Healthy Habits Intervention

Behavioral Research Informed Consent

Title of Study: The Pick Two to Tick To (P2S2) Habit Development Intervention

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Study location: Detroit Receiving Hospital and
Wayne State University

Funding Source: Wayne State University, Eugene Applebaum College of Pharmacy and Health Sciences

Heather Fritz is being paid to conduct this study.

A. Purpose

You are being asked to take part in a research study to determine if a habit development lifestyle intervention can be successfully delivered to people with metabolic syndrome and if the intervention will lead to weight loss, a smaller waistline, and lower blood pressure. When we use the word habit, we mean simple everyday behaviors that you do without even realizing it (putting on a seatbelt when you get into a car). When we use the work lifestyle, we mean eating a healthy diet and getting enough physical activity. When we use the word metabolic syndrome, we mean a cluster of conditions that increase your risk for diseases like diabetes and heart disease. These conditions include having a waistline > 40 inches for men and > 35 inches for women; having blood pressure > 130/85; and having HbA1c (blood sugar levels) of 5.7%-6.4%. You have been asked to participate in this study because you are African American, age 40 or older, live in Detroit, and have at least two of the risk factors identified above.

Dr. Heather Fritz from the College of Pharmacy and Health Sciences and the Institute of Gerontology and Aaron Brody M.D., and Phil Levy M.D. from the Department of Emergency Medicine are conducting this study. The estimated number of study participants to be enrolled at Wayne State University is about 80. Participants will be recruited from Detroit Receiving Hospital. **Please read this form and ask any questions you may have before agreeing to be in the study.**

In this research study, we want to know whether or not it is possible to teach people to use certain strategies to develop healthier dietary and physical activity habits. Strategies include making small changes to your home, such as placing the TV remote control in a different location, and making detailed plans about what you will do and when, where, and how, you will improve your diet or increase your daily physical activity. Understanding whether or not it is possible to teach individuals these strategies, and whether they help people lead a healthier lifestyle is an important topic of study and this project will contribute valuable data on this issue.

B. Study Procedures

If you agree to participate in this study, we will ask you to participate in a minimum of five health coaching sessions. The first session will be in our study lab and the rest will occur over the telephone with a researcher. We will also ask you to commit to developing two new simple habits (one dietary habit and one physical activity habit) every 2 weeks over the 8-week study period (8 habits total). We will also ask you to allow us to send you text messages to help remind you of the habits that you have decided to work on. All participants will be asked to return to the lab 20 weeks after their initial face-to-face session for a follow-up data collection visit. If you want to participate, we will give you compensation for your time and effort. The following is a list of all of the study activities.

Initial Visit:

1. *Baseline data collection and initial coaching session:* A researcher will ask you to come to the Clinical Research Support Center (CRSC) (the study lab) at a day and time when it is convenient to you. This visit will be done within the next two weeks if you decide to participate in the study. When you come to the study lab, a researcher will ask you to fill out pencil and paper forms. On these forms we will ask you questions about things like your age, race, and how many people live with you. You will also be asked to answer questions about how confident you feel making lifestyle changes, how about your perception of having risk factors for diabetes and heart disease, and questions about your current health habits. During the initial visit we will also ask you to allow a researcher to record your weight, height, to measure around your waist, and to take your blood pressure. We will do these in a private exam room and you will be fully clothed.

2. The research study has two parts and you will randomly be assigned to one of the two parts. If you are assigned to part 1, you will be given some educational materials after the researcher has completed all of the form with you and taken your body measurements. If you are assigned to part one, you do not have to do anything else until 20 weeks later. The researcher will ask you to come back to the lab in 20 weeks to complete the body measurements again and make arrangements to call you to remind you to come back. We anticipate that it will take 30 minutes to complete the visit if you are assigned to part 1.

3. If you are assigned to part 2, you will be asked to meet with a health coach. If you are asked to meet with the health coach, the health coach will meet with you in person directly after you have completed the forms and the body measurements. The health coach will talk with you about your metabolic syndrome risk factors and dietary and physical activity recommendations to reduce your risk. If needed the coach will provide you additional information about topics (e.g., weight loss, blood pressure, diabetes risk). The coach will then talk with you about how you can develop healthier habits. The coach may ask you to complete some forms and to talk about your daily routines and to think about the ways that you could improve your diet or increase your physical activity. The coach will then guide you through the process of developing a plan to change two simple habits over the following two weeks. These will be simple things that you can start doing right away and do every day. The coach will give you a workbook to help you stay on track and to make it easier for you to talk about

your progress during the telephone sessions. The initial coaching session is expected to last about 60 minutes. We will call you before you some to the study lab to let you know which part of the study you have been assigned to so that you can plan to stay for the necessary amount of time (30 or 90 minutes).

a. *Additional coaching sessions:* The remaining four sessions will be conducted over the phone. The coach will call you at an agreed upon day and time that works for you. The coach will call you once every 2 weeks. During the telephone session, the coach will ask about your progress with building your new habits over the previous two weeks. The coach will also guide you through the process of identifying two new habits (one for improving your diet and one for increasing your physical activity) that you will start doing the next day and continue doing every day. The telephone coaching sessions will follow the same format for each session. The telephone sessions are expected to last about 30 minutes. After the final telephone session, the coach will make arrangements to contact you with a reminder call so that you do not forget to come back to the lab at week 20 for the follow up data collection visit.

