DREXEL UNIVERSITY
Office of
Research & Innovation

Title:	Piloting a patient navigator program to facilitate uptake and persistence with evidence-based weight loss interventions
Protocol Number:	2405010565
Sponsor:	National Institutes of Health
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Research Consent Summary

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

- Your consent and participation in this study is completely voluntary.
- The purpose of this research is to test the use of counselors to facilitate use of evidence-based interventions for weight loss.
- Participants will be ***randomly assigned*** to one of two conditions: the **navigator condition** or the **usual care condition**.
- Participants will be enrolled in the study for a total of 12 months, with assessments at baseline (0 months), 6 months, and 12-months.
- You will be provided with a Withings smart scale, which you will use to weigh yourself at home for three days at each assessment point.
- Participants assigned to the **navigator condition** will have 12 months of contact with a counselor. The counselor's job is to help you identify a weight loss treatment option or weight loss program that best meets your needs. The counselor isn't providing the weight loss treatment him/herself or prescribing a specific option to you. S/he provides information, support, and accountability to help you pursue a weight loss intervention that you choose.
- Meetings with the counselor happen on Microsoft Teams videoconferencing software, so you can join from your own home. You will meet with the counselor for a minimum of 5 and maximum of 8 times, over the course of the year.
- Half of the participants who enroll are assigned to the **usual care condition. They do not have a counselor to work with.** In this condition, we are eager to learn about what it is like for adults to try to make decisions about weight loss options on their own, and to have you share valuable information with us about what is challenging or not about trying to do that. In this condition, at month 12, after we've collected our last set of information from you, you have the option to attend a two-hour educational workshop (via Microsoft Teams videoconferencing software), to learn more about evidence-based approaches to weight loss.
- We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include weight loss.
- Participation in this study can include risks such as the need to have dosage adjusted for any medications you take if you lose weight; gallstones; injury from physical activity; poor self-esteem or a sense of shame if you do not meet weight loss goals; others could share or access your private information.
- Participation in the study also may involve unforeseen risks, e.g., medical illnesses or psychological problems that are not anticipated to be caused by the research. If unforeseen risks are seen, they will be reported to the Drexel Office of Human

Protection. 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, we can provide you with a list of referrals for weight loss programs in the Philadelphia area or you can talk to your doctor.
- You can receive a total compensation of $200 for completion of all assessments. Contingent upon completing all assignments, you will receive $25 for baseline (0-months), $75 at 6 months, and $100 at 12-months. Payment will be in the form of direct ACH payments (or an Amazon or Visa gift card if you cannot receive ACH payment).

Detailed Research Consent

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. In this consent form, "you" generally refers to the research subject.

1. 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 anything on this consent form, ask questions.
- Ask all the questions you want before you decide.

2. Why is this research being done?

The purpose of this research is to test the use of a navigation program to facilitate use of evidence-based interventions for weight loss. Counselors in this program will assess treatment preferences, provide information about evidence-based treatment options for weight loss, support decision making, and facilitate action during the intervention initiation process.

About 74 subjects will take part in this research.

3. How long will I be in this research?

We expect that your taking part in this research will last 1 year (12 months).

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

Intervention

You will be put into a study group by chance (like a coin toss/ like drawing straws). You have a 50% chance of being placed in each group. **You cannot choose your study group.** You will be randomly placed in 1 of 2 groups: the **navigator condition** or the **usual care condition**. We will purchase and ship your scale from Amazon. By consenting to the study, you agree to have us enter your name and address information in the shipping fields with this third party website.

Please carefully review the difference between these two conditions below:

Navigator Condition

Participants assigned to the navigator condition will have 12 months of contact with a counselor. The counselor's job is to help you identify a weight loss treatment option or weight loss program that best meets your needs. There are many options the counselor can help you learn more about, including lifestyle modification programs in your community, nutritional counseling, medications, and surgery. The counselor can help you learn about things like location, cost, and effectiveness for the options you are interested in. Once you find an option to pursue, the counselor will want to keep in touch to learn how it is going. If you run into challenges, the counselor can help you problem solve or reconsider your options.

The **counselor isn't providing the weight loss treatment him/herself**. S/he provides information, support, and accountability to help you meet your goals for pursuing weight loss treatment.
Meetings with the counselor happen on Microsoft Teams videoconferencing software approved by Drexel University, so you can join from your own home. You will meet with the counselor for a minimum of 5 and maximum of 8 times, over the course of the year. All sessions will be 20 minutes long, except session 1, which will be 75 minutes. These sessions may be recorded and viewed by a supervisor in order to give study personnel feedback about adherence to study procedures. You would also communicate via **email** with your counselor throughout the year to check in. These email exchanges may be examined by the study team as part of our research, for instance to calculate the length and frequency of these communications.

Usual Care Condition

Participants assigned to the usual care condition **do not have a counselor to work with**. In this condition, we are eager to learn about what it is like for adults to try to make decisions about weight loss options on their own, and to have you share valuable information with us about what is challenging or not about trying to do that. In this condition, at month 12, after we've collected our last set of information from you, you have the option to attend a two-hour educational workshop (via Microsoft Teams videoconferencing software), to learn more about evidence-based approaches to weight loss.

Assessments

If you choose to participate in this research, you will be provided with a digital smart scale, which will be connected to an app on your phone. You will weigh yourself for 3 days at each assessment point and the weights will be automatically transmitted to the study team. If the study team notices that your weights are not valid, if your scale is not properly transmitting information to our system, or if we are missing weights for you, you may be asked to add more days of self-weighing. You will also complete self-report questionnaires on a website (REDCap) at each assessment and do a brief interview with a member of the study team. Due to study requirements, you may only be eligible if you own a smartphone. Some of these interviews may be audio-recorded.

