Title: Optimizing an mHealth Intervention to Change Food Purchasing Behaviors for Cancer Prevention

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DREXEL UNIVERSITY
Office of
Research &
Innovation

Research Subject Consent Form

Title:	Optimizing an mHealth Intervention to Change Food Purchasing Behaviors for Cancer Prevention
Protocol Number.:	2003007695
Sponsor:	National Cancer Institute
Investigator:	Meghan Butryn, PhD 3141 Chestnut St. Stratton Hall 119 Philadelphia, PA, 19104
Daytime Phone Number:	(267) 702-6838

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Consent to Take Part in a Research Study

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

Concise Summary of Key Information:

- This research is being done to examine the utility of a remotely delivered mHealth intervention on modifying dietary intake for cancer prevention.
- Your consent and participation in this study is completely voluntary.
- You will attend a workshop consisting of at least three 90-minute sessions conducted over Zoom.
- You will receive weekly messages through a mobile smartphone application that act as recommendations and reminders for food purchasing.
- Depending on your random condition assignment:
    - You may receive 1-2 additional messages per week, 0-9 phone calls from a coach (20 min each), and/or 1-2 additional workshop sessions.
    - You may be asked to allow the mobile application to track your location in order to receive messages when you enter a grocery store.
    - Your adult household member may or may not also be asked to receive weekly messages, participate in three 20-min phone calls with your coach, and join you in one 60-min workshop session.
- Participants will be enrolled in this study for a total of 20 weeks (or 4 weeks if you are enrolled in pilot testing), with assessments at baseline (0 weeks), mid-treatment (at 10 weeks during experimental phase; there is no mid-treatment assessment for pilot participants), and post-treatment (at 20 weeks during experimental phase, or 4 weeks during pilot testing).
- We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include reduced risk of cancer incidence and weight loss.
- Participation in the study may involve unforeseen risks. If unforeseen risks are seen, they will be reported to the Drexel Office of Human Protection Office. If any events occur that might be related to the treatment, you should bring them to the attention of your personal physician.
- If you do not wish to take part in this research, your choices may include seeking guidance about your diet from a registered dietician or seeking behavioral weight loss treatment if you are interested in weight loss.
- You are responsible for the cost of any smartphone data use incurred from using the program app.
- You can receive a total compensation of $180 for completion of all assessments. Contingent upon completing all assignments, you will receive $75 for baseline, $30 for mid-treatment (pilot participants will not be eligible for mid-treatment assessment payments because there is no mid-treatment assessment), and $75 for post-treatment. Payment will be in the form of e-gift cards (Target or Amazon) or direct ACH payments.

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What should I know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to examine the utility of a remotely delivered mHealth intervention on modifying dietary intake for cancer prevention.

84 subjects (20 during pilot testing and 64 during experimental phase) will take part in this research.

How long will I be in this research?

We expect that your taking part in this research will last 20 weeks (or 4 weeks if you are enrolled in pilot testing).

What happens to me if I agree to take part in this research?

The study will require participation in a group-based, interactive, nutrition education workshop, delivered via Zoom. Content will be focused on eating a diet consistent with the World Cancer Research Fund/American Institute for Cancer Research (WCRF/AICR) guidelines: 1) eat a diet rich in whole grains/vegetables/fruit; 2) limit consumption of highly processed foods; 3) limit consumption of red meat and processed meat; and 4) limit consumption of sugar sweetened drinks. Following the workshop, you will receive at least one message per week for a period of 20 weeks (or 4 weeks if you are enrolled in pilot testing) that provide recommendations and reminders for food purchasing. You will be required to download the program app to your smartphone for the duration of the study to receive these message notifications. Your food purchasing will be monitored via your respective grocery store's loyalty program, in order to assess change over time.

You will be randomly placed in 1 of 16 conditions. Neither you nor the study investigator will choose your study condition.

Every participant receives at least three workshop sessions (90 min each) and weekly messages. Based on your condition assignment, you may also receive the following:

- Half of participants will receive one additional workshop session (approximately 60 min) designed to further enhance motivation for dietary change, along with one extra motivational message per week and three phone calls (20 min each) with a behavioral coach to discuss benefits of dietary change.
- Half of participants will receive one additional workshop session (approximately 60 min) along with an adult household member, in order to increase support for dietary change. This household member will receive weekly messages and the participant and household member will complete three phone calls (20 min each) together with a behavioral coach.
- Half of participants will have a coach who monitors food purchases and provides personalized feedback in one extra message each week plus three phone calls (20 min each).
- Half of participants will use the study app in a way that tracks location, so that messages can be delivered when arriving at a grocery store.

In summary, you will receive either 3, 4, or 5 workshop sessions; 1, 2, or 3 weekly messages from the app; and 0, 3, 6, or 9 brief coaching phone calls.

Remote assessments will be completed at 0, 10, and 20 weeks (or weeks 0 and 4 if you are enrolled in pilot testing). The first assessment, at week 0, will consist of a one-on-one, 30-60 minute Zoom session with an accessor in which you will be oriented to the study and be asked to complete a series of questionnaires. The week 10 assessment requires completion of self-report questionnaires (you will not complete a mid-treatment assessment if you are enrolled in pilot testing). The final assessment, at week 20 (or week 4 if you are enrolled in pilot testing), will require the completion of questionnaires and participation in a focus group (held via Zoom) in which you and other participants will reflect on your experience with the study and provide study investigators with relevant feedback.

