STUDY INFORMATION:

Study Title: DigiMe: Pain, Stress, Sleep

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SUMMARY OF THIS RESEARCH STUDY:

In medicine there are many unanswered questions. A research study is when scientists try to answer a question about something that we don't know enough about. Participation in a research study may or may not directly help you or others. Participation is entirely voluntary. It is completely up to you whether or not you take part. You can also change your mind at any time and it will not affect your ability to get medical care within the Mount Sinai Health System.

The purpose of this project is to learn more about your pain, stress and sleep symptoms on a daily basis. We are hoping to learn more about how these symptoms are interrelated and also how it affects more major health outcomes (such as a heart attack) in your health past or health future. You will have the option to connect any wearable device to the app, such as your Fitbit or Apple Watch. Information that wearable devices track, such as activity, heartrate, and sleep, can also help us understand how your symptoms related to pain, stress and sleep work together to affect your daily life.
We aim to integrate your digital (app) and clinical (medical record) data to track your symptoms and your health outcomes over time. By staying connected to the study and sharing data, we will learn more about you and your health. The more we know, the more accurately we may be able to recommend other digital studies at Mount Sinai that you may be eligible to participate in. We will also look at your behavior on the study/app (such as how long you spend on each page of the consent, or how long you spend taking the surveys) to assess the performance of our app/platform itself so we can make improvements to the app itself for you and everyone using it. This is similar to everyday commercial products to see how to make them work better for users or participants.
Entering your data will allow you to track your health overtime, so this study app could be a useful tool for you if you are interested in tracking these symptoms in yourself.

If you choose to participate, you will be asked to

- Download and install the digital study platform
- Complete study surveys and tasks through the digital platform on a recurring basis
- (Optional) Share your electronic medical record with the study
- (Optional) Share data from your wearable device

The main risks to you if you choose to participate are the risk of loss of private information; this risk always exists, and there are procedures in place to minimize the risk as much as possible.

Participating in this research may not benefit you. The first 20 users of the application, who want one, will receive an apple watch or a Fitbit as a loan to track symptoms such as steps and heart rate, in real-time. You may not be eligible because the watches are all claimed, or you may decide you don't want one to use. The choice is up to you. Other than this loan, you will not be compensated by the study.

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

PARTICIPATION IN THIS RESEARCH STUDY:

Feel free to ask all the questions you want before you make a decision about whether or not to participate. You may contact the study team at digime.pss@mssm.edu. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

You may qualify to take part in this research study because you interacted with the Mount Sinai Health System before, have a smartphone, can read and write in English, and you feel that stress, pain and/or sleep impacts your daily life, and you are not currently pregnant.

Funds for conducting this research are provided by the Hasso Plattner Institute for Digital Health at the Icahn School of Medicine at Mount Sinai.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

Your participation in this research study is expected to last for as long as you wish.
The number of people expected to participate in this study is 1,000 participants each year across the Mount Sinai Health System and its affiliates.

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to participate in this research study, the following information describes what may be involved.

Upon consenting for the study through your study app, you will be asked a series of baseline surveys. You will need to sync your wearables (if you choose) to this platform as directed in the study "set up". There will be recurring activities taking place on the phone through the study application. You will be expected to complete the study surveys at the times you are prompted to, ranging from daily to weekly to monthly tasks all related to your pain, stress and sleep symptoms. Researchers of this study team may access your responses to surveys, such as your medical history survey, to see if you're eligible to participate in other studies which utilize this digital platform and may be specific to you or your condition based on what we learn about you. **By signing this consent, you agree to be re-contacted for potential participation in future studies. You may change this preference at any time in the app settings.**

We will obtain your medical health information. This can be controlled by you. We will share information through the app on how you can share your medical record information with us. If you do not wish to go through these steps, the study team will request it with your consent another way. **Before signing the consent, you can opt in to share your medical health information with the study team by checking the box when prompted.**

We may send you a wearable device. During the onboarding of this study, we are offering the first 20 participants an apple watch or Fitbit to wear as a loan for the duration of your participation. You will have the option to use one or not. If you choose to, the Apple Watch or Fitbit will be shipped directly to you. You are expected to wear it devices at all times. The data from the devices will be uploaded into the digital study database so researchers can study it. You will not have to do anything besides install the devices at the start of the study and sync them with the digital study platform and make choices about which data you will share, aka steps, sleep.

