THIS IS AN IMPORTANT DOCUMENT – KEEP FOR FUTURE REFERENCE

PARTICIPANT INFORMATION AND CONSENT FORM

Sponsor / Study Title:	**IdentifyHer Limited / "An observational virtual trial to investigate the accuracy of a wearable device in collecting data related to perimenopausal symptoms in women"**
Protocol Number:	**24IDCFI01**
Principal Investigator: (Study Doctor)	**David Crowley, MD**
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You are invited to participate in a virtual clinical research study. Participation in this study is strictly voluntary. To make an informed decision about participating in this study, it is important that you understand the potential risks and benefits of the study. This process, known as informed consent, ensures you have all the information needed to decide. This consent form outlines the study's purpose, procedures, potential benefits, risks, and how your medical information will be handled.

Take your time to thoroughly read all the details about the study, and do not hesitate to ask any questions you may have regarding the information given and about the study. Study staff will answer all your questions. You have access to this form and can review it at your leisure before making a decision.

You should not sign this form until you fully understand the information provided, feel comfortable with your decision to participate, and have had all your questions about the study answered to your satisfaction. You will be provided with a signed copy of this form, which you should keep for your records. Once consent has been obtained, the virtual study assessments will proceed.

If you have questions and wish to contact study staff, please use the phone number or email address provided at the top of this page.

Background And Purpose

Menopause is a natural biological transition in the life of a woman and is diagnosed by the absence of a menstrual cycle for 12 months. While the average age of menopause is 51 years old, the perimenopausal period ranges from 2-8 years before menopause and lasts up to one year after last menstruation.

Vasomotor symptoms—which are signs of hormonal changes affecting how the body controls temperature and blood flow—are commonly reported perimenopausal symptoms. These include hot flashes, night sweats, mood disturbance, and poor sleep quality. Perimenopausal symptoms may negatively impact a woman's quality of life, health, and work productivity. Many women seek help to manage their symptoms but because there are no clear tests for perimenopause and many clinicians lack training in it or are too busy, women often suffer longer with symptoms.

Therefore, the purpose of the study is to investigate how well a sensor, referred to in this form as the study device, collects data related to perimenopausal symptoms in women, including vasomotor symptoms, anxiety and sleep quality compared to self-reported symptoms.

Study Population

This study will include approximately 110 healthy females between 35-55 years of age who are experiencing perimenopausal symptoms.

How Long Is the Study?

If eligible after the screening assessment, your participation in this study will last approximately 15 days.

Important Things to Note

- This study is conducted entirely virtually. All study-related activities, including screening, consent, assessments, and follow-ups, will take place remotely using secure digital platforms. There will be no in-person visits required for participation.
- To determine your eligibility to participate in this study, detailed information about your lifestyle, medications, and medical history will be collected during the virtual screening assessment. This information will help determine if you meet the necessary criteria to participate in this study.
- By signing this consent form, you are not guaranteed to be enrolled in the study. Your participation depends on meeting the study's specific eligibility criteria, which will be determined through a series of questions and assessments.
- This study will use competitive enrollment. This means when the target number of participants begin the study, all further enrollment will be closed. Therefore, it is possible that you could be in the screening phase, ready to begin the study, and be discontinued without your consent if the target number of participants have already begun the study. If this occurs, you will not be eligible for study compensation.
- You will receive the study device at no cost to you, and you are responsible for returning it in working condition.
- You will need to download a mobile application (app). The app is compatible with Apple devices running iOS 14 to 17 and Android devices running Android 5.0 (SDK 21) to Android 14 (SDK 34). The smartphone must be Bluetooth enabled.

What Will Happen During the Study?

During this study, you will be required to complete the following:

Daily Assessments (Day 0 – Day 14):

- **Electronic Diary –** You will record any perimenopausal symptoms (including, but not limited to, hot flashes, night sweats, awake at night, stressful event, feeling anxious or nervous, irritable, joint pain, brain fog), sleep quality, anxiety, self-esteem, menstrual cycle status, exercise, diet (including alcohol intake) and changes in health.

