

Official Title:

Influencing Basic Behavioral Mechanisms of Action While Targeting Daily Walking in Those at Risk for Cardiovascular Disease: Science of Behavior Change Factorial Experiment of Behavioral Change (MOST Study)

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Northwell Health

Consent for Participation in a Research Study

Study Title: Influencing Basic Behavioral Mechanisms of Action While Targeting Daily Walking in Those at Risk for Cardiovascular Disease: Science of Behavior Change Factorial Experiment of Behavioral Change (MOST Study)

Principal Investigator: Karina W. Davidson, PhD, MASc

Sponsor: National Heart, Lung and Blood Institute of Health (NHLBI), part of the National Institutes of Health (NIH)

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About this research

You are being asked to participate in a research study that aims to identify which behavior change techniques (BCTs) are most important to reduce sedentary behavior. Reducing sedentary behavior has been shown to be important for cardiovascular health.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Important Information

This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

Why am I being asked to provide my consent?	This is a research study, which is different than personal medical care. Scientists do research to answer important questions which might help change or improve the way we do things in the future.
Do I have to join this research study?	<p>No. Taking part in this research study is voluntary. You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled.</p> <p>This study may enroll employees of Northwell Health. Employee participation or non-participation will have no bearing on an employee's position at Northwell Health.</p>

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	This study may also enroll students, including those that may attend Hofstra University. Student participation or non-participation will have no bearing on a student's grades nor academic standing.
Why is this research study being done?	The main purpose of this study is to test how (the mechanism of action) behavior change techniques help sedentary people who have a risk factor for cardiovascular disease (such as hypertension, high cholesterol, diabetes or pre-diabetes, overweight) to be less sedentary and take more steps each day.
What will happen to me during the study?	In this study, you will test the effects of zero- to-four behavior change techniques, delivered by text message. Behavior Change Techniques (BCTs) are also called "behavior change strategies" and can be described as tools to help someone adopt a new behavior. In this study, we are testing BCTs shown to promote physical activity. They include Action Planning, Feedback on Behavior, Goal Setting, and Self-Monitoring. Participants will receive a daily text message with a link to a secure survey that may ask you to provide a brief response. For example, if you are assigned to Goal Setting, you will receive a message that says "Is your goal today to walk an extra 1,000 steps more than your baseline average? Yes/No" Your daily activity will be monitored using a Fitbit® Fitness Tracking watch. Once every two weeks, you will receive a text message with a secure link to a longer survey that measures how confident you are with your walking. If you are in an intervention arm that receives BCTS, once per month during the intervention, you will receive a brief survey that asks you to rate your satisfaction with the BCTs you have been assigned. At the end of the study, we will send you a satisfaction survey to share your opinions about your study experience and the BCTs.
How long will I participate?	The study will take place over the course of 24 weeks. Study participation will end upon completion of the satisfaction survey
Will taking part expose me to risks?	Some people may possibly experience mild skin irritation from wearing your Fitbit activity tracker or experience mild side effects from increased walking. Possible side effects may include fatigue, muscle aches or strains. These side effects normally go away quickly on their own. Some people may experience soreness, tingling, numbness, burning or stiffness in your hands or wrists from wearing the Fitbit, particularly if the Fitbit wrist band is too tight. You should wear the band loosely enough that it can move back and forth on your wrist. If you have ensured your band is not too tight and you are still experiencing these issues, please stop wearing the Fitbit and contact a member of the study team. If you

	<p>experience severe side effects, you should immediately stop walking and contact a member of the study team.</p> <p>Another risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means 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. The study team plans to protect your privacy. Their plans for keeping your information private are described in the sections below.</p>
Are there any benefits to participation?	<p>This study may not benefit you directly. You may or may not experience an increase in your step count or reduction in cardiovascular risk in response to study participation. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include demonstrating an understanding of exactly how BCTs work. This can help doctors and scientists discover new ways to help people increase their physical activity and reduce cardiovascular risk.</p>
What are my alternatives to participation?	<p>You do not need to participate in this study to use BCTs to encourage you to take more steps. You can consult experts in the field or pursue apps that track your step count and provide motivational messages.</p>

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research.

