Using factorial design to examine efficacies of technology-based augmentations for improving treatment adherence and skills utilization in a self-help CBT program for binge eating (CONQUER)

4/4/2023

NCT Number

DREXEL UNIVERSITY
Office of
Research &
Innovation

Research Subject Consent Form

Title: Using factorial design to examine efficacies of technology-based augmentations for improving treatment adherence and skills utilization in a self-help CBT program for binge eating

Protocol Number: 2205009229

Sponsor: NIMH

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Research Consent Summary

You are being asked for your consent to take part in a research study because you experience binge eating and are interested in receiving behavioral treatment. 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.

1. What should I know about this research?

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

2. Why is this research being done?

The purpose of this study is to test the feasibility, acceptability and efficacy of two technology-based intervention systems (including Advanced Digital Data Sharing (DDS) with coaches or a smartphone-based just-in-time, adaptive interventions (JITAIs) system) for improving treatment adherence, skills utilization and binge eating when used in conjunction with a remote behavioral treatment (i.e., self-help cognitive behavior therapy [CBT] delivered via a smartphone application [app]). The study is being conducted to test a novel approach to delivery of evidence-based treatment for binge eating in a routine clinical setting.

3. How long will I be in this research?

We expect that your taking part in this research will last 7 months (4 months of treatment and 3 months of follow up assessment).

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

If you decide to take part in this research study, the general procedures include the following:
At the start of the study, you will be interviewed to determine if you are fully eligible to participate in the study. After we determine you are eligible for the study, you will complete the baseline assessment (pre-treatment) using a HIPAA-complaint Zoom software, which is a videoconferencing platform, with Drexel University WELL Center study staff. This baseline assessment will take approximately four hours. If you continue with the study, you will complete a total of 4 research assessments (pre-, mid-, post-treatment, and 3-months follow up), each assessment will take approximately four hours to complete, with a total of 24 hours of assessments throughout the clinical trial.

You will be assigned to one of the four treatment conditions including, 1) Self-help CBT program only, 2) Self-help CBT program plus Advanced Digital Data Sharing (DDS) with coaches, 3) Self-help CBT program plus just-in-time, adaptive interventions (JITAIs) system, and 4) Self-help CBT program plus Advanced DDS with coaches and JITAIs system. All treatment conditions involve receiving 12 weeks of self-help CBT treatment program delivered via a smartphone application over the 4 months period. You will be expected to install a smartphone app on your mobile device to access learning modules each week over 12 weeks of treatment. You will also be required to use this smartphone application to record your eating patterns and maladaptive eating behaviors several times a day during 12 weeks of treatment. Treatment will be completed remotely.

5. Could being in this research hurt me?

The most important risks or discomforts that you may expect from taking part in this research include: This treatment program is purely behavioral in nature and are associated with minimal risks. However, when undergoing treatment for binge eating, you may feel uncomfortable or anxious, because you will be asked to stop binge eating and/or purging, a process that is difficult given the nature of the illness. During study interventions, you will learn skills to adaptively cope with emotional experiences that may come up due to abstinence from binge eating and purging. If it is determined that you are demonstrating discomfort/distress due to abstinence from binge eating and purging, they will invite you for an individual meeting with staff to assess your discomfort/distress and to determine whether or not referral to a higher level of care and/or another treatment would be the best decision for you. All efforts will be made to minimize the risk to participants in this study, with medical monitoring occurring on a regular basis.

It is possible you might experience some distress during the assessment procedures. You will be asked to fill out questionnaires that ask about sensitive information about your eating behaviors and emotional experiences. You can choose to not answer any of these questions at any point. It may be the case that you report a clinically significant problem to us over zoom or on an online form. If a clinically significant problem is discovered, Dr. Srivastava will talk with research staff, and she may call you to discuss further. If there is a problem, there will be several steps taken to make sure the problem gets solved. You may be asked several questions about your mood and thoughts and may be encouraged to think about things in a different way. You may also be given a list of strategies to try at home to help you feel better. If needed or requested, you will be given an appropriate counseling referral.

Other potential risks include another individual outside of research staff gaining access to the data on your mobile device due to theft or loss of your mobile device, interception of transmission.

6. Will being in this research benefit me?

The most important benefits that you may expect from taking part in this research include the proposed self-help CBT treatment program will help to improve binge eating and cooccurring conditions, and improvement in quality of life and associated distress. Thus, it is expected that

you will directly benefit from the study intervention. All efforts will be made to minimize the risk to you in this study, with medical monitoring occurring on a regular basis and your data being securely stored. Indirect benefits include increased knowledge regarding treatment for binge eating.

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

Instead of being in this research, your choices may include cognitive behavioral therapy (CBT) with a clinician, other self-help CBTs, to receive treatment from the WELL clinic for a fee for service, and any other behavioral treatment for binge eating disorder and bulimia nervosa. If the research participant chooses not to participate, they are given the option to be added to our study database to be contacted for other studies they might be eligible for at the WELL Center in the future. They will also be offered referral lists for other resources or treatment providers if they are interested.

8. What else should I know about this research?

Other information that may be important for you to consider so you can decide whether to take part in this research is listed here:

In order to safeguard your data and privacy, it is recommended that you set a password for entry to the smartphone or laptop, setting an automatic timer to lock the device after a certain number of seconds of non-use, keeping the device on their person at all times.

If you become ill during this study, please contact our study team member at telephone no. (267) 888-7403. 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. It is important for you to follow your physician's instructions including notifying your physician in addition to our study team as soon as you are able to of any complication or injuries that you experienced.

If you agree to take part in this research study, we will pay you up to $150 for your time and effort.

You are given the option to be added to our database to be contacted for other studies you might be eligible for at the WELL Center in the future. If you would like your information to be added, please initial here _____.

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. This study tests the feasibility, acceptability and efficacy of two technology-based intervention systems (including Advanced Digital Data Sharing (DDS) with coaches and just-in-time, adaptive interventions (JITAIs) system) for improving