponsor information

Organisation
Wlness Science LTD

Funder(s)

Funder type

Funder Name
Wlness Science LTD

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date