Introduction

You are being asked to join a research study. The purpose of a research study is to answer specific questions. You do not have to be in this study to receive medical care. You should ask questions before you decide if you want to participate. You can also ask questions at any time during the study by emailing mostwalkingstudy@northwell.edu or calling (347)-802-5970.

Why is this research study being done?

The main purpose of this study is to test how (the mechanism of action) behavior change techniques help sedentary people who have a risk factor for cardiovascular disease be less sedentary and take more steps each day. You are being asked to participate in this study because you have self-identified as someone who is sedentary and has one or more of the following risk factors for cardiovascular disease:

- More than 20lbs over ideal weight-for-height ($BMI \geq 30$)
- Have high blood pressure (greater than 130/90)
- Have a high cholesterol level
- Have diabetes or pre-diabetes
- Smoke cigarettes

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- Take medication to lower your cholesterol or blood pressure
- Have a family history of cardiovascular disease

The data collected in this study will help us understand exactly how BCTs work to reduce sedentary behavior. We aim to discover which BCT or combination of BCTs are the most helpful in reducing sedentary behavior. This information can help providers and patients to reduce the risk of cardiovascular disease.

How many people will take part in this study?

This research study hopes to enroll up to 820 people. Up to 624 participants will be randomized (like the flip of a coin) to complete research procedures.

How long will I be in this study?

If you are selected to take part in this study, study activities will last for 24 weeks. The first four weeks of study participation is called “baseline” and will monitor your daily step count using the Fitbit® fitness tracking watch. Once you have been objectively confirmed to be sedentary, you will be randomly assigned to an intervention schedule that is 8 weeks in duration. Once you complete the intervention period, you will be asked to complete a 3 month follow-up period that continues to monitor your steps and questionnaire responses, but does not send you daily BCTs. At the end of this follow-up period, you will complete a satisfaction survey. This ends your participation in the study.

If you will be traveling outside of the United States during the study period, or if you will not have access to text-messaging or internet for more than a few days during the study period, you should talk to a member of the study team to determine your eligibility for this study.

What will happen in this research study?

This study uses text-messages to deliver interventions and surveys throughout the study. Completing the surveys will require cellular data if you are not connected to Wi-Fi. You will not be reimbursed for text messages or data charges, and standard carrier rates may apply.

If you are selected as a potential participant in this research study, you will be mailed a Fitbit® (owned by Google) activity tracker and sent links to instructional materials and videos to help guide you through this study. The study team will send you 3 onboarding surveys, text messages via Twistle to confirm next steps, and your study start date. You will also receive a text message the day before your study begins. You will be asked to download the Fitbit® app to your smart phone if it is not downloaded already, and use or create a Google account to log in to the Fitbit app. If you do not already have a Google account, the study team will provide you instructions to create one. Using and/or creating an account with Google to log in to the Fitbit app requires providing personal information. If you do not want to do this, you should not agree to be in this study.

The first four weeks of the study is considered your baseline period. The purpose of this baseline period is to help us determine your usual activity level. This “baseline phase” will determine your eligibility for the intervention. If you are confirmed eligible for the intervention phase, you will be notified by text message of the date that you will begin receiving text messages. You will be randomly assigned (like the flip of a coin) to one of 16 possible intervention plans. You may receive only one BCT, you may receive multiple BCTs, or you may be assigned to a group that receives no BCT messages (control group).

If you are found ineligible for the intervention, your study participation will end and you may keep the Fitbit® as a “thank you” for your participation.

If you are not adherent to study procedures during baseline (answering all 3 onboarding surveys, answering at least 1 of the 3 bi-weekly self-efficacy (confidence in walking) surveys, at least 75 % satisfactory completion (21/28 days) of daily surveys and wearing the Fitbit® activity tracker for at least 10 hours each day.), you will be asked to return your Fitbit® activity tracker to the study team. A member of the research team will provide a pre-paid mailer.

Once per day, you will receive a text message with your BCT, BCTs or control group message. Some BCTs require a documented response. BCTs that require a response will have a link to a secure survey in which you can directly enter your answer. Each message will begin by reminding you of your baseline average step count (“Your average step count during baseline was XXXX steps per day.”).

