A Personalized Trial for Testing the Effects of a Mind-Body Intervention (MBI) on Sleep Duration and Quality in Middle-Aged Women Working in Health Care

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Northwell Health

Consent for Participation in a Research Study

Study Title: A Personalized Trial for Testing the Effects of a Mind-Body Intervention (MBI) on Sleep Duration and Quality in Middle-Aged Women Working in Health Care

Principal Investigator: Karina W. Davidson, PhD, MASc

Sponsor: National Institutes of Aging (NIA)

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About this research
You are being asked to participate in a research study pilot.

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 pilot 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?	No. Taking part in this pilot research study is voluntary. You may choose not to take part in the pilot study or may choose to leave the pilot study at any time. Deciding not to participate, or deciding to leave the pilot study later, will not result in any penalty or loss of benefits to which you are entitled. This study will enroll employees of Northwell Health. Employee participation or non-participation will have no bearing on an employee's position at Northwell Health.
Why is this research study being done?	The goal of this project is to evaluate the effects of a combined Mind-Body Intervention on increasing sleep duration in middle aged women

	working in health care, and to determine which intervention component proved most effective for each individual participant.
What will happen to me during the study?	In this pilot study, you will evaluate your response to three different components of a Mind-Body Intervention: Yoga, Mindfulness and Guided Walking. Each component will be done for 30 minutes, 3 times per week in 2 week blocks. During the study, you will be asked to manage your sleep as you normally would. Each day you will answer questions about your sleep duration and quality. Surveys about your pain, stress, fatigue, mood, confidence, and concentration will be sent bi-weekly. Every other week you will answer questions about your symptoms during the previous two weeks. You will also wear a Fitbit activity monitor each day and night to track your daily activity and sleep. After 12 weeks, you will enter a 2-week follow-up period. You will not receive any MBIs, but you will continue to wear your Fitbit and answer surveys. You will receive a participant report at the end of the study that tells you which MBI (yoga, mindfulness or guided walking) was observed to influence your sleep duration. After being sent your report, you will be asked to complete a satisfaction survey. We will also offer you the option to participate in an audio-recorded virtual follow-up interview with a research coordinator to share your opinions about your Personalized Trials experience. For a detailed description of study procedures, see the below section "What will happen in this research study."
How long will I participate?	The Personalized Trial will take place over the course of 16 weeks.
Will taking part expose me to risks?	It is not uncommon for individuals to experience temporary muscle soreness or fatigue after low-intensity physical activity like walking and gentle yoga. There is always a risk of injury with physical activity. Another risk of taking part in this pilot study is the possibility of a loss of confidentiality or privacy. Some of the questions we ask in the survey are personal. You may feel embarrassed or stressed. You could also experience mild skin irritation (rash) from wearing the Fitbit activity monitor.
Are there any benefits to participation?	You may or may not experience any effects of the MBIs on your sleep duration. However, in receiving your observed data trends when participating in MBIs, you will find out information about your own personal response to each MBI which may give you information on how to manage your sleep duration. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include demonstrating that a Personalized Trials design can help individuals discover new ways to manage their health and wellness.

What are my alternatives to participation?	Your alternative is to not participate.

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. You should ask questions before you decide if you want to participate. You can also ask questions at any time during the study: p30mbi@northwell.edu

Introduction and Research Purpose:
You are being asked to join a pilot research study. The purpose of this study is to evaluate the effects of a combined Mind-Body Intervention on increasing sleep duration in middle aged women working in health care, and to determine which intervention component proved most effective for each individual participant. The study will also examine how your sleep duration may be influenced by feelings of stress and anxiety.

You do not have to be in this pilot 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 pilot study by emailing p30mbi@northwell.edu or calling (646)385-4385.

Why am I being asked to participate?

You are being asked to participate in this study because you have self-reported poor sleep duration and are experiencing stress.

How many people will take part in this study?
Up to 60 eligible participants will complete all research procedures in this study.

How long will you be in this study?

If you are selected to take part in this pilot study, the study procedures will last for 16 weeks.

If you will be traveling outside of the United States during the pilot study period, or if you will not have access to text-messaging or internet for more than a few days during the pilot 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?
After filling out this consent form, you will be asked to provide more information about yourself. This will include your home address. This pilot study uses text-message reminders to help you through the study protocol. Receiving the text messages will require cellular data and 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 research participant in this pilot research study, you will be sent your study kit. This will include a Fitbit device and materials to help guide you through this pilot study. You will be sent confirmation of your pilot study start date, and you will also receive messages ahead of when your study begins to prepare you for your study start date. You will be asked to download the Fitbit app to your phone to collect your data. Correspondence sent by the study team will reference "the sleep duration study" or "the personalized trial to improve sleep duration." Other than the reference to the study title, e-mail correspondence from the study team will not contain protected health information. Communications sent over the REDCap platform are encrypted, which means that others will be unable to access the information transmitted.