4. *Week 20 follow*-up: All participants will be asked to come back to the lab 20 weeks after the initial data collection visit. The researcher will call you a few weeks before you visit to remind you. At that time, if you would like an additional reminder, the researcher will arrange a second reminder call. When you come back to the lab, the researcher will take your body measurements again and ask you to complete paper/pencil questions about your health habits. If you met with the health coach, the researcher will ask you to participate in an interview about your experience of being in the study. Your participation in the interview is optional and you do not have to participate in the interview if you do not want to. The interview will include questions about what you liked or didn't like about the program, and what we could do to improve it. The researcher will ask your permission to audio-record the interview. You do not have to agree to be audio recorded. You can still participate in the interview even if you do not agree to be audio recorded. You will receive extra compensation if you participate in the interview. After the 20-week follow up, you will have completed the study. We anticipate that the final follow up visit will last 30 minutes for the body measurements, and 75 minutes total if you complete the body measurements and participate in the interview.

5. *Estimated Time Commitment:* We estimate that each part of the study will take the following amount of time to complete (see table 1. below). The time you spend completing the study will depend on how many activities you decide to participate in.

Table 1. *The Estimated Time Commitment by Study Component.*

Activity	Time (min) across entire 8 weeks
• Complete consent	30
• Complete standardized surveys and body measurements	30
• Participate in face-to-face coaching session	60
• Biweekly telephone coaching session (4 sessions x 30 minutes each)	120
• Follow-up data collection visit at the study lab	30

• Interview (optional)		45
	Total Time	**315 mins. or 5.25 hours**

C. Benefits
As a participant in this research study, there may be no direct benefits for you; however, information from this study may benefit other people now or in the future. No medical care will be given to you as part of the study.

D. Risks
By taking part in this study, you may experience the following risks:

1. *Loss of confidentiality:* We make every effort to maintain confidentiality. There is a very small chance your identity would be revealed unintentionally. This risk is very small. We take measures to keep your data anonymous.

2. *Discomfort:* Personal questions may make you feel uncomfortable (For example, "What you to know about metabolic syndrome?"). You don't have to answer any questions you don't want to. You don't have to give us any information you don't want to, and you may terminate the discussion with us at any time.

3. *Inconvenience:* You may experience inconvenience in completing the study activities. Inconvenience may include the hassle of scheduling the telephone coaching sessions or traveling to the study ab for the initial session and follow-up data collection visit.

The following information must be released/reported to the appropriate authorities if at any time during the study there is concern that:

- child abuse or elder abuse has possibly occurred,
- you have a reportable communicable disease (i.e., certain sexually transmitted diseases or HIV)
- you disclose illegal criminal activities, illegal substance abuse or violence

E. Alternatives to Participation
You do not need to participate in this study if you do not wish to do so. The alternative is not to participate.

F. Study Costs
You will not be charged for participating in the study. The study sponsor will pay for all costs and charges from your participation in this research study.

G. Compensation
For taking part in this research study, you will be paid for your time and inconvenience
Each participant who completes all of the study activities will receive $50 in the form of a debit card (ClinCard) and you will decide how it will be used. Participants who are asked to and agree to complete the end of study interview are eligible to earn an additional $25. Payments will disbursed upon completion of each study activity.

1. *Payment Schedule: If you:* *You will receive:*

Core Study Activities	
1. Initial face-to-ace visit to the study lab to complete standardized surveys, body measurements, and coaching session	$25
2. Complete week 20 follow-up data collection visit at study lab	$25
3. Completes optional post-intervention interview (group 2 only)	$25
4. **Complete all study activities (3 segments possible)**	**$75**

H. Research Related Injuries

In the event that this research related activity results in an injury, treatment will be made available including first aid, emergency treatment, and follow-up care as needed. No reimbursement, compensation, or free medical care is offered by Wayne State University.

If a "research related- injury" results from your participation in this research study, medical treatment will be provided at no cost to you and paid by the sponsor of the study. A "research related-injury" means injury caused by the product or procedures required by the research which you would not have experienced if you had not participated in the research study. You, or your medical insurance, will be responsible for other medical expenses resulting from your medical condition.

I. Confidentiality

All information collected about you during the course of this study will be kept confidential to the extent permitted by law. You will be identified in the research records by a code name or number. Information that identifies you personally will not be released without your written permission. However, the study sponsor, the Institutional Review Board (IRB) at Wayne State University, or federal agencies with appropriate regulatory oversight [e.g., Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Office of Civil Rights (OCR), etc.) may review your records. When the results of this research are published or discussed in conferences, no information will be included that would reveal your identity.

