## STUDY INFORMATION:

**Study Title:** Personalized exercise recommendations for pain self-management in endometriosis

**Study site(s):** Icahn School of Medicine at Mount Sinai

**Lead Researcher (Principal Investigator):** Ipek Ensari, PhD

**Physical Address:** Icahn School of Medicine at Mount Sinai, 1468 Madison Ave, Annenberg Building, 11th Floor, New York, NY 10029

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**Email:** ehivexrx@mssm.edu

## SUMMARY OF THIS RESEARCH STUDY:

This document explains a research study you might be interested in joining. Participation in the study is voluntary. You can agree to join or not. Your decision will not limit your ability to receive care at Mount Sinai. You should only agree to take part if you understand the study and if all of your questions about the research study are answered. If you do join the study, the research team must share any new information with you that may change your mind about taking part.

About 20% females are diagnosed with a chronic pelvic pain (CPP) disorder such as endometriosis with severe lower abdomen and pelvic pain. The condition affects their work productivity and quality of life. The type and intensity of symptoms experienced vary between patients and there are daily fluctuations in symptoms. Existing research suggests that physical activity (PA) and exercise can be an effective pain management approach.

The purpose of this research study is to better understand how various exercises might influence day-to-day variations in pain among individuals with a diagnosis of endometriosis or suspected endometriosis. The data collected will be used to help train an AI (artificial intelligence) algorithm to personalize exercise recommendations based on an individual's symptoms and responses. The ultimate goal of the study is to help understand how exercise could be used by CPP patients to manage their condition and complement other treatments.

Participation in this study involves using a mobile health (mHealth) application called ehive, to track daily symptoms and health behaviors and receive exercise recommendations for 9 weeks. The data will be used to identify types of exercises that might be helpful for your pain symptoms and factors that could influence this relationship.



If you choose to take part, you will be asked to:

- Download a mHealth app, ehive, to self-track your daily symptoms, well-being, self-management techniques.
- Complete brief standardized questionnaires on pain and quality of life each week through the ehive app.
- Wear an activity tracker, provided by the study, on your wrist every day for 9 weeks.
- Meet with our research coordinator (virtually) upon enrollment for them to orient you to using ehive and the tracker, discuss exercise safety and your exercise preferences to help tailor the recommendations.

The orientation meeting is anticipated to take approximately 40 minutes and you will have a chance to ask any questions you might have. The time frame for your involvement in the study thereafter is 5-10 minutes per day for 9 weeks. The study does not require any in-person visits to Mount Sinai premises, and there are no costs associated with participating in this study. You will be compensated for your participation.

If you choose to take part, the main risks to you are loss of private information and temporary feelings of fatigue and muscle soreness after exercising.

You will not benefit directly from taking part in this research. However, you might learn about how different exercises influence your pain and other symptoms on a day-to-day basis.

If you are interested in learning more about this study, please continue to read below.

## STUDY PARTICIPATION:

You may qualify to take part in this research study because 1) you are a female between the ages of 18 and 64, 2) have a clinician or surgical diagnosis of endometriosis OR have experienced endometriosis symptoms including chronic pelvic pain, pain during periods, pain during or after sex, painful urination or bowel movements, heavy bleeding during periods or between periods for at least 1 year, and 3) you feel comfortable engaging in basic physical activities.

You should not participate in this study if you consider yourself to be completely physical inactive (i.e., less than 60 minutes of brisk walking per week), you are currently pregnant, or given birth in the past 6 months, or if you have any other major illnesses (e.g., active cancer, acute coronary syndromes).

Your participation in this research study is expected to last 9 weeks. There are 45 people expected to take part in this research study at the Icahn School of Medicine at Mount Sinai. Funds for conducting this research study are provided by Mount Sinai.

## DESCRIPTION OF WHAT IS INVOLVED:

If you agree to take part in this research study, here is what may be involved:

- *You will be asked to download a research smartphone app (ehive) to track your daily symptoms, medications, and health behaviors, as well as your pain before and after engaging in exercise.*
- *You will receive personalized exercise recommendations 3 times a week and you will be asked to follow the recommendations provided you feel comfortable and safe doing so.*
- *You can skip the exercise recommendation if you are feeling unwell for any reason, in which case we ask that you track this within the App.*
- *You will be asked to respond to brief questionnaires once a week, about pain symptoms, daily activity, and quality of life.*
- *These tracking activities can take approximately 10 minutes a day and any recommended exercise will not exceed 45 minutes unless you specifically request this.*
- *As part of the research study, you will receive a Fitbit activity tracker. You will be asked to wear the activity tracker every day, which will be synched with the ehive app. We will collect data on your physical activity and sleep through this tracker.*