The first two weeks of the study is considered your baseline period. The purpose of this baseline period is to help us determine your usual activity and sleep duration. You will not receive any interventions during your baseline period. Each morning you will receive a survey asking you a few questions about your previous night's sleep. This survey will take approximately 5 minutes to complete. Every 2 weeks you will receive a text message asking you about your health such as your pain, fatigue, stress, mood, confidence, and concentration levels at that exact moment. This survey will take approximately three minutes of your time.

You will be asked to wear your Fitbit all day and night, especially while you are sleeping. You will be asked to charge your Fitbit device at least every four days. Your Fitbit can be charged during periods of extended sitting, like when you are in your car, sitting at a desk, or while showering. At least every two days you will need to sync your Fitbit device. You can sync your device by opening the Fitbit app and waiting for your data to load. You will receive a reminder asking you to sync your Fitbit if you have not done so in 48 hours, and you will receive a reminder asking you to charge your device when the battery is approaching being empty.

It is very important that you wear your Fitbit device all day and night, that you sync your Fitbit device at least every two days, that you charge your Fitbit device at least every four days, and that you answer the survey questions sent to you each day. Completing these requirements is often referred to as adherence or compliance and is very crucial in the study. You will be able to select the best times to receive your surveys and reminders before your baseline period begins, and you will have the opportunity to change these times if there is a change in your schedule. 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.

If satisfactory adherence completion is achieved during your baseline period, and poor sleep duration is objectively confirmed, you will be contacted by a member of our pilot study team with your intervention schedule for the rest of the study. You will be assigned a random order of 6 intervention periods. Each intervention period will last 2 weeks. An intervention period may consist of 30 minutes of yoga, mindfulness or guided walking done 3 times per week. The interventions are delivered in video format and may be accessed through a link provided in a text message. You are only able to access the assigned intervention and you cannot access it more than 3 times in one week.

During intervention weeks, you will also be asked to continue wearing your Fitbit device each day and night. You will continue to receive messages every day with survey questions about

your sleep and bi-weekly surveys about your health such as pain, fatigue, stress, mood, concentration, and confidence levels. If you are concerned about any side effects you may be experiencing, you may stop the intervention and contact a member of the research team for more information about continuing your study. You will also continue to receive a slightly longer biweekly survey at the end of each intervention block reflecting on your sleep from the last two weeks.

During the pilot study period, you may also receive additional messages to remind you of next steps for this study or with reminders about study protocol. We will send a maximum of 5 text message surveys per day during the study, as well as these reminders and the survey questions outlined above.

The study will end once you have completed one baseline period (two weeks), two periods of yoga, two periods of mindfulness, 2 periods of guided walking and two weeks of follow-up: 16 weeks total.

Your participation in this pilot research study is voluntary. 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. We will then turn this analysis into a report of your observed data and symptoms over the study period. You will be sent this report in a secure message by our study team. This report is not meant to offer medical advice, but you may find it useful for your own knowledge because it could help you understand your personal response to each MBI. You will be sent a satisfaction survey within one week of receiving your report.

After being sent your report, you will be asked to complete a satisfaction survey and offered the option to participate in a virtual follow-up interview (such as a video call over Microsoft Teams) with a member of our study team to talk about your experience as a research participant in this pilot study. We will ask you several questions about what it was like to participate in the study. We will also ask about your opinion on Personalized Trials. This interview will be audio-recorded and transcribed for data collection purposes only; however, if you decline to be audio-recorded, you may still participate in the follow-up interview.

Your participation in the pilot study is complete after you completed 16 weeks of data collection.

You may keep your Fitbit (value $150) as a thank you for your participation. Every week during your intervention and follow-up periods (14 weeks total), if you wear your Fitbit 80% of the time, and answer 80% of messages and surveys, you will be eligible for a random drawing to receive a $50 clincard. You can use this card like a credit or debit card anywhere MasterCard is accepted, including online. You may win up to a maximum of eight times ($400 total) during the 14 weeks. You will also receive a $50 clincard upon completion of all study activities.