J. Voluntary Participation/Withdrawal

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you decide to take part in the study you can later change your mind and withdraw from the study. You are free to only answer questions that you want to answer. You are free to withdraw from participation in this study at any time. Your decisions will not change any present or future relationship with Wayne State University or its affiliates, or other services you are entitled to receive.

The PI may stop your participation in this study without your consent. If you have any side effects that are very serious or if you become ill during the course of the research study you may have to drop out, even if you would like to continue. The PI will make the decision and let you know if it is not possible for you to continue. The decision that is made is to protect your health and safety, or because it is part of the research plan that people who develop certain conditions or do not follow the instructions from the study doctor may not continue to participate.

K. Questions

If you have any questions about this study now or in the future, you may contact Heather Fritz or one of her research team members at the following phone number 313-577-1217. If you have questions or concerns about your rights as a research participant, the Chair of the Institutional Review Board can be contacted at (313) 577-1628. If you are unable to contact the research staff, or if you want to talk to someone other than the research staff, you may also call the Wayne State Research Subject Advocate at (313) 577-1628 to discuss problems, obtain information, or offer input.

L. Consent to Participate in a Research Study

To voluntarily agree to take part in this study, you must sign on the line below. If you choose to take part in this study you may withdraw at any time. You are not giving up any of your legal rights by signing this form. Your signature below indicates that you have read, or had read to you, this entire consent form, including the risks and benefits, and have had all of your questions answered. You will be given a copy of this consent form.

_____	_____
Signature of participant / Legally authorized representative*	Date
_____	_____
Printed name of participant / Legally authorized representative *	Time
_____	_____
Signature of witness**	Date
_____	_____
Printed of witness**	Time
_____	_____
Signature of person obtaining consent	Date
_____	_____
Printed name of person obtaining consent	Time

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HIPAA Authorization

A federal regulation, known as the "Health Insurance Portability and Accountability Act (HIPAA)" gives you certain rights concerning the use and disclosure (sharing with others) of your Protected Health Information (PHI). This regulation provides safeguards for the privacy and security of your information. Your permission (authorization) is required for the use and sharing of any protected health information collected as part of this research study. If you are not willing to sign this authorization to use and/or disclose your PHI by the research team, you will not be eligible to take part in this research study.

The principal investigator (PI) and her research team will use your medical records and information created or collected as part of this research study. Your PHI is important for the PI and her research team in order to collect information about you during the study, to be able to contact you if needed, and to provide treatments to you during the study, if required. The PI may send out your study related health information to the sponsor or other entities involved in this study.

Your medical records, which may contain information that directly identifies you, may be reviewed by representatives from groups identified below. The purpose of these reviews is to assure the study is being conducted properly, that data is being obtained correctly or for other uses authorized by law. These reviews occur at the study site or in the PI's research office and can take place anytime during the study or after the study has ended.

The PHI that will be "USED" for this research includes the following: name, address (street address, city, state and zip code), and social security number, and any unique identifying numbers or characteristics or code.

The PHI that will be "DISCLOSED" or shared with others for this research includes the following: name, address, social security number, elements of dates and identifying numbers or characteristics or code.

Your study information may be **used** or **shared** with the following people or groups:

- The PI, co-investigators, and key personnel of WSU associated with the research project WSU's Institutional Review Boards (IRB)
- Authorized members of WSU's workforce who may need to access your information in the performance of their duties. [*For example, to provide treatment and services, ensure integrity of the research, or for accounting and/or billing matters.*]
- Federal agencies with appropriate regulatory oversight (e.g., FDA, OHRP, OCR, etc.) may review your records.

Once your information has been released according to this Authorization, it could be released again and may no longer be protected by the HIPAA regulations.

This Authorization does not expire. The research team may need to correct it or provide missing information about you even after the study has ended, and your medical records may be needed to assist in this process.

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- During your participation in this research project you will not be able to access that part of your medical record involved in the research. This will be done to prevent the knowledge of the research results from affecting the reliability of the project. Your information will be available to the treating physician should an emergency arise that would require for him/her to know this information to best treat you. You will have access to your medical record when the study is ended or earlier, if possible. The PI is not required to release research information that is not part of your medical record.

You may withdraw (take back) your permission for the **use** and **disclosure** of your PHI for this research at anytime, by **writing** to the PI at the address on the first page of this form. Even if you withdraw your permission, the PI for the research project may still use your PHI that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission for use of your PHI, you will also be withdrawn from the research project. Withdrawing your authorization **will not** affect the health care that will be provided by the Detroit Medical Center and/or the WSU School of Medicine Practice Plans.

Authorization to use and disclose PHI

- By signing this document, you are authorizing the PI to **use** and **disclose** PHI collected about you for the research purposes as described above.

_____ _____

Signature of participant Date

_____

Printed name of participant