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

If you take part in this research, you will be responsible to:

- Attend all required study visits and assessments via Zoom.
- Shop at one of the approved grocery stores and use your loyalty card and/or designated credit card while checking out. These stores include: Target, Walmart, Wegmans, and ShopRite. If you fail to use your credit card/loyalty card at time of purchase, send the study staff a photo of your receipt.
- Download the designated smartphone application and allow for notifications. If applicable, allow for the app to track your location in order to be sent messages while grocery shopping.
- Read all messages sent to you.
- Participate in all phone calls with your coach.
- Contact the investigator if any complications arise.

Could being in this research hurt me?

Participation in this research study includes minimal risk. During this study, you will be encouraged to change your food purchasing behavior which may cause weight loss as a result of dietary change. If you are taking any medication you should carefully coordinate the oversight of these medications with your primary care physicians to make any necessary adjustments of dosage necessary if weight loss occurs. There may also be psychological risks to you such as feelings of shame or embarrassment related to eating habits, however, your coach will be trained to deliver the program in a way that feels positive to you. Lastly, there is always a risk for loss of privacy and confidentiality, though the research team will take many precautions to protect against this.

Participation in the study may involve unforeseen risks. If unforeseen risks are seen, they will be reported to the Drexel Office of Regulatory Research Compliance.

Will it cost me money to take part in this research?

You are responsible for the cost of any smartphone data use incurred from using the program app. There is no cost to you for downloading this program app.

Will being in this research benefit me?

We cannot promise any direct benefits to you or others from your taking part in this research. However, possible benefits to you include reduced risk of cancer incidence due to dietary change. Improving dietary quality also can improve other aspects of health and quality of life. It is also possible that clinically significant weight loss will occur along with dietary change, which is an additional medical benefit.

What happens to the information collected for this research?

Your private information will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor(s): National Cancer Institute (NCI)
- People who work with the research sponsor(s)
- Government agencies, such as the Food and Drug Administration or the Department of Health and Human Services
- The Institutional Review Board (IRB) that reviewed this research
- Drexel University and its affiliates

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

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

Data or specimens collected in this research might be de-identified and used for future research or distributed to another investigator for future research without your consent.

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 Web site at any time.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (267) 359-2471 or HRPP@drexel.edu if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- If there is a change in your medical condition.
- If the study is discontinued for any reason by the sponsor, investigator, university authorities, or government agencies.
- If new information is available to the investigator.
- If there are harmful unforeseen reactions experienced by you or other participants in the study.

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?

You can agree to take part in the research now and stop at any time.

Participation in this study is voluntary, and you can refuse to be in the study or stop at any time. Any fee you may be paid will be determined by the amount of participation you completed and, if you do not complete the study, the reason for leaving the study early.

If you stop being in the research, already collected data may not be removed from the study database.

Will I be paid for taking part in this research?

For taking part in this research, you may be paid up to a total of $180 (or $150 if you are enrolled in pilot testing) in the form of e-gift cards (Target or Amazon, your choice) or direct ACH payments to your bank account. ACH is a very common, secure and fast electronic payment method used by all major banks. The use of ACH as a payment option allows for remote payment and helps us protect the privacy and safety of the participants and the research staff. To use this form of payment, we will provide JPMorgan Chase Bank your study ID, name, and email or phone number. Chase will then send you an invitation to receive payment either as an email or a text message. Once you accept the invitation the funds will be deposited to your bank account. Drexel University and the research team do not have any access to your account information, and they are not directly involved in the disbursement of the funds.

- You will be paid $75 for completing the 0-week assessment. In order to receive full payment for this assessment, you must complete 3 separate ASA-24 questionnaires ($20 each) and other measurements ($15).
- You will be paid $30 for completing the 10-week assessment. Participants enrolled in pilot testing will not complete a mid-treatment assessment. Therefore, if you are enrolled in pilot testing, you are not eligible for this compensation.
- You will be paid $75 for completing the 20-week assessment (or 4-week assessment if you are enrolled in pilot testing). In order to receive full payment for this assessment, you must complete 3 separate ASA-24 questionnaires ($20 each) and other measurements ($15).
- If you choose to stop participating in the study, your compensation will be determined by the amount of participation you completed and, if you do not complete the study, the reason for leaving the study early.

Federal tax law requires to you to report this payment as income to the Internal Revenue Service if you are compensated more than $599.00 (in total) this year for participating in research. You may be asked to tell us your social security number or other identifying information (e.g., full name). If payments for this study are more than $599.00, we will report them to the Internal Revenue Service and send you a Form 1099-MISC. This information will not be associated with the information or data you provide for this research. It will be stored separately from your data, it will not be linked in any way, and your identifying information will be destroyed within 1 year of study completion.

What else should I know about this research?

If in your initial assessment, we determine that you do not meet the eligibility for this particular study, you have the option to elect to be screened for other studies at Drexel University's WELL Center as well as to remain in the WELL Center database for future studies. Please initial below if you are interested in one or both of these options:

_____ *I elect to be screened for other studies at Drexel University WELL Center if I am not eligible for this study.*

_____ *I would like to be added to the WELL Center database to be contacted for future studies that I might be eligible for.*

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Signature Block
Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	Form Date