The **Goal Setting** BCT message is: “Is your goal today to walk an extra 1,000 steps more than your baseline average?” Yes/No

The **Action Planning** BCT message is: “Take one minute and plan for today how, where and when you can walk an extra 1,000 steps more than your baseline average. Have you planned for today?” Yes/No

The **Self-Monitoring of Behavior** BCT message is: “Check your Fitbit® for yesterday. Type in the number of steps you did yesterday”

The **Feedback on Behavior** BCT message is one of two possible messages:

IF you DID NOT meet your step goal:

“Your goal is to walk 1,000 steps more than your baseline average. Yesterday you did not meet your goal. If you think this is incorrect, you can check your step count from yesterday on your Fitbit® app to confirm.”

OR

IF you DID meet your step goal:

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“Your goal is to walk 1,000 steps more than your baseline average. Yesterday you met your goal. If you think this is incorrect, you can check your step count from yesterday on your Fitbit® app to confirm.”

Should you experience walking related side effects, study coordinator contact information is readily accessible on the bi-weekly surveys. If you are concerned about any side effects, you may stop walking at any time and contact a member of the research team for more information about continuing your study participation. Once every two weeks, you will receive a longer survey that asks about your confidence in walking for longer time periods. Once per month during the intervention, if you are not in the control group, you will receive a brief survey about your satisfaction with your assigned BCTs

Any e-mail correspondence that you send to the study team or the study team sends to you during your participation in the study will be sent via encrypted email. If you are a Northwell employee, we would like to send to your Northwell email address via the Northwell email system. Any e-mail correspondence sent by the study team will reference “ MoST.”

You will be asked to wear your Fitbit® for at least 10 hours per day, every day throughout the entire study. Your Fitbit® can be charged during periods of extended sitting, like when you are in your car or sitting at a desk, or while you are showering. You will need to sync your Fitbit® device daily. You can sync your device by opening the Fitbit® app and waiting for your data to load.

It is very important that you wear your Fitbit® device a minimum of 10 hours per day, that you sync your Fitbit® device daily, and that you answer the survey questions sent to you each day. You will be able to select one of three possible time periods to receive your text message before your baseline period begins. You may be asked to discontinue your participation in this study if you are not wearing your Fitbit® long enough, or if you do not answer enough survey questions each day. This is often referred to as adherence or compliance, and will be measured by answering all 3 onboarding surveys, answering at least 1 of the 3 bi-weekly self-efficacy (confidence in walking) surveys, at least 75 % satisfactory completion of daily surveys and wearing the Fitbit® activity tracker for at least 10 hours each day.

During the study period, we monitor to ensure that your Fitbit® data is downloaded and that you are responding to daily text messages. You may also receive additional text messages to remind you to respond to surveys, to charge your Fitbit® or to ask you to sync your data if it is not appearing correctly. You will receive your study onboarding instructions in multiple text messages, but during the course of the study you will receive a maximum of 5 text messages per day, including these reminders and the survey questions outlined above. We may even call you to make sure you are not experiencing any physical or technical issues and to confirm that you remain interested in study participation.

You may stop participating at any time by the methods described in the relevant section below. Alternatively, you may be asked to end your study participation by a member of our research team for any reason.

We will compile the data from your questionnaires and your Fitbit®. Any identifying information about you will be removed. A statistician will then analyze your coded data. Only the research team will have the key to identify you based on your research code.

Your trial is complete after you completed 24 weeks of data collection and you have completed your satisfaction survey.

What are the risks of the research study? What could go wrong?

Although this is a minimal risk study, there are some potential risks to participating.

Intervention Side Effects

Walking

Although it is not anticipated that increased low-intensity walking by generally healthy persons will pose risks greater than those in everyday life, it is possible that participants may feel fatigued or experience muscle soreness related to increased walking. If you are concerned about any of these side effects or any others you may experience, you should immediately stop walking and contact a member of the study team. You may still be able to continue with the study or you may be asked to end your participation in the study.

Fitbit Band:

You may experience mild skin irritation (rash) from wearing the Fitbit band during this research study. To reduce irritation, keep the band clean and dry. To provide relief for your skin if this mild risk occurs, remove the band for a short period of time.

You may experience soreness, tingling, numbness, burning or stiffness in your hands or wrists from wearing the Fitbit, particularly if the Fitbit wrist band is too tight. You should wear the band loosely enough that it can move back and forth on your wrist. If you have ensured your band is not too tight and you are still experiencing these issues, please stop wearing the Fitbit and contact a member of the study team.

