Informed Consent Form

Official Title	Feasibility of a Yoga Intervention in Sedentary African-American Women
NCT Number	NCT04710979
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Title of Research Study: Feasibility of a Yoga Intervention in Sedentary African-American Women (IRB Approval: STUDY00010979)

Investigator Team Contact Information:

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Investigator Name: Daheia Barr-Anderson Investigator Departmental Affiliation: School of Kinesiology Phone Number: 612-301-1309 Email Address: barra027@umn.edu	Student Investigator Name (if applicable): Phone Number: Email Address: Study Staff (if applicable): Phone Number: Email Address:

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Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?

The goal of research is to learn new things in order to help people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.

Why am I being invited to take part in this research study?

We are asking you to take part in this research study because you are a self-identified African-American woman who is sedentary.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of the study is to develop a yoga program to decrease sedentary behavior, stress and blood

pressure in African-American women age 18 years or older who are sedentary. By participating in the yoga program, you can provide feedback about what you liked and what you didn't like so that we can continue to improve the program.

How long will the research last?

We expect that you will be in this research study for 9 months participating in the following activities:

- Month 1: Baseline data collection (surveys completed in an hour, saliva samples collected on your own over two days, and activity monitor worn for 7 days)
- Months 2-4: Yoga program for approximately 4-5 hours per week
- Months 5: Post-intervention data collection (same as baseline) and post-intervention focus group for approximately 30-60 minutes
- Month 8: Follow-up data collection (same as baseline and post-intervention)

What will I need to do to participate?

You will be asked to participate in: 1) a yoga program that meets three times per week for three months, 2) data collection at three different time points, and 3) a potential group discussion about what you liked and didn't like about the yoga program.

More detailed information about the study procedures can be found under "What happens if I say yes, I want to be in this research?"

Is there any way that being in this study could be bad for me?

It is possible for injuries due to participation in the yoga program, such as muscle strain, fainting, and falling, may occur.

Will being in this study help me in any way?

Participation in the yoga program may result in health benefits associated with regularly practicing yoga

What happens if I do not want to be in this research?

There are no known alternatives, other than deciding not to participate in this research study.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

We expect about 60 African-American women to be in this research study. All participants will be local.

What happens if I say "*Yes, I want to be in this research*"?

- Month 1: Baseline data collection (surveys completed in an hour, saliva samples collected on your own over two days, and activity monitor worn for 7 days). Saliva samples are being collected to measure stress and the activity monitor will measure your physical activity.

    - You will interact with research staff.
- Months 2-4: If chosen for the yoga program, approximately 4-5 hours per week at the intervention location
    - You will interact with research staff and the African-American yoga instructors.
- Months 5: Post-intervention data collection (same as baseline) and post-intervention focus group for approximately 30-60 minutes
    - You will interact with research staff.
- Month 8: Follow-up data collection (same as baseline and post-intervention)
    - You will interact with research staff.

Whether you are assigned to the yoga intervention group or the no control group, will be chosen by chance, like flipping a coin. Neither you nor the investigator will choose what group you get. You will have an equal chance of being given either group. Those chosen to be in the control group will participate in three data collection periods (baseline, 3-month, and 6-month), but will not participate in in-person yoga in Months 1-3. Instead, these participants will receive a three-month membership to a local yoga studio with three locations and receive a catalog of virtual yoga classes led by the intervention yoga instructors.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for: completing baseline, post-intervention, and follow-up data collection assessments; participating in the yoga program for three months IF you are chosen for the yoga program group; and participate in a post-intervention focus group discussion IF you are chosen for the yoga program group if invited.

What happens if I say "Yes", but I change my mind later?

You can leave the research study at any time and no one will be upset by your decision.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. This means that your choice not to be in this study will not negatively affect your right to relationship with the University of Minnesota.

What are the risks of being in this study? Is there any way being in this study could be bad for me? (Detailed Risks)

The potential risk for participating in the yoga program is minimal and related to physical injuries such as muscle strain, fainting, and falling – all potential risks from engaging in any type of physical activity.

Will it cost me anything to participate in this research study?

- There will be no cost to you for the salivary cortisol test to measure stress.

Will being in this study help me in any way? (Detailed Benefits)

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include health benefits associated with regularly practicing yoga.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research

study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Additional sharing of your information for mandatory reporting

If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Current or ongoing child or vulnerable adult abuse or neglect;
- Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law; or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

Certificate of Confidentiality

To help protect your privacy, the National Institutes of Health has granted a Certificate of Confidentiality. The researchers can use this Certificate legally to refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children or vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

You also should understand that 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. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

What will be done with my data when this study is over?

Your data will not be used for any future research after this study is complete.

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to

z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, you will be directed to visit your primary care physician to get treatment. You will be responsible for any costs related to the injury.

Will I be compensated for my participation?

If you agree to take part in this research study, we will pay you $50 for each data collection time point for a total of $150 and provide a meal and additional $25 for your participation in the post-intervention focus group discussion for your time and effort. You will also be given yoga equipment (mat, block, and strap).

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

Yes, I agree	**No, I disagree**	
_____	_____	The investigator may audio or video record me to aid with data analysis. The investigator will not share these recordings with anyone outside of the immediate study team. If NO is selected, the investigator may not use the recording for data analysis.
_____	_____	The investigator may audio or video record me for use in scholarly presentations or publications. My identity may be shared as part of this activity, although the investigator will attempt to limit such identification. I understand the risks associated with such identification. If NO is selected, the investigator may not use the recording for scholarly presentations or publications.

_____ _____	The investigator may audio or video record me during yoga sessions to share with other intervention participants. Nobody outside of the study will have access to these videos. If NO is selected, the investigator will edit footage to remove your likeness and/or voice as needed.
_____ _____	The investigator may contact me in the future to see whether I am interested in participating in other research studies by Daheia Barr-Anderson.

Informed Consent Form

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent

WITNESS STATEMENT:

The participant was unable to read or sign this consent form because of the following reason:

☐ The participant is unable to read the information

☐ The participant is visually impaired

☐ The participant is non-English speaking

☐ The participant is physically unable to sign the consent form. Please describe:

_____

☐ Other *(please specify)*:

_____