Day 0 Assessments:

- **Generalized Anxiety Disorder-7 (GAD-7) Scale –** This is a self-reported assessment of the severity of an individual's anxiety.

- **State-Trait Anxiety Inventory (STAI) –** This is a widely used self-reported assessment of the intensity and frequency of an individual's anxiety symptoms.
- **Hospital Anxiety and Depression Scale (HADS) –** This is 14-item self-assessment scale for detecting states of depression and anxiety.
- **Pittsburgh Sleep Quality Index (PSQI) –** This is a self-reported questionnaire that assesses sleep quality and disturbances.
- **Greene Climacteric Scale (GCS) –** This is a 21-item self-assessment of menopause symptoms where three main areas are measured: psychological, physical, and vasomotor.

Schedule of Virtual Study Visits

Virtual Screening
• Informed Consent for participation in the study will be obtained • After providing consent, you will receive an email with a link to the screening assessment. You will be required to enter details about your medical history, medications, demographics, and health status to complete the assessment • Once the assessments are complete, your eligibility will be assessed. You will receive an email from KGK Science informing you of your eligibility status
• If you are eligible, a virtual baseline visit will be scheduled, and the study device along with instructions on proper use will be shipped to you • You will receive an email from KGK Science notifying you when the study device has been shipped. This email will contain an orange button that you will need to click once you have received the study device • After receiving the study device, you will need to return to the email that notified you of its shipment, click the orange button, and complete the form to confirm receipt of the study device
Virtual Baseline – Device Acclimation Day (Day 0)
• Medications and current health status will be reviewed • Instructions for device application, charging, and mobile app use will be given • You will apply and activate the study device during the visit and you will wear the device for 14 full days • You will complete GAD-7, STAI, HADS, PSQI, GCS questionnaires and daily diaries in the app
Compliance Touchpoint (Day 7)
• Compliance means you have been following the directions to participate in the study • Study staff will contact you to review any changes in health or medications
Virtual End of Study (Day 14)

- Medications and any changes in health will be reviewed
- You will complete your daily diary in the app
- You will wear the device for the full day (Day 14) and remove it the following day (Day 15)
- You will be instructed on how to ship the device back to KGK Science

Medications, Supplements, And Food/Drinks

- If you are taking any prescribed or over the counter medications or supplements, you must agree to maintain you dosing regimen during the study, unless otherwise recommended by your general/nurse practitioner. If they recommend any medication or dose changes, please notify the study staff immediately.
- You should not discontinue your regular medications unless instructed by your general/nurse practitioner. Stopping regular medications without medical advice to join this study may worsen your health. If you stop your regular medications, inform the study staff immediately.
- Some medications may affect how well the study device works. If you are taking one of these medications, you may not be allowed to participate in the study

Birth Control, Pregnancy, And Breastfeeding

The effect of the study device on pregnancy and breast milk is not known. You must not participate if you are pregnant, breastfeeding or planning to become pregnant during the study. Individuals able to become pregnant (not post-menopausal, have had a menstrual period in the past 1 year, or have not had any of the following surgeries: hysterectomy, bilateral oophorectomy, complete endometrial ablation, or bilateral tubal ligation) must agree to use a medically approved method of birth control for the duration of the study.

Some examples of approved methods of birth control include:

- Double-barrier method
- Intrauterine devices (IUD)
- Non-heterosexual lifestyle or agree to use contraception if planning on changing to heterosexual partner(s)
- Vasectomy of partner at least 6 months prior to screening
- Abstinence and agree to use contraception if planning on becoming sexually active during the study

If you are of child-bearing potential, you must self-report confirmation that you are not pregnant, do not plan to become pregnant, and agree to use a medically approved method of birth control for the duration of the study.

If you become pregnant during the study, you must stop wearing the study device immediately and contact the study staff. You may be withdrawn from the study if, in the opinion of the study doctor, it is not in your best interest to continue.

Since the study device is investigational, there may be other risks that are unknown. Additionally, there may be unknown risks to a pregnancy, embryo, or fetus if you become pregnant.