*The study does not require you to come to Mount Sinai during the course of the study. We will check in with you once a week regarding how the study is going, either via email or ehive. If you are having any trouble with the activity tracker or the app, you can ask for the research coordinator to contact you to help troubleshoot by replying to the check-ins. In addition, study coordinators may reach out to you to remind/reinforce study procedures. This may happen at most twice a week. It is important that you do not skip a day of entering data. Any feedback you provide on the exercise recommendations in the ehive app will help us monitor the study for safety, feasibility, and user satisfaction.*

### Randomization

After enrollment, you will be assigned two exercise interventions:

A) generic exercise recommendations based on the national physical activity (PA) guideline for 4 weeks and
B) tailored exercise recommendations for 4 weeks.

The order in which you will receive the assignment is random i.e., AB or BA. No one, not you, or anyone from your research team will be able to choose what sequence you are assigned. It will be by chance, like flipping a coin. You will have a 50% chance of being given either exercise assignment combination. You will not be told which group you are getting; however, the Lead Researcher, research team, etc. will know.



## Pregnancy

You cannot be included in the study if you are or become pregnant, as the study exercises could harm your fetus. You also should not be in the study if you have given birth in the past 6 months or plan to get pregnant in the next 3 months. During your study participation, you should use effective birth control. Unless you are sexually abstinent (not having genital sex) the recommended methods of birth control are:

- The consistent use of approved hormonal birth control (pill, patches, or rings),
- An intrauterine device (IUD),
- Contraceptive injection (Depo-Provera),
- Double barrier methods (Diaphragm with spermicidal gel or condoms with contraceptive foam),
- Sexual abstinence (no sexual activity),
- Sterilization (a vasectomy, getting tubes tied, or a hysterectomy).

All birth control methods (other than abstinence and sterilization) are only effective if you use them properly, start them at least one month before you begin the research study, and continue using them throughout the research study. If you are unsure whether the method of birth control you use is approved to use while you are in this study, you should ask the Lead Researcher before you begin the study. If you are less than one-year post-menopausal, you could still become pregnant. If you become pregnant, or may be pregnant, at any time during your study participation, you must tell a person from the research team immediately. The team may stop the study intervention and refer you to an obstetrician/ gynecologist for follow-up.

Should you become pregnant, whether or not you have the baby, the people funding and overseeing the research may ask for information on the pregnancy, even if you are no longer part of the study. You will be asked for additional written consent to share this information if that happens.

## User feedback interview (optional)

At enrollment you may be asked to participate in a 1-hour virtual interview to provide feedback on the study app usability and usefulness. This is optional. You can choose not to participate in the interview and still enroll in this study. If you agree to the interview, the study team will set-up a virtual call with the lead researcher, Dr. Ensari. During the call, the ehive app will be described to you and you will be guided through its different components. Next, you will be asked to complete simple tasks on the app such as tracking a symptom and entering medications. The tasks will take approximately 20 minutes to complete. You will then be asked to complete 2 brief questionnaires on the ehive app and answer open-ended questions to share your perceptions and feedback. The session will be audio recorded for analysis. Do you agree to participate in the optional user feedback interview?

Please initial your choice: Yes_____ No_____



## Future Contact:

The researchers may wish to use your personal contact information to contact you in the future. Do you give the researchers permission to **contact you** in the future to request the collection of additional information about you, discuss how your private information, study data and/or samples might be used, or discuss possible participation in another research study?

Please initial your choice: Yes_____ No_____

If "Yes", please indicate your preferred method of contact: (initial all that apply)

[ ] Email [ ] Phone

## USE OF YOUR DATA:

In addition to being used to complete this research study, your personal information (such as, name, address, date of birth, social security number), and study data may also be used and shared for additional (future) research. Before anything is shared, all of your identifying personal information will be removed and it will be replaced with a code. Researchers are not planning on giving you the details of any of this future research nor the results. That means that a research project might be done that you would not consent to if provided with the details of that research project. If you do not want any future research to be done with your data and/or samples, even with your identity removed, please do not sign this consent form or take part in the study.

## YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study, you will be responsible for the following things: 1) have access to a smartphone with wi-fi to download the ehive app, 2) wear a 24-hour activity tracker for the duration of the study, 3) track your daily symptoms, physical exercises, self-management and health behaviors, 4) track your daily exercises and your pain symptoms before and after exercise, and 5) respond to brief questionnaires once a week using your smartphone.

## COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

*Being in this study will not cost you anything extra.* If you agree to take part in this study, you will be paid up to $180 for your time and effort. You will receive $20 for each week of data collection so a total of $180 for completing the entire study (i.e., 9 weeks of the data collection). You will be paid an additional $50 if you participate in the optional user feedback interview. An electronic gift card will be emailed to you at the end of each month of the study.