Always when you set up the monitors and applications through the phone, you will have to agree to the different manufacturers' terms and conditions and set up a unique account with each manufacturer. In doing so, you will be allowing their collection of some personal information like your name, email address, GPS coordinates and other technology specific data. The Apple Watch (as well as other devices like a Fitbit, if you sync it up with the study app) will measure physiological parameters (such as heart rate, heart rate variability, respiratory rate, temperature, and movement) and sleep related parameters (such as time in each sleep stage, time in bed, and # of wake ups a night). Some of this data will also include GPS, date, and time stamps. It is possible that Apple or Fitbit may be collecting some data through the information you provide on the research platform and if you chose to wear the Apple Watch or Fitbit. These companies could use the data that they collect to make money. This does not include health information, which is protected by this research study. There are data specific to the company's terms and conditions which Apple and/or Fitbit has set up with you upon download and participation in the study application (or any application that you choose to download to your phone). We urge you to look over the terms of agreement with Apple/Fitbit to see what types of data they collect. The research team has no control over these device companies; ie. Apple, Fitbit and we don't have any visibility into what data may be used, sold and shared and used for these companies to make profits through marketing and other initiatives. See software agreements

here: Apple: https://www.apple.com/legal/sla/ , Fitbit: https://www.fitbit.com/global/us/legal/terms-of-service

The study surveys and activities will include:

Onboarding:

1. Logging in through your MyChart account and clicking on the app link
2. Consenting – you will be walked through informed consent, take a comprehension quiz, and sign
3. 3rd party app set-up - sync other apps needed for study including Apple Health application (for iphone users)
4. Reminders - participants who have not completed onboarding will receive push notifications and text message reminders

In-app data collection:

1. In-app surveys, aka. medical history intake form, demographics, pain survey etc.
2. Active tasks, aka. a 2 minute cognition test
3. WiFi address
4. Device battery level
5. Study app usage

We will NOT be collecting this such as:

1. Sound recordings
2. Pictures
3. Video recordings
4. Location data

Check-ins: A member of the study team may contact you outside of regular app notifications. In your app settings, you can choose the method of contact you prefer (call, text, email). This may happen for any of the following reasons:

1. Making sure you're using your wearable devices
2. Making sure you're complying with the digital study tasks
3. Asking you to take some surveys – either additional surveys or ones you may have missed
4. Understanding your general attitudes towards the study as you progress

Interactions throughout the study via the study application (you are able to set your preferences for the following through the app):

1. Push notifications
   - Task reminders
   - Announcements

- Updates
- Non-compliance alerts

2. Activity feed
   - Announcements
   - Survey/active task delivery
   - Links to FAQ and Contact Info pages
   - Acknowledgement of data upload
   - Alerts when non-compliance is detected

USE OF YOUR DATA:

In the future, your identifiable information may be removed from the private information that are collected as part of this research. After this removal, the information could be used for future research studies or shared with other research teams for future research studies. You will not be informed of the details of specific research that is done with your medical information. That means that a research project might be done that you would not consent to if provided with the details of that research project. The future research may be related or unrelated to any of your medical conditions and your identity will always be linked to a code and not revealed, as we and any future researchers who may participate will not need to know who you are while using your data.

This study will limit sharing of data to only those databases, which are restricted and require approval to access. Researchers may be approved to do research related or unrelated to any of your medical conditions and you will not be notified. Please note that traditionally-used identifying information about you, such as your name, address, telephone number, or social security number, will NOT be put into these scientific databases.

Additional Future Digital Research Opportunities

The study team may contact you about future digital research studies you qualify for based on the health information we learn about you.
You may be contacted about the study so you can decide if you want to participate and receive more information. There may be a new consent process just for that study. It may involve you signing up for additional studies within your study application because you were found to be eligible for additional digital studies. In both cases, this means we will have to look up the code to see who the data came from.

By signing this consent form, you give researchers permission to **contact you** in the future to discuss possible participation in another research projects. You can opt out of re-contacting in the app settings at any time after you enroll.

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:

- Downloading and installing the digital study platform
- Complete study surveys and tasks through the digital platform on a recurring basis
- (Optional) Connecting your wearable devices and other health data to the digital study platform

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You will not be paid for participating in this research study. Being in this research study will not lead to extra costs to you.