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

It is not uncommon for individuals to experience temporary muscle soreness or fatigue after low-intensity physical activity like walking and gentle yoga. There is always a risk of injury with physical activity. Mindfulness meditation may include experiences that are pleasant, unpleasant, or neutral. It can lead to states of ease, joy, relaxation, peace and a sense of wellbeing. Unpleasant experiences such as agitation, physical discomfort, sleepiness, sadness and anger are also common. Such experiences are usually temporary.

If participants experience discomfort during their treatment sessions, they will be instructed to immediately stop the activity and contact a research coordinator.

You may also 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.

In addition, another potential 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.

Lastly, some of the questions we will ask you are personal. You may feel embarrassed or emotional answering questions about your stress. You may ask to see the questions before deciding whether or not to take part in this study.

What are the benefits of this research study?

This study may not benefit you directly. The goal of this study is to evaluate the effects of a combined Mind-Body Intervention on increasing sleep duration in middle aged women working in health care, and to determine which intervention component proved most effective for each individual participant.

You may or may not experience any effects from the Mind-Body Interventions, but in receiving your observed data trends in response to the interventions, you may receive useful information on how to manage your sleep duration. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include demonstrating that a Personalized Trial design can help individuals address health and wellness issues.

Will I receive my results?

The data we collect from you during study activities could impact how you treat your poor sleep duration. For this reason, much of the information collected about you during the pilot study will be analyzed and provided back to you. You will receive this data in the form of a personalized participant report. The data included in the participant report will include graphs and statistics about your self-reported sleep duration; self-reported pain, stress, fatigue, mood, confidence, and

concentration; activity patterns; sleep patterns; and adherence (i.e., how closely you followed the study procedures). These data will be shown in relation to weeks you had each Mind-Body Intervention. This report is meant to summarize your observed data and self-reported symptoms and should not be considered medical advice.

If you do not want to take part in this research study, what are your other choices?
The alternative to participating in this study is to not to participate.

If you are interested in learning about effective interventions for your poor sleep duration, or if you want to learn more about your personal results, you may wish to meet with professionals with expertise to help you learn more about available interventions. 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 pilot research study is funded by the National Institutes for Aging (NIA), part of the National Institutes of Health (NIH). All study related equipment, devices, and procedures will be provided to you at no cost. Neither you nor your insurance company will be billed for your participation in this research.

This pilot study uses text messages to deliver 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?

Your participation in the pilot study is complete after you completed 16 weeks of data collection and the satisfaction survey You may keep your Fitbit (value $150) as a thank you for your participation. Every week during your intervention and follow-up periods (14 weeks total), if you wear your Fitbit 80% of the time, and answer 80% of messages and surveys, you will be eligible for a random drawing to receive a $50 clincard. You can use this card like a credit or debit card anywhere MasterCard is accepted, including online. You may win up to a maximum of eight times ($400 total) during the 14 weeks. All participants who complete the study will receive a $50 clincard.

If the total payment you receive from Northwell Health, during this year, is equal to $600 or more, the payment is required to be reported to the IRS. Although this study does not pay $600, if you participate in other Northwell Health studies, it is possible your payment could end up totaling $600. If this occurs, the payment you receive on this study will be reported to the IRS. In this case, you will be issued a 1099 form and be required to provide your social security number at that time for reporting purposes. You will also be responsible for reporting this income while filing your tax return

What are your rights as a research participant?
Your participation in this project is voluntary. The quality of your medical care will be the same, whether you join, refuse to join, or decide to leave the pilot study.

If you do not join the pilot 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 will enroll employees of Northwell Health. Employee participation or non-participation will have no bearing on your position at Northwell Health.

Could you be taken off the study before it is over?
It is also possible that your participation in this pilot study may end without your consent. This decision may be made by a researcher, study sponsor or the Institutional Review Board (IRB- the committee that oversees research at this institution).

Reasons for withdrawal may include:

- Failure to follow instructions, including maintaining less than 80% adherence to survey responses and Fitbit use,
- Failure to follow the study protocol,
- Significant cell phone carrier issues that prevent you from receiving study text messages
- It is not in your best interest to continue this pilot study, or
- The pilot study is stopped.

If you withdraw from this pilot study or if you are withdrawn from the pilot 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 pilot study may be obtained again.

What information will be collected and used for this study?
If you agree to be in this pilot study, we will collect information that identifies you. We may collect the results of questionnaires, interviews, Fitbit activity and sleep, and video views. 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. This permission is called authorization. Your authorization to use and share your health information will never expire. If you do not want to provide authorization, then you cannot participate in this research study. Text messages will alert you to a new message from the MBI team and will contain a link to open messages directly on your phone. No identifying information will be shared via text message. The study team will have direct access to the survey and Fitbit data, as applicable, through Fitabase.