Study Device Information

The study device is a wearable non-invasive sensor designed to characterize perimenopausal symptoms. The device is worn under the breast on either the right or left side and is secured to the skin using a double-sided adhesive patch. Please note that the study device cannot be used to diagnose any medical issues or for treatment purposes.

- Instructions on how to wear and use the study device will be provided during the Baseline (Day 0) virtual visit.
- You will begin wearing the study device during the Baseline (Day 0) virtual visit and you will wear it for 14 full days. You will remove the device the day after your Day 14 Virtual End of Study visit.
- Please be cautious that the device you wear does not get caught on fixed structures or heavy objects when moving yourself or heavier objects.

You are responsible for shipping the device back to KGK Science (at no cost to you) in its original working condition, upon exiting the study. Failure to return the device as instructed may result in withholding of any applicable compensation and may also hold you responsible for the replacement cost of the device (approximately USD $150) if it is not returned or is damaged due to your actions.

Alternative Treatments

This study is not designed to diagnose, treat, or prevent any disease. Your alternative is to not take part in the study.

Additional Safeguards

If you need regular medical care for current medical conditions, you should continue with this medical care unless otherwise instructed by your regular physician or other healthcare professional. For your safety, you must report in your study diary your current medical care, changes in medical conditions, and/or all changes in medications —including supplements and natural health products (NHPs)— during the study.

The study device is intended for your use only, as the study participant.

Risks To You

It is possible that you could have problems or side effects from wearing the study device that nobody knows about yet. There may be unknown risks with wearing the study device. Potential side-effects may include:

- Redness or skin irritation around the area where the device is applied.

Make sure your skin is clean and dry before reapplying the device. If you experience redness or skin irritation around the area where the device is applied, remove it immediately. If symptoms last longer than 2-3 days of not using the study device, you should contact your primary care practitioner or a dermatologist for treatment.

If you think you are experiencing a side effect, you should report it in your study diary and inform the study staff.

Could I Have an Allergic Reaction?

It is possible for people to have allergic reactions to the adhesive used for the study device. If you have a serious allergic reaction, you could die. Some effects of an allergic reaction that could be life-threatening (anaphylaxis) include:

- Rash
- Difficulty breathing
- Wheezing
- Sudden drop in blood pressure (making you feel dizzy or lightheaded)
- Swelling around the mouth, throat, or eyes
- Fast pulse
- Sweating

If you experience any of the above-listed effects or any other side effects during the study, you should get medical help or go to the emergency room immediately, and then contact the study staff. Refer to section "Whom to Contact About This Study" for instructions on what to do in case of an emergency.

Contact the study staff if you have questions about the signs or symptoms of any side-effects you read about in this consent form.

You are should report in your study diary and notify the study staff right away if you experience any side-effects, problems with your health or the way you feel during the study, and whether you think these problems are related to the study device or not.

Potential Risks From E-Consent

You will receive a link via email/text message to download a PDF copy of this signed consent form. There may be risks of loss of privacy and confidentiality if the PDF copy of this consent form is viewed and/or stored on a personal electronic device (PED), especially if that PED is shared with other users or is lost, hacked, or subject to a search warrant or subpoena. Also, the PDF copy of the consent may not be able to be permanently removed from a PED.

Withdrawal From the Study

- Your participation in this research is strictly voluntary. You have the right to choose not to be in the study or leave at any time, for any reason, without affecting your relationship with the study doctor or study staff and without penalty or loss of benefits to which you are otherwise entitled.
- If you discontinue the study for whatever reason, you are expected to return all study materials, such as the study device, to KGK Science.
- If the study doctor or study staff finds out any related information that may greatly affect your well-being (for example, information related to your health), they will share it with you immediately.

The Sponsor has the right to stop the study at any time.

The study doctor may also stop your participation in the study at any time without your consent, but you will be informed about the reason. Reasons for this may include, but are not limited to:

- Missing scheduled virtual study visits
- Not using the study device as directed
- Not completing required assessments or procedures

- Development of medical conditions or serious side-effects that may pose a health risk to you or the study outcomes
- The need for restricted medication(s) during the study
- If you become pregnant during the study

New Findings

Any significant findings that become available during the study which may influence your continued participation in the study will be disclosed to you as soon as possible.

