NYU Langone Health

Official Title:	Physical Activity Assessment, Promotion and Monitoring in a Preventive Cardiology Clinic: A Pilot Study
NCT Number:	NCT04656132
Study Number:	20-00388
Document Type:	Informed Consent Form
Date of the Document:	August 29, 2019

Consent

Please complete the survey below.

Thank you!

Form Status

1) Complete? _____

First Page of Consent Form

Study #: s20-00388
Version date: 020521

Research Subject Informed Consent Form

Title of Study:	Physical Activity Assessment, Promotion and Monitoring in A Preventive Cardiology Clinic: A Pilot Study s20-00388
Principal Investigator:	Margaret M. McCarthy, PhD, RN, FNP-BC Rory Meyers College of Nursing 433 First Avenue New York NY 10001 mmm529@nyu.edu 212-992-5796
Emergency Contact:	Margaret McCarthy 917-886-6136

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.
NYU Employees: Your employment will not be affected by your decision to participate in this study.

2. What is the purpose of this study?

The purpose of this research study is to pilot test the effects of a physical activity promotion intervention on patients’ cardiovascular health. We are asking you to take part in this research study because you are a patient in Preventive Cardiology where the study is taking place.

3. How long will I be in the study? How many other people will be in the study?

Involvement in this study will be 3 months. The total duration of the study will be approximately one year. There will be 59 subjects in this study, all patients being treated in the NYU Langone Preventive Cardiology Center.

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4. What will I be asked to do in the study?

Subjects will be asked to:

1. Fill out four surveys (stages of change, quality of life, depressive symptoms, demographic information)
2. Have your blood pressure, weight, height, and waist circumference measured either all by the PI in person on visit 1 or by the office staff during your office visit and then you may elect to take your own waist circumference at home.
3. Participate in a 6-minute walk test at your own pace
4. Have a fingerstick for a blood test of your lipids; or if you prefer we may use your most current lab values from your electronic health record.
5. Wear a Fitbit activity monitor for 3 months during the daytime hours and sync your step counts to your MyChart account in Epic
6. You may be asked to answer a few questions about your experience with the study after you have participated. This interview will be audiotaped.

Any identifiable information collected and/or used for the purposes of this research will not be used or distributed for future research studies.

5. What are the possible risks or discomforts?

Potential risks associated with this research are fatigue from data collection, inconvenience caused by the need to schedule visits, and loss of confidentiality. There are also inherent risks to participating in physical activity. This will be minimized with the appropriate clinical judgement of the physician in the physical activity promotion process. There is a slight risk of loss of confidentiality in the data collection from the electronic health record, but this will be minimized by the collection of de-identified data only. There are some risks during the fingerstick blood collection of lipids and glucose. With respect to fingerstick blood collection in general (requiring a small sample size of 40µL of blood), some participants may experience temporary discomfort. Some may bruise. Extremely rare risks associated with a fingerstick are bleeding, feeling lightheaded, hematoma, or infection. This risk will be minimized by following established hospital protocols for blood collection.

6. Can I be in the study if I am pregnant or breastfeeding?

If you are currently pregnant, you will not be able participate in the study. If you become or you think you have become pregnant during the study, you must tell the principal investigator right away and must tell your obstetrician or other health care provider caring for you during your pregnancy that you took part in this study. If you become pregnant, you will have to stop taking part in the study for safety reasons. The principal investigator may ask you to provide information about the outcome of your pregnancy and the health of your baby.

7. What if new information becomes available?

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During the course of this study we may find more information that could be important to you.

This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

8. What are the possible benefits of the study?

There may not be direct benefit to patient subjects of this study. However, subjects may increase their physical activity levels enough to reduce their cardiovascular risk by reductions in weight, blood pressure or hemoglobin A1c or improvements in lipids. Subjects may gain of sense of contribution to the process of improving physical activity assessment and promotion. Also, you may not get any benefit from being in this research study. Others with cardiovascular disease may benefit in the future from what we learn in this study.

9. What other choices do I have if I do not participate?

If you choose not to participate in this study you will continue to receive your usual care from your cardiologist.