POSSIBLE BENEFITS:

It is important to know that you may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits may be that the data you share here can help benefit people in the future as we learn more about how to build digital platforms for clinical research and also how the symptoms of pain, stress, sleep and movement contribute to complex disease.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

Privacy Risks

Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk. The information you provide through the digital platform for the purposes of the research, does not contain your name or other identifiers. Therefore, no one outside of the DigiMe research team can access your name. There are procedures in place to further minimize this risk. For example, all data is stored on secured, password-protected servers.

Your name and other information that could directly identify you (such as address or social security number) will never be placed into a public database.

Use of Devices

If you have been given a wearable device (such as an Apple Watch or a Fitbit) through the study and it has been damaged, you are obligated to let the study team know. We will send you a pre-paid label to send back the wearable if something happened to it and it is no longer working.
If your device is lost or stolen you must notify the study team immediately. We will declare it lost or stolen with the wearable company.
Third party use of your data as it applies to your wearable device and smartphone: As mentioned above and independent from this study and what you chose to share with the study team, your smartphone (ie. Apple, Samsung etc.) may be collecting data from you just because you are using an app on their device or wearable ie. Apple Watch. They may use your data, such as your GPS information to sell for profit. We urge you to please read over your smartphone and wearable company's Terms and Conditions before you consent to this study to have an understanding of what data is being collected of you outside this research study.

OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. The choice is totally up to you. Your medical care will not be affected by your decision.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you believe that you have suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in the project at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you are otherwise entitled. If you decide to stop being in the study, please contact the Principal Investigator or the research staff.

You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must request this in writing to the Principal Investigator at the address on the first page that your data be erased and no longer used in future research. Data that has already been used will not be affected by your decision. Any data that is still linked to your identity by a code the researcher has will be withdrawn so that no future sharing of your data will take place. The DigiMe: Pain, Stress, Sleep Study may also be terminated at any time and any data that was collected can be destroyed without informing you.

Withdrawal without your consent: The study doctor, the sponsor or the institution may stop your involvement in this study at any time without your permission. This may be because the study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in

your best interest, or for any other reason. If data has been stored as part of the study, they too can be destroyed without your permission.

CONTACT INFORMATION:

If you have any questions, concerns, or complaints at any time about this research, or you think the research has hurt you, please contact the office of the research team and/or the Principal Investigator at email digime.pss@mssm.edu

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for the Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours 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 subject.
- You want to get information or provide input about this research.

DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk your physician/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 you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

<u>What protected health information is collected and used in this study, and might also be shared with others?</u>

As part of this research project, the research team at the hospital(s) involved in the research will collect your name, address, medical records number, telephone number, dates related to you, and email address. The researchers will also get information from your electronic medical records and other sources as outlined above.

Why is your protected health information being used?
Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

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 School's Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, 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. If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Mount Sinai, might receive your protected health information?
As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your protected health information, 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 Principal Investigator.)

- The United States Department of Health and Human Services and the Office of Human Research Protection.

In almost all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Some records and information disclosed may be identified with a unique code number. The Principal Investigator 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 Institutional Review Board allows it after determining that there would be minimal risk to your privacy. The Certificate of Confidentiality obtained from the Department of Health and Human Services will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others. It is possible that a sponsor or their representatives, a data coordinating office, or a contract research organization, will 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, *the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services 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. They are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access.* We may publish the results of this research. However, we will keep your name and other identifying information confidential.
For how long will Mount Sinai be able to use or disclose your protected health information? Your authorization for use of your protected health information 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 investigator is not required to release to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use or share your health information?
NO! If you decide not to let us obtain, use or share your health information 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?
You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

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, even if your information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored

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) 306-5070. These agencies are responsible for protecting your rights.

Certificate of Confidentiality:
To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services. This is intended to ensure that your identity as a participant in this research study will not have to be disclosed as a result from a subpoena, for the purpose of identifying you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings other than to the FDA or OHRP as identified above.
The research staff will not share any of your research information or biospecimens with anyone who is not a member of the research team, including any family members or friends, other than to those identified above. However, you should know that if we learn that you or someone else is threatened with serious harm, such as a child or an elderly person being abused, the investigators may notify the appropriate authorities if necessary to protect you or others. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. This means that you and your family must also actively protect your own privacy. If an insurer or employer learns about your research participation, and you agree that they can have your research information, then the researchers may not use the Certificate of Confidentiality to keep this information from them.

Your name and digital signature on the next page documents your permission to take part in this research and to the use and disclosure of your protected health information. A signed and dated copy will be available to you in the study app at all times.

If you have any questions before signing the consent, please contact the study team at ddp@mssm.edu.