It is possible that during an intervention session or assessment, a member of the study team could become concerned that you appear at risk for suicide. In that instance, we could refer you for further assessment to WELL Center personnel who are trained in suicide assessment and safety planning but who are not part of the team for this specific study.

5. Could being in this research hurt me?

Risks, and plans to minimize risk, are as follows:

- As you lose weight, you may need to have **dosage adjusted** for any medications they take, such as for hypertension or diabetes.
- As you lose weight, you also may develop **gallstones**.
- If you engage in physical activity as part of your weight loss efforts, you may **injure** yourself.
- Psychological risks include **reduced self-esteem** in people who fail to lose weight, or a sense of **shame** if not meeting weight loss goals.
- In the usual care condition, there is a small group workshop offered at the end of the study period, in which there is a risk that **group members could share information** about that participant outside of the program.
- It is possible that **a data breach of university systems** could occur which would compromise participant privacy. All participant data, including the fact of your participation, will be treated as confidential and will be safeguarded to minimize the risk of data breaches that compromise participant privacy.
- It is possible that a **data breach of Withings systems** could occur which could compromise participant data. The study team will create a unique log-in and password for your Withings account so as to reduce the risk that any of your other accounts become compromised. Additionally, the study team will create a proxy name and date of birth for your Withings accounts to further minimize this risk.

6. Will being in this research benefit me?

- We cannot promise any benefits to you or others from your taking part in this research.
- However, possible benefits to you include the following:
    - The knowledge gained from this study also has the potential to benefit the broader population of adults with overweight and obesity in the future, by linking them with evidence-based interventions.

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6. What other choices do I have besides taking part in this research?

This research is not designed to diagnose, treat or prevent any disease. Your alternative is to not take part in the research.

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

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

- If assigned to the navigator condition, attend all scheduled meetings and engage in emails with your counselor throughout the year
- Attend all scheduled assessment visits
- Complete all assessment tasks as described in the "What happens if I agree to be part of this research" section
- Contact the investigator if any complications arise, if there is a change in your medical conditions, or if you become pregnant

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

There is no cost to being in the study or having a counselor to work with. However, **any treatments you pursue will be at your own expense**. Additionally, you will be responsible for covering any costs related to your internet use to participate in this study e.g., Wi-Fi costs.

9. 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, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDKK)
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration
- The Institutional Review Board (IRB) that reviewed this research

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.

A description of this clinical trial and study results will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. You can search this website at any time.

Data collected in this research might be deidentified and used for future research or distributed to other investigators for future research without your consent. We will submit data from this study

to a public access repository. All private information that could identify you will be removed or changed before data are put in a public repository. Anyone can use information from a public access repository.

Your private information such as your weight data will be shared with Withings, and your name and address will be shared with Amazon when we ship you the scale. The study team will be creating a proxy Gmail address through Google to create your Withings account, but your health data will *not* be shared with Google.

Calendly is a third-party web-based software tool that will be used for study scheduling. You will be asked to provide your name and contact information in this tool for scheduling study visits.

10. What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. A Certificate of Confidentiality helps protect your identifiable information and biological samples. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by The National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as child abuse and neglect, or harm to self or others.

11. 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 reviews of research studies. You may talk to Drexel IRB 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.

12.What if I am injured because of taking part in this research?

If you become ill during this study, please contact Dr. Butryn at telephone no. (215)553-7108. If you require immediate medical attention, you should go to the nearest emergency room or call 9-1-1. It is important that you inform all emergency medical staff that you are participating in this study.

If a "research related injury" results from your participation in this research study, medical treatment will be provided. The costs for all your medical treatment will be billed to you and/or your insurance. 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.

The university and hospital make no commitment to provide free medical care or payment for any unfavorable outcomes resulting from participation in this research. Medical services will be offered at the usual charge. However, you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research, including the hospital.

13. 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:

- It is in your best interest
- Harmful unforeseen risks are experienced by you or other participants of the study
- You need a treatment not allowed in this research
- You become pregnant
- The research is canceled by the sponsor (NIDKK)
- You are unable to keep your scheduled appointments
- There is a change in your medical conditions
- New information is available to the investigator

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

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

You may withdraw from the study at any time. If you stop being involved in the research, already collected data may not be removed from the study database.

If you decide to leave this research, contact the research team so that the investigator can:

- Update your study status in the study database
- Notify your assigned counselor of your departure from the study

15. 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 $200. In order to receive the full payment amount, you must complete all assigned assessment tasks. If you complete some, but not all, of the required tasks at each assessment point, you will receive a prorated payment of 50% of the original amount. Your compensation will be broken down as follows if you complete all assessment tasks:

- Month 0 (Baseline): $25
- Month 6: $75
- Month 12: $100

Payment will be provided primarily through direct ACH payments via the JPMorgan Chase Concourse system 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.

If you cannot, or do not want to, receive a direct, electronic payment, you have the option of receiving a gift card, such as Amazon or Visa. This option takes 6-10 weeks to process.

Federal tax law requires 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 all research studies you participate in at Drexel total more than $599.00 in a year, Drexel will report those payments to the Internal Revenue Service and send you a Form 1099-MISC.

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Statement of Consent:

Signing your name indicates that you understand that your consent is being obtained through this digital consent form on the REDCap website.

Your signed name on this digital document reflects your consent to take part in this research.

Name of adult subject capable of consent:	Date:
Participant signature:	
Name of person obtaining consent:	Date:
Signature of person obtaining consent:	

As an assessor, please provide your email in case reminders are required for your completion of this form: _____

Here there will be a field to automatically download the signed informed consent form in REDCap. Once cosigned, it will automatically be emailed to participants for their own records.