Columbia University Consent Form

Protocol Information

Attached to Protocol: IRB-AAAQ9812
Principal Investigator: Noemie Elhadad (ne60)
IRB Protocol Title: Phendo: Phenotyping Endometriosis through a Mobile App

General Information

Consent Number: CF-AABE4250
Participation Duration: 3 months
Anticipated Number of Subjects: 15000
Research Purpose: To use the Phendo app, the following information will explain the research study to help you decide whether you want to participate. After reading, we will briefly quiz you to make sure you know what is involved in the study.

Learn More:
This form explains why we are doing this study and what you will be asked to do if you choose to participate in this study. It also describes the way we (Researchers) would like to use and share information about you. Please take the time to read the following screens. You can be eligible for this study as a participant or as a control. Both participants and controls have menstruated at least once. A participant has experienced symptoms of endometriosis in the past three months at least, while a control has not. This consent form is written to address a research subject. A research subject can be a participant or a control. If consent will be obtained from the parent (or legal guardian) of a minor, the words “you” and “your” should be read as (“your child” or “the research participant”). This study takes place at the Columbia University Department of Biomedical Informatics.

Tracking Endometriosis:
To better understand the daily experience of endometriosis, we will collect data about endometriosis that you track in this app. This includes signs and symptoms of the disease, co-occurring conditions, and self management information.

Learn more about tracking endometriosis:
The purpose of our research is to understand and characterize endometriosis through patient's daily experiences, and to help patients make sense of their endometriosis symptoms. There are several apps available to help women track their periods, but this research is primarily concerned with understanding the “phenotype” of endometriosis and the way endometriosis affects patients on a daily basis. A phenotype simply means a set of observable characteristics. In endometriosis, this can be as simple as the symptoms that patients experience, such as endo belly, shooting leg pain, or fatigue. Phenotyping endometriosis will allow us to identify different types of endometriosis. Researchers have already found that there is more than one phenotype of endometriosis by looking at histological samples from excised

lesions. But, we do not know how many different phenotypes there are in endometriosis, nor what each one looks like when we take all the symptoms of endometriosis into account.

If you experience symptoms of endometriosis, you can track your experience of endometriosis in Phendo at your convenience, track more or fewer signs, symptoms, comorbid conditions, and self management information, or stop tracking at any time. If you don't experience symptoms of endometriosis and are participating as a control, we encourage you to explore the app upon download and track your experience of your daily life. Phendo is an observational research study to establish a catalog of the signs and symptoms of endometriosis as experienced by patients, along with the patient's medications, self-management strategies, and daily quality of life. We might remind you to track your experience of endometriosis using mobile notifications, if you accept them.

The entire study will be conducted virtually by requiring participants to download the mobile phone application ("App") Phendo. If you join this research study, we will ask you to record (or track) your daily experience of endometriosis using Phendo. You will:

- Be asked to complete a baseline questionnaire
- Track individual instances of symptoms as they occur in a moment- to- moment basis.
- Track symptoms at a daily level by reviewing your day and the experiences you had in relation to endometriosis.
- Be able to review items you have entered into the app through time.

Having this information will allow for precise treatment and and prognosis of the different ways that endometriosis can affect women. Looking for these sub-types will help us answer questions like why some women respond well to some treatments, why some are infertile, and why some see no relief in their symptoms after menopause.

Information on Research

Study Questions

You can track your experience of endometriosis at your convenience, track more or fewer signs, symptoms, comorbid conditions, and self management information, or stop tracking at any time.

Learn more about the study questions:
The research team will email you a link to a baseline questionnaire administered through a secure online portal at Columbia University Medical Center. The baseline questionnaire will ask about your endometriosis, such as your surgical history, treatment history, and potential other conditions you may have been diagnosed with.

In the app, we will ask you a few questions about yourself and your management of endometriosis. If you are participating as a control, we will ask you to answer the same questions as those experiencing symptoms. Daily questions will focus on your experience of the disease. To better understand endometriosis, we will collect data about endometriosis that you track in this app.

We will ask you initial questions such as your age, height, weight, regular medications, regular exercise preferences, diet preferences, and whether you are sexually active or not. Daily tracking questions will relate to your physical and

mental experience of endometriosis, including questions about your experience of pain, other bodily symptoms, menstruation and bleeding, mood, sex (if you indicated in the initial questions you are sexually active), self management used, and overall rating of your day.

You can skip any questions that you do not wish to answer.

The mobile app offers you an option to record audio of your voice as an additional method of describing your experience of endometriosis.
1. Please write your initials next to the choice you make below:
_____ (initial) yes, I agree to recording as described above
_____ (initial) no, I do not want to be recorded

Time Commitment

This study will ask you to track your daily experience of endometriosis over at least a 3-month period. Daily self tracking should take only minutes to complete.

Learn more about the study's impact on your time:
This study involves an initial set-up survey upon enrollment in the study. After this, you will be asked to use the app for three months at least. If you are a participant, this means tracking your daily experience of endometriosis. If you are participating as a control, this will simply mean tracking your experience of daily life.

For most people, participating in this study will take no more than a few minutes every day. You can adjust your level of participation as you see fit. The number of times you decide to track a moment related to endometriosis in a given day, as well as the overall tracking of any given day, is entirely up to you.

Risks

Potential Risks

There are risks, discomforts, and inconveniences associated with this research study.

Learn more about potential risks:
You may find it uncomfortable to track your experience of endometriosis (or daily life if you are participating as a control). This risk is considered low since all tracking within the app is optional, and you can choose to stop tracking at any time.