Data collected by Fitbit® includes activity data (steps, activities, intensity, heart rate, heart rate variability, floors climbed), sleep data (total sleep minutes, sleep stage estimates, sleep and wake times), and device data (last sync date and Fitbit battery level). Additional Fitbit data (e.g., breathing rate, temperature, oxygen saturation) will be collected and potentially used to help explain the outcome of interest.

You will be asked to download the Fitbit app to your personal phone in order to use the Fitbit device. You will also be sent instructions on how to create and connect the device to a study account. It is important that you use the study account during the study to protect your information, and to allow us to collect your data. Your IP address may be collected by the Fitbit app which could be considered identifiable information. Your Fitbit data will be securely stored in Fitbit electronic platforms as is standard for all Fitbit users. 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
- Fitbit's Additional Terms of Service: https://support.google.com/product-documentation/answer/13511576
- Google's Privacy Policy: https://policies.google.com/privacy
    - As explained in more detail in Fitbit's FAQs on Privacy: https://support.google.com/product-documentation/answer/13532616

We do not control these terms and policies, which can change at any time. You should read the terms and the policies 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. No information that can be used to identify you will be associated with your study account. We will only collect this data through the 16-week pilot study period. Once your study period is complete, you will be sent instructions on how to un-link your Fitbit device from the account. If you have questions about setting up this device, please contact the study team.

Data from your Fitbit device may be shared with Northwell Health for research purposes through an online portal called Fitabase. The study account given to you to connect your Fitbit 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 Fitabase ID. Fitabase will stop sharing your data at the end of your study, but as an added step, you will be asked to remove the study account from your device if you would like to keep your Fitbit. Survey data will be collected via a secure web browser and stored in a HIPAA-compliant, Northwell approved database called REDCap. Secure text messages will alert you to a new message from the MBI Team and will contain a link to open messages directly on your phone. No identifying information will be shared via text message. The study team will have direct access to the data shared through RedCap

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 pilot research study with:

- Study sponsor (NIA) and/or its agents,
- Other researchers,
- Accrediting agencies,
- Data safety monitoring personnel,

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)

We will do our best to protect the privacy of your records but it is possible that once information is shared with people listed on this form, it may be released to others. If this happens, your information may no longer be protected by the federal law. In the future, we may publish results of this pilot 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.

If you agree to let us use and disclose your protected health information, we will collect your health information until the end of the research.

Can you change your mind?

If you change your mind about being in the pilot study, you may withdraw at any time. If you want us to stop collecting your health information, you need to send an email to the researcher at the following address: p30mbi@northwell.edu. 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 the researcher to collect and share your health information. You may also need to leave the pilot 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 finish it.

Will information about this study be available to the public?

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. In addition, the researcher also plans to share information about the pilot 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 posted to this website or used in future studies.

Certificate of Confidentiality

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, pooled with other personalized trial participants or shared with other researchers for future research. If this happens, information which could 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 data to be used by future researchers without additional consent. We will also contact you and tell you about future research studies that may require your 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 Personalized Trials, if you've indicated you may be interested at the end of the study. 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 pilot 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 Institutes of Aging (NIA).

Who can answer your questions about this study?

If you have any questions about the pilot study, you may call Jordyn Rodillas at (646)385-4385 or email p30mbi@northwell.edu . If you have questions about side effects or injury caused by research you should call Joan Duer-Hefele 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 (the committee that oversees research at this institution) at (516) 465-1910. 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 (the committee that oversees research at this institution) at (516) 465-1910.

A signed copy of this consent form will be sent to you.
[Signature Page Follows] 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 24 hours a day, even while I am sleeping.

   ☐ True

   ☐ False

2. As a participant, I will be instructed to complete my assigned Mind-Body Intervention 3 times per week.

   ☐ True

   ☐ False

3. As a participant, I can remove myself from the pilot study at any time by contacting the researcher.

   ☐ True

   ☐ False

4. As a participant, I will receive at most 5 text message surveys per day, along with other important text message communications.

   ☐ True

   ☐ False

Signature Page Follows]

Summation/Signature

You have read the above description of the research study. You have been told of the risks and benefits involved and all your questions have been answered to your satisfaction. A member of

the research team will answer any future questions you may have. You voluntarily agree to join this study and know that you can withdraw from the study at any time without penalty. By signing this form, you have not given up any of your legal rights.

_____

Printed Name of Participant

_____ _____

Signature of Participant Date