Benefits

While there may be no immediate benefit to you, the results of this study will provide some of the required scientific evidence for the study device in this clinical research study. Your participation in this study supports the research that is required to ensure the science behind the study device.

Costs To You

- There is no cost to you to participate in this study. For your study participation, the study device will be provided and mailed to you at no cost. You may be responsible for the replacement cost of the device (approximately USD $150) if it is not returned or is damaged due to your actions.
- You, the public health plan, or your personal medical insurance (if any) should continue to pay for expenses for your current medical care and/or prescriptions. These expenses will not be paid as part of your participation in this study.
- The Sponsor of this study is paying your study doctor for the time, effort, and expenses to conduct this study.

Compensation For Participation

For your time and participation in the study, you will be compensated a total of $200 if you complete the entire study, all associated requirements, and return the study device.

You will receive your compensation after the completion of the study—provided that you return the device to KGK Science—on a Clincard, which can be used like a prepaid Mastercard. It can be used anywhere that accepts Mastercard, or the funds can be withdrawn from an ATM (ATM fees apply). Processing times may apply before funds become available on your Clincard. The Clincard and instructions on how to activate the card will be shipped to you along with the study device.

If you are enrolled into the study at Virtual Baseline (Day 0), the compensation breakdown is as follows:

- Virtual Screening: $0
- Virtual Baseline (Day 0): $25
- Compliance Touchpoint (Day 7): $50
- Virtual End of Study (Day 14): $125

Once enrolled, for any case in which you or the study doctor determine you cannot complete all the virtual study assessment days, you will receive compensation only for the visits you have completed.

Important to note: You are responsible for shipping the device back to KGK Science (at no cost to you) in its original working condition, upon exiting the study. Failure to return the device as instructed may result

in loss of any applicable compensation and may also hold you responsible for the replacement cost of the device (approximately USD $150) if it is not returned or is damaged due to your actions.

Compensation And Treatment for Injury

- In case of an injury or illness suffered while, and solely as a result of, participating in this study, you will receive appropriate medical care. The Sponsor will cover necessary medical costs not covered by the provincial health plan or your private medical insurance (if any). By signing this form, you are not giving up your legal rights, nor releasing the study doctor or Sponsors from their legal and professional obligations.
- Be aware that the provincial health plan or your health care payer/insurer might not cover the costs of study-related injuries or illnesses.

Confidentiality Of Records

- Staff at KGK Science (the contract research organization managing this study) will keep all your medical information confidential to the extent permitted by law.
- All research data (health information, past medical history, and test results from this study) will be kept in a secure location. Forms on which your information is entered will not contain your name (except for the study intake form and/or external requisitions if applicable).
- Any of your personal information that is stored electronically will be password protected, accessible only to authorized personnel and coded wherever possible. Electronic data may be stored on secure servers which are physically located in Canada and/or the United States.
- You will not be identified in any publication that might result from the study. Unless required by law, only the following may have access to confidential study data (not your personal information) at the study site:
    - The study doctor and study staff
    - The Sponsor (including its monitors and auditors)
    - Members of the Research Ethics Board (REB) — Univo REB (an independent ethics committee that reviewed the ethical aspects of this study to help ensure that the rights and welfare of participants are protected and that the study is carried out in an ethical manner)
    - Government regulatory authorities including Health Canada and other foreign regulatory agencies.
- While the Sponsor will not have access to your personal identifying information, the study doctor, study staff, monitors, auditors, REB, and regulatory authorities may review study records, which could include your personal identifying information (such as the signed consent form) for compliance and verification purposes.
- All study data will be archived for a minimum of 15 years from the date of completion of the study in accordance with Health Canada regulatory requirements.
- Information from this study will be submitted to the Sponsor. Information sent from the study site will not contain your name.
- You have the right to check your study records and request changes if the information is incorrect.
- While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy.
- As part of this research, you may be required to use one or more of the following: a phone or web app/site, an electronic study diary (eDiary), or a device that tracks information about you. While using these, information about you may be collected and shared with the researchers or people outside of

the study. This data might include personal health information, location, call logs, text message history, web browsing history, or social media use. A complete description of the data collection and sharing for an app, eDiary, or device can commonly be found in the Terms of Use, End User License Agreement, or Privacy Policy associated with the device. If you would like to read these documents, request a copy or instructions about how to access this information from the study staff.