Tax law may require the Mount Sinai Finance Department to report the amount of payment you receive from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally, this happens if you receive payments that equal $600 or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.

## POSSIBLE BENEFITS:

This study is not designed to benefit you personally. The effectiveness of exercises for endometriosis is not well established but it is being explored as part of this study. Through the self-tracking activities, you may learn new information about your individual health and well-being patterns. You may also learn how different exercises influence your daily pain and other symptoms. Findings from this study may help us understand how to best utilize patient-tracked data to define impact of exercise on primary symptoms in CPP disorders. Thus, possible benefits in the long term include development of an exercise-based pain self-management program for endometriosis patients that have applicability across a wide range of settings.

## POSSIBLE RISKS AND DISCOMFORTS:

The possible risks related to participating in the study include:

- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk. Loss of private information includes having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information.
- Engaging in sub-maximal exercise is typically considered minimal risk in healthy, asymptomatic individuals. Expected risks are muscular soreness and fatigue after exercising. These symptoms are mild in nature and subside after a day (or a few days in the case of post-exercise muscle soreness). To mitigate any serious risks, we take several precautions.
    - During eligibility screening, we will use the Physical Activity Readiness Questionnaire (PARQ) to identify any risks. This is the commonly used physical activity eligibility screener to identify those who might pose risks to engaging in exercise.
    - Next, upon enrollment, you will have a brief orientation with our research coordinator. This orientation will include information on how to engage in exercise safely without overexertion, how to monitor heart rate, perceived exercise intensity, and types of physical activities (e.g., aerobic, strength, stretching).
    - We will also ask you about types of exercises you are comfortable with, and preferences. This information will be used for generating the exercise recommendations for you during the study.
    - We will monitor all exercise recommendations and any negative responses and evaluate with clinical experts to ensure continued safety and plausibility of the recommendations.
    - You will have the opportunity to provide feedback via ehive on the exercise recommendation. You also have the freedom to opt out of an exercise recommendation if you are feeling unwell



or for another reason. In these instances, we ask that you track these and provide feedback within the ehive App. We will use these communications as additional information while monitoring the recommendations to refine them as needed and ensure your safety. Our coordinator might also reach out to you at various times points during the study to check in with you and make sure everything is going well.

- Use of the Fitbit tracker provided by the study will include agreeing to Fitbit's data sharing and privacy policies. You will read through and review this as part of the device set-up. This agreement would be the same if you bought the device yourself.
- If you are pregnant or become pregnant, this research may hurt your baby or your pregnancy in ways that are unknown. The unknown risks could be minor or major (death) for the pregnancy. You should not become pregnant while you take part in this study. Please read the acceptable methods of birth control found under the Description of What Is Involved section of this document.
- Group Risks - Although your name will not be given to researchers, basic information such as your race, ethnic group, and sex may be shared. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes or discrimination.
- Privacy Risks - Your name and other information that could directly identify you (such as an address, date of birth, or social security number) will never be placed into a database. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small but may grow in the future. Since the database contains genetic information, a break in security may also pose a potential risk to blood relatives as well as yourself. For example, it could be used to make it harder for you (or a relative) to get or keep a job or insurance. If your private information was misused, it is possible you would experience other harms, such as stress, anxiety, stigmatization, or embarrassment from revealing information about your family relationships, ethnic heritage, or health conditions.

## OTHER OPTIONS TO CONSIDER:

You may decide not to take part in this research study. If you decide not to take part, this will not affect the clinical care you receive at Mount Sinai. The choice is totally up to you.

## IN CASE OF INJURY DURING THIS RESEARCH STUDY

If you believe that being in this research study has harmed you, you should contact the Lead Researcher. Their contact information is listed at the beginning of this consent form.

## ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this study at any time. No matter what you choose, your care and benefits through Mount Sinai will not be negatively impacted.

If you decide to stop being in the study, please contact the Lead Researcher or the research staff.

You may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page. Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

If you decide you don't want your data to be used for research anymore, you can contact the researcher and ask to have your data withdrawn or labeled so that they will not to be used in additional projects or shared. If your data has already been shared with researchers, those researchers will be asked to stop using them. However, if any data has already been shared without your identity or a linking code, it won't be possible to retrieve them. Data that has already been used will not be affected by your decision. If your data has already been deposited in an external repository, the study team will request that your data be removed.

Withdrawal without your consent: The Lead Researcher, the funder or Mount Sinai may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the research team have not been followed, the Lead Researcher believes it is in your best interest, or for any other reason. If data and/or samples have been stored as part of the research study, they too can be destroyed without your consent.