10. Will I be paid for being in this study?

You will be paid for completing the baseline data collection. If you chose to leave or are withdrawn from the study for any reason before finishing the entire study, you will be able to keep the first payment and the Fitbit activity monitor. If you complete all the study visits, you will receive $100 in gift cards for being in this study.

As is required by the laws that apply to NYU Langone, in order for you to receive a payment (i.e. check, Clincard or bank gift card), you need to give the study staff either your Social Security number or your Alien Registration number and will be asked to complete a IRS W9. If you do not have either of these numbers or are not willing to complete the IRS, you may be in the study but will not receive any payment.

You are required to track all payments made to you by NYU Langone for your participation in any research for this calendar year. You must let us know immediately if/when the total research payments presently equal or is likely to exceed $600.00 total (not including travel reimbursements) for this calendar year. If your total payments (for one or more studies) reach $600.00, please advise *[insert pi's or coordinator's name/contact]*.

In order to receive payments for your participation in research, you may need to provide your Social Security number. This is because NYU Langone is required to report to the Internal Revenue Service (IRS) any amounts that are paid to research participants that are equal to or greater than $600.00, and you may be taxed on these research payments above $600.00. If you will receive payments in any amount by a check, you will need to provide your Social Security number or Alien Registration number and will be asked to complete a IRS W9. If you do not have either of these numbers or are not willing to complete the IRS, you may be in the study but will not receive any payment.

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11. Will I have to pay for anything?

You will not have to pay anything to participate in this study.

12. What happens if I am injured from being in the study?

We do not anticipate any life-threatening adverse events for this proposed research project. However, we have developed a protocol for any potential adverse events. If a patient participant experiences an adverse event during physical activity (e.g. experiencing a fall or musculoskeletal injury), they will be instructed to contact their physician immediately. If the event is an emergency that requires immediate medical attention (e.g. chest, jaw or arm pain, severe shortness of breath, rapid heart rate) they will be instructed to activate the emergency response system (e.g. call 911). The PI will monitor all reports of adverse events related to this intervention. In the event an adverse event occurs, this will be reported immediately to the Data Safety Monitoring Board, the NYU IRB and to the sponsoring agency. A thorough investigation will be initiated, including review of the protocol to insure no undue exposure to risk occurred.

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

13. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped or your participation ended at any time by your physician, the study sponsor without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The study sponsor, the principal investigator, the Food and Drug Administration (FDA) or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

14. How will you protect my confidentiality?

Your medical information is protected health information, or "PHI", and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

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Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

Certificate of Confidentiality
To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents, or biospecimens) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).
The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

By agreeing to be in this research and signing below, you are giving your consent to share research information with others at NYU Langone Health. This means that your research information, including lab results, x-rays, MRIs, information about the investigational drug used in this study, may be included in your NYU Langone Health electronic medical record.

15. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

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What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.
[Note: Genetic testing, HIV results, substance abuse treatment and mental health records may require different consents or language under applicable law.]

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: *National Institute of Nursing Research*
- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.
What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.
Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.
How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

16. Optional permission for future use

NYULMC would also like to store, use, and share your health information from this study in research databases or registries for future research conducted by NYULMC or its research partners. Such health information may include biological samples from the study.

To give this additional permission, check the box below and write your initials where indicated. You may still participate in this study even if you do not give us this additional permission.

NYULMC will continue to protect the confidentiality and privacy of this information as required by law and our institutional polices. If you give this additional permission, you will continue to have the rights described in this form. You have the right to take back this additional permission at any time.

☐ Checking this box indicates my permission to store, use, and share my health information from this study in research databases or registries for future research conducted by NYULMC or its research partners. Subjects initials: ☐

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2) Choosing "yes" indicates my permission to store, use, and share my health information from this study in research databases and registries for future research conducted by NYULMC or its research partners.

◯ Yes
◯ No

3) Subject Initials

_____

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16. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of:

- Doctors, nurses, non-scientists, and people from the Community

17. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website site at any time.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

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4) Participant First Name

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5) Participant Last Name

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6) Participant Signature

_____

7) Date

_____

8) Consenting Team Member First Name

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9) Consenting Team Member Last Name

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10) Consenting Team Member Signature

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11) Consenting Team Member Date

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