Transmitting data collected in this study may count against your existing mobile data plan. You may configure the application to only use WiFi connections to limit the impact this data collection has on your data plan.

Benefits

Potential Benefits

Your participation may help us understand the underlying phenotypes of endometriosis. You will be able to visualize and track your own data and potentially learn more about trends in your health.

Learn more about the potential benefits:
The Phendo app could create an unprecedented dataset of daily experience of endometriosis. It may provide insight into phenotypic clusters, that is, potential subgroups of the disease.

You may or may not personally benefit from this study. However, using the Phendo app may help you monitor your endometriosis over time. If you are participating as a control, you may not personally benefit from participating in the study, however you will be a crucial part of furthering understanding of endometriosis as a disease. You may also notice trends and patterns in your health by recording your daily experience.

Confidentiality

Your Privacy

We will make every effort to protect your privacy. Your data will be identified through a study number. However, total anonymity cannot be guaranteed.

Learn more about how your privacy and identity are protected:
Your privacy is important to us. We will use strict information technology procedure to safeguard your data and prevent improper access.

The data you track through Phendo will be handled securely to maintain confidentiality. All the data gathered through Phendo is sent securely and stored on HIPAA-certified servers. To further ensure confidentiality of data gathered for the study, identifying information will be kept separate from other research data gathered throughout the duration of the study.

We will not access your personal phone contacts, texts, emails, personal photos, or websites visited. Your authorization to use and share your tracked data will expire when the research is completed or when you opt out of the study. We will not share any of your data with any non-research third party. If you are participating in another research study and have consented to that study as well as to linking data from the other study to ours, your data will be linked. The list of research studies we link with, under your consent, can be found at www.citizenendo.org/collaborators.

The following people and/or agencies will be able to look at, copy, use and share your research information:
-The research team and staff and collaborators associated with the study (a complete list of research collaborators can be found at www.citizenendo.org/collaborators);

-Authorities from Columbia University, including the Institutional Review Board ('IRB');

-The Federal Office of Human Research Protections ('OHRP')

Please consult our Privacy Policy at
http://www.cumc.columbia.edu/hipaa/pdf/Research_and_HIPAA_Policy.pdf for more details.

Data Use

The data you track through Phendo will be used to identify patterns of endometriosis for you and across all participants.

Learn more about how your data are used:
Your de-identified study data (i.e., the data you track through Phendo, and any survey questions you answer, but not any information that can identify you like your name or your email) will be combined with the similarly de-identified data from other study participants.

The data collected through Phendo will be used to display your daily experience of endometriosis, and will be viewable at the day, week, month, and three-month time point. This will allow you to interpret your experience of endometriosis for self management purposes. If you are participating as a control, you will be able to see your tracked data across these variable time periods.

By analyzing the data from many Phendo app users, we hope to better understand endometriosis signs and symptoms (phenotypes). We also hope to learn whether a mobile app can help women with symptoms of endometriosis better self-manage the disease.

Compensation

You will not receive any payment or other reward for taking part in this study.

Additional Costs

There will be no costs to you for being in this study.

Voluntary Participation

Voluntary Participation

Your participation is voluntary. You may stop participating at any time.

Learn more:
You can continue to use the Phendo app and participate in the study beyond the three-month time period. Taking part in this study is your choice. You can decide not to take part in or stop being in the study at any time. Your choice will not change the treatment you receive from doctors and staff at Columbia University Medical Center and New York-Presbyterian Hospital.

You may decide not to participate in the study, or you may leave the study at any time. If you leave or decide not to participate, you cannot use the Phendo app. To withdraw from the Phendo study, please use the "Leave Study" link in the profile page of the Phendo app.

If you leave the study, we will stop collecting new data. The coded study data collected prior to withdrawing may still be used in the study; it will not be destroyed or deleted.

The study team may decide to withdraw you from the study at any time for any reason.

Additional Information

Issues to consider

Phendo does not replace your medical care. It is a research study and doesn't provide diagnosis or treatment recommendations.

Learn more about issues to consider:
This study will NOT provide you with information related to your specific health or health risks. This is NOT a medical diagnostic tool and is not designed to provide medical advice, professional diagnosis, opinion, treatment or healthcare services.

You should not use the information provided in Phendo, the study documentation, or the Citizen Endo Project in place of a consultation with your physician or healthcare provider. If you have any questions or concerns related to your health, you should seek the advice of a medical professional.

The study does not involve any costs to you as the App is free to download. The App does require Internet connectivity to work but any data utilization is minimal and can be adjusted to only operate on WiFi. The study does not provide any payments or remunerations of any kind.

If you have any questions, feedback or concerns about the study you can email us, the research staff, at citizenendo@columbia.edu
If you have any questions about your rights as a research participant, or if you have a concern about this study, you may contact:

Institutional Review Board (CUMC)
Columbia University Medical Center
154 Haven Avenue, 1st Floor
New York, NY 10032
Telephone: (212) 305-5883
irboffice@columbia.edu

The Institutional Review Board will not be able to answer study-specific questions. However, you may contact them if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Statement of Consent

Statement of consent

I have read this consent. The research study has been explained to me. I agree to be in the research study described above.

A copy of this consent form will be provided to me after I sign it.

By signing this consent, I have not given up any of the legal rights that I would have if I were not a participant in the study.

Signatures

Participant Signature Lines

Parent/Guardian

Print Name _____ Signature _____

Date _____

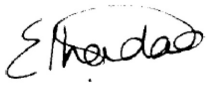
Study Participant

Print Name _____ Signature _____

Date _____

Research Signature Lines

Principal Investigator

Print Name Noemie Elhadad, PhD Signature 

Date _____