Behavior Change Techniques (BCTs)

There are no known risks to using BCTs. Should a participant experience any distress participating in the study, the principal investigator is a licensed clinical psychologist and can make appropriate referrals for the participant.

Loss of Confidentiality or Privacy

One risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means 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. The study team plans to

protect your privacy by only sharing necessary information about you to those outlined in the “Who else will see your information?” section below.

Any information collected during this study that can identify you by name will be kept confidential. We will separate your personal information (name, address, cell phone number) from all the information you provide us (this is called giving a “code” to your data). The key to your identifiable information will be stored separately in a secure, password-protected, HIPAA compliant database. Your personal or identifiable information is not stored on any of the study devices used in this study.

Your questionnaire responses will be obtained by a text message link from a secure web application that is used to collect survey data. We will do everything we can to keep your data secure, however, complete confidentiality cannot be promised.

What are the benefits of this research study?

You may or may not experience any change in your walking behavior or reduction of cardiovascular risk in response to the interventions. However, your personal observations when testing the different BCTs associated with promoting walking may help you to manage your walking behavior and potentially be less sedentary. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include demonstrating that BCTs can help doctors, scientists and individuals discover new ways to help patients at risk of cardiovascular disease be less sedentary in the future.

Will I receive my results?

No individual results will be provided in this study. However, participants will be sent a copy of the primary results manuscript when published.

If you do not want to take part in this research study, what are your other choices?

You do not need to participate in this study. You can consult with professionals about BCTs or pursue commercial apps to help you become less sedentary. The study team/study will not cover the costs of any follow-up consultations or actions.

Are there any costs for being in this research study?

This research study is funded by the National Heart, Lung and Blood Institute, part of the National Institutes for Health (NIH). The Fitbit® activity tracker will be provided to you at no cost. Neither you nor your insurance company will be billed for your participation in this research.

This study uses text messages to deliver links to notifications, reminders, and study questionnaires. Standard message and data rates from your wireless carrier may apply. You will not be compensated for any costs related to data usage or sending or receiving text messages by the study or by members of the study team.

Will you receive any payments for participating in this research study?

After successfully completing the intervention phase of the study (Month 3), you will be sent a \$100 payment card called a ClinCard that can be used like a credit or debit card anywhere MasterCard is accepted, including online.

During the follow-up phase of the study (Months 4-6), participants who answer surveys, sync their data, and continue to wear their Fitbit® activity trackers for a minimum of 10 hours per day at least 5 days per week will be eligible for a lottery in which a randomly selected participant will receive a \$100 ClinCard. There are no limitations on the amount of times a participant can win the follow-up lottery.

At the conclusion of the follow-up phase of the study (Month 6), participants will receive a \$150 ClinCard upon completion of the final survey.

As a thank you for participation, you will also be able to keep your Fitbit® (a value of approximately \$150). During baseline, if you are not adherent to study procedures (answering text messages, wearing your Fitbit® at least 10 hours per day for a minimum of 75 % of days (21/28 days), you will be asked to return your Fitbit® activity tracker to the study team. A member of the research team will provide a pre-paid mailer.

What are your rights as a research participant?

Your participation in this project is voluntary. The quality of your medical care and/or employment or enrollment status will be the same, whether you join, refuse to join, or decide to leave the study.

If you do not join the study you will not be penalized or lose benefits to which you are entitled. If you join the study you may withdraw at any time without prejudice to your future care and/or employment at Northwell Health.

This study may enroll employees of Northwell Health. Participation or non-participation will have no bearing on your position at Northwell Health. This study may also enroll students, including those that attend Hofstra University. Student participation or non-participation will have no bearing on your grades or standing at your academic institution.

Could you be taken off the study before it is over?

It is also possible that your participation in this study may end without your consent. This decision may be made by a researcher, study sponsor or the Institutional Review Board, (the committee that oversees research at this institution).

Reasons for withdrawal may include:

- Failure to follow instructions, including maintaining less than 75 % adherence to survey responses and Fitbit® use
- Significant cell phone carrier issues that prevent you from receiving study text messages

- It is not in your best interest to continue on this study, or
- The study is stopped

If you withdraw from this study or if you are withdrawn from the study, any data already collected will continue to be used. However, no new data will be collected.