## CONTACT INFORMATION:

If you have any questions, concerns or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Lead Researcher at ehivexrx@mssm.edu.

## DISCLOSURE OF FINANCIAL INTERESTS:

Researchers sometimes get paid for consulting or doing work for companies that produce drugs, biologics or medical devices. If you have questions regarding industry relationships, you are



encouraged to talk to the Lead Researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

## MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As part of this study, some of your private and/or protected health information will be obtained, used, and shared with your permission. There is a Federal Health Insurance Portability and Accountability Act (HIPAA) that makes sure this is done correctly and safely.

What is protected health information (PHI)?
PHI is the combination of two things:

1. PHI contains information that identifies you. It will be used to contact you and link you to your health information, like name, date of birth, medical record number, and address.
2. PHI also contains health information, including information about your mental and physical health from your visits to doctors or hospitals, or from study visits.

Every time you visit a hospital or your doctor, PHI is created and recorded in your medical record by your healthcare providers. In the same way, the PHI created as part of this study will be linked to who you are and your medical information.

What PHI is collected and used in this research study, and might also be shared with others?
As part of this study, the research team at the hospital(s) involved in the research will collect your name, address, telephone numbers, date of birth, email.

During the study, the researchers will gather information by:

- Reviewing and/or taking your medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- Completing the self-tracking items and questionnaires explained in the description section of this consent.
- Using an activity tracker to collect data on physical activity and sleep.
- Audio recording during the user feedback interview (optional)

Why is your PHI being used?
Researchers need the information that identifies you so they can contact you during the study. They need your health information and the results of any tests and procedures being collected as part of this study to answer the questions posed in the study. The purpose of the study is discussed earlier in this consent form. Before researchers analyze the data, they remove any information that would let others know who you are or that you took part in the study. If researchers publish or present study results at scientific meetings, lectures, or other events, their presentations would not include any information that would let others know who you are, unless you give separate permission to do so.



The Lead Researcher may also use and share the results of these tests and procedures with other healthcare providers at Mount Sinai who are involved in your care or treatment. The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example:

- The Mount Sinai Program for the Protection of Human Subjects is responsible for overseeing research on human participants and may need to see your information.
- If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- I*f the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.*

Who, outside Mount Sinai, might receive your PHI?
As part of the study, the Lead Researcher, research team and others in the Mount Sinai workforce may disclose your PHI, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Lead Researcher.)

- The United States Department of Health and Human Services (DHHS) and the Office of Human Research Protection (OHRP) (the government organization that is responsible for protecting human research participants).
- A Data Safety Monitoring Board or other committee that will monitor the study on an ongoing basis for safety.

In all disclosures outside of Mount Sinai, you will not be identified by name, address, telephone numbers, date of birth, email unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Lead Researcher will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board (IRB) allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, *OHRP, as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access.* The results of this research may be published. However, your name and other identifying information will be kept confidential.

For how long will Mount Sinai be able to use or disclose your PHI?
Your authorization for use of your PHI for this specific study does not expire.



Will you be able to access your records?
During your participation in this study, you will have access to your medical record and any study information that is part of that record. The research team is not required to release research information to you that is not part of your medical record.

Do you need to give the researchers permission to obtain, use or share your PHI?
NO! If you decide not to let the research team obtain, use or share your PHI, you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment, or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?
If you decide to stop being in the study, please contact the Lead Researcher or the research staff. The research team may ask you whether they can continue to collect information from your medical record. You will also have to decide if you wish to limit the continued use of the information collected during the study. Under US privacy laws you may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page.

Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected, but only to complete this research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your PHI.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If researchers are reviewing your medical records or asking questions about your medical history or conditions, it is possible that they may learn information related to your HIV status. If that is the case, the following information concerns you. If researchers are not reviewing your medical records or asking questions about your medical history or conditions, then you may ignore the following section.



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**Notice Concerning HIV-Related Information**

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 416-0197. These agencies are responsible for protecting your rights.

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## How the Institutional Review Board (IRB) can help you:

This research has been reviewed and approved by an Institutional Review Board (IRB). You may reach a representative of the Mount Sinai Program for Protection of Human Subjects at telephone number (212) 824-8200 during regular work hours (Monday-Friday, 9am-5pm, excluding holidays) for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

## ADULT PARTICIPANT:

Your signature below documents your permission to take part in this research study and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

| Signature of Participant | Printed Name of Participant | Date | Time |
|---|---|---|---|

## PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

| Signature of Consent Delegate | Printed Name of Consent Delegate | Date | Time |
|---|---|---|---|

## WITNESS SECTION:

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

| Signature of Witness | Printed Name of Witness | Date | Time |
|---|---|---|---|