- While the Terms of Use, End User License Agreement, or Privacy Policy may include statements limiting your rights if you are harmed as a result of your use of the app, eDiary, or device in this study, you do not release the investigator, sponsor, institution, or agents for responsibilities from mistakes. You also do not waive any of your rights as a research participant.

By signing and dating the consent form, you give your consent to collect, use and disclose your health information as described above.

A description of this clinical trial will be available on https://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Data Collection and Privacy

The app and study device are intended for research purposes only. They are designed to collect data for scientific research and analysis.

The study device will collect various types of data, including but not limited to, physiological and activity-related data. Data collected by the study device will be transmitted via the App for storage and analysis on the IdentifyHer cloud platform. The Company may use the collected data for research purposes, including but not limited to, scientific studies, product development, and improving user experience. Your personal data will be handled in accordance with the company's Privacy Policy.

By signing this informed consent form document, you agree to use the app and study device responsibly and you will not attempt to tamper with or modify the study device or app in any way.

Future Contact

By participating in this study, you agree that the study staff may contact you in the future should additional information be needed. This contact would only occur if more data specifically related to your participation in this study were required after you have completed the study, or the study has concluded/expired. Any additional information gathered will be handled with the same confidentiality and privacy protections outlined in this consent form. You may choose not to provide additional information if contacted in the future, without any penalty or effect on the care or benefits you receive.

Whom To Contact About This Study

You can contact the study staff via email or by telephone listed on the first page of this document during the study if you experience any medical problems, suffer a research-related injury, or have questions, concerns, or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;

- The study doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study and then please inform the KGK Science study staff.

A research ethics board (REB) is an independent committee that helps to protect the rights and welfare of research participants. If you have any questions about your rights and welfare as a research participant, or have concerns or complaints regarding this research study, please contact Univo REB at (919) 910-7743 or via email at info@univo-group.com.

Voluntary Consent to Participate

By signing and dating this document I agree that I have been provided enough time to read and consider whether to participate. I have reviewed the informed consent form explanation video, Frequently Asked Questions (FAQ) form, read and understand all pages of the consent form and information it contains regarding the study in a language I understand. I have been given the opportunity to ask all my questions regarding the study with answers to my satisfaction. I understand that I may consult with the study staff, should anything become unclear or if I have further questions.

I volunteer to be in this study at my own free will and without being pressured by the study doctor or the study staff knowing I have the opportunity to leave at any time without giving a reason and without affecting my health care. I understand that if I choose to withdraw from the study, I must notify the study staff. The risks involved with participating in this study are clear to me. I agree to follow the study instructions provided to me by the study staff and understand I may not participate in another study while I am enrolled in this study.

It is clear to me that my data derived from this study will be kept anonymous and may be reviewed by the Sponsor, their agents, the Research Ethics Review Board, Health Canada and other foreign regulatory agencies. I understand that all my personal information will be treated as strictly confidential, except where disclosure is required by law, and will not be made publicly available; however, absolute confidentiality cannot be guaranteed.

By signing and dating this document, I do not waive any of my rights under the law or release the study doctor or Sponsor from their legal and professional obligations.

I know that the study device is for my use only. I understand that I am required to return the study device at the end of my participation in the study and failure to do so may result in being held responsible for the replacement cost of the equipment (approximately USD $150) or if I were at fault in any way for breaking it.

I understand that I will receive a copy of this signed and dated consent form and am expected to keep it for my records.

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FOR ELECTRONIC CONSENT:

For electronic consent, your name, digital signature, date, and time of consenting will be added below by the consenting software. By adding your electronic signature, you consent to the material provided as if you were physically signing a hard copy of this document. By signing this informed consent document, you acknowledge that you have read and fully understand all pages of the information presented in it, had an opportunity to ask questions, and voluntarily agree to be in this study.

Participant

I voluntarily agree to participate in this study

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