What happens if new information is learned?

You will be told of any new findings that may change your decision to continue to participate. Your consent to continue to take part in this study may be obtained again.

What information will be collected and used for this study?

If you agree to be in this study, we will collect information that identifies you. We may collect the results of questionnaires and Fitbit® activity and sleep data. We will only collect information that is needed for the research. This information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your health information.

Fitbit®/Google

Data collected by Fitbit®, which is owned by Google, includes activity data (steps, activities, intensity, heart rate, floors climbed), sleep data (total sleep minutes, sleep stage estimates, sleep and wake times), and device data (last sync date and Fitbit® battery level). We will only collect this data through the study period.

Google and Fitbit’s Terms of Service and Privacy Policy are separate from this research consent form. Using the Fitbit activity tracker and app requires that you agree to the following:

- [Google’s Terms of Service](https://policies.google.com/terms): <https://policies.google.com/terms>
- [Fitbit’s Additional Terms of Service](https://support.google.com/product-documentation/answer/13511576): <https://support.google.com/product-documentation/answer/13511576>
- [Google’s Privacy Policy](https://policies.google.com/privacy): <https://policies.google.com/privacy>

We do not control these terms and policies, which can change at any time. You should read the terms and the policies before enrolling in this research and before using the Fitbit activity tracker and app. You may want to periodically check for any updates to Google and Fitbit policies. You should also review your privacy settings often. Google and Fitbit’s Terms of Services include information about your legal rights when using Fitbit’s products that may differ from your rights as a participant in this study. Google’s Privacy Policy and Fitbit’s FAQs on Privacy describe how Fitbit collects, uses, shares, and protects your data. You can exercise your right to access your personal information by logging into your account and using your account settings. Fitbit may also have access to device identifiers so they may be able to identify that you are a participant in this research. For more information about the information that Fitbit may have access to, refer to Google’s Privacy Policy and/or Fitbit’s FAQs on Privacy listed above.

N1Thrive

Survey data will be collected via a secure web browser and stored in a HIPAA-compliant, Northwell approved database. Text messages will alert you to a new message from “N1Thrive”

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and contain a link to open this secure browser directly on your phone. No identifying information will be shared via text message.

What information will be shared outside of Northwell Health?

Your privacy is important to us. We will only share information that is necessary to complete the study.

If you agree to be in this study, and if you are selected as a participant, you will be sent a Fitbit®. You will also be sent written and video instructions on how to connect the device to the Fitbit app using a Google email account via text message and/or email and have the option to call the study team for assistance.

Data will be shared from your Fitbit® to the research team by direct sharing from Fitbit and by using an online portal called Fitabase™. Your account will be linked to an identification number in the Fitabase™ system. No information that could be used to identify you will ever be shared with Fitabase™. Only the research team will have access to data that will be able to connect a research participant to their Fitbit account or Fitabase™ ID. Both Fitabase™ and Fitbit will stop sharing your data with the study team at the end of your study.

Data collected from Fitabase and directly from Fitbit will include activity data (steps, activities, intensity, heart rate, floors climbed), sleep data (total sleep minutes, sleep stage estimates, sleep and wake times), and device data (last sync date and Fitbit® battery level). De-identified data from Fitbit will remain stored in a Northwell-approved HIPAA-compliant drive indefinitely. N1Thrive, the company the study team is partnering with to develop the technology to analyze data for current and future trials, will send study messages via a HIPAA-compliant manner on behalf of the study team.

Survey data will be collected by 4Peacocks/N1Thrive, a company that was formed specifically for the development of technology to support our research methods. Additional study data will be collected and stored using the Northwell REDCap system. The study team will continuously have direct access to the data shared through N1Thrive. At the end of the study, your identifying information will be removed from the N1Thrive database.

Who else will see your information?

Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside Northwell Health, except as detailed below.

Investigators will share information collected from this research study with:

- Study sponsor (NHLBI) and/or its agents,
- Other researchers,
- Accrediting agencies,
- Data safety monitoring board.

The following reviewers may access your study records to make sure that this study is being done properly:

- Representatives from federal and state government oversight agencies, such as the Department of Health and Human Services, and the National Institutes of Health
- Representatives from Northwell Health's Human Research Protection Program, (a group of people that oversee research at this institution)

In the future, we may publish results of this study in scientific journals and may present it at scientific meetings. If we do, we will not identify you.

If the researchers learn about potential serious harm to you or someone else or other public health concerns, it will be shared with the appropriate authorities.

Can you change your mind?

If you change your mind about being in the study, you may withdraw at any time. If you want to withdraw from the study, you need to send an email to the researcher at the following address: mostwalkingstudy@northwell.edu . You may also reach out to us through Twistle. Alternatively, you can send a letter to the researcher at the following address:

Dr. Karina W. Davidson
Institute of Health System Science
130 East 59th Street, Suite 14C
New York, NY 10022

Your email or letter needs to say that you have changed your mind and do not want to continue to participate. You may be asked if it's ok to keep collecting your step counts but not send you text messages. You will be able to say "yes" or "no" at that time. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

Will information about this study be available to the public?

The researcher also plans to share information about the study, including de-identified data, on the following data sharing website: <https://cos.io/>. The Open Science Framework is a free, open-source web application built to provide researchers with a free platform for data and materials sharing. There will be no identifiable data (like your name) posted to this website or used in future studies.

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

Certificate of Confidentiality

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To help us protect your privacy, this research is covered by a Certificate of Confidentiality from the US Department of Health and Human Services (DHHS). The Certificate of Confidentiality means that researchers cannot be forced to identify you, even under a court subpoena. The Certificate does not mean the Secretary of DHHS approves or disapproves of the project. It adds special protection for the research information about you. You should know, however, that researchers may provide information to appropriate individuals or agencies if harm to you, harm to others or child abuse becomes a concern. 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. However, if an insurer, employer or other person learns about your participation and gets your consent to receive research information, then the researchers will have to provide your information.

Will my information be used for research in the future?

Information collected from you for this research may be used for future research studies or shared with other researchers for future research. If this happens, information which could directly identify you will be removed before any information is shared. Since identifying information will be removed, there will not be an additional consent for future research. By consenting to participate in this study you are agreeing to allow your coded data to be used by future researchers without additional consent.

Some information collected during this study that can identify you will be kept on file. This information may be used in the future to contact you for future participation in research studies. This information will be stored on a secure database. It will only be accessible by trained members of the study team. If you change your mind about being contacted in the future, you may follow the procedures outlined above to notify the researcher.

Does the investigator of this study receive money if you take part?

The investigators on this study receive money to conduct the study, but do not financially benefit from your participation. The money they receive is to pay them back for the costs of conducting the research study. Funding for this research study is provided by the National Heart, Lung and Blood Institute (NHLBI), part of the National Institutes of Health (NIH).

Who can answer your questions about this study?

If you have any questions about the study, you may call a Clinical Research Coordinator, at (347) 802-5970 or email mostwalkingstudy@northwell.edu. If you have questions about side effects or injury caused by research you should call Joan Duer-Hefe RN, MA, CCRC, Director of Clinical Research, at (646) 766-7153. If you need emergency care, dial 911 or go to the nearest Emergency Room. If you have questions about your rights as a research participant, concerns about being in the study, or would like to offer input, you may contact the Office of the Institutional Review Board at (516) 465-1910.

A signed copy of this consent form will be mailed to you.

[Signature Page Follows]

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Please respond to the following questions to demonstrate your understanding of study procedures and your rights as a research participant.

1. As a participant, I will need to wear my Fitbit® a minimum of 10 hours a day,
☐ True
☐ False
2. As a participant, I will receive a daily text message with 0-4 BCTs. Some may require me to enter a response.
☐ True
☐ False
3. As a participant, I can remove myself from the study at any time by contacting the researcher.
☐ True
☐ False

Summation/Signature

- ☐ I consent to be a part of the Influencing Basic Behavioral Mechanisms of Action while Targeting Daily Walking in Those at Risk for Cardiovascular Disease (MoST) Study.

By checking the box and signing this form I have read the above description of the research study and are consenting to participation. I have been told of the risks and benefits involved and all my questions have been answered to my satisfaction. A member of the research team will answer any future questions I may have. I voluntarily agree to join this study and know that I can withdraw from the study at any time without penalty. By signing this form, I have not given up any of my legal rights.

Electronic Signature
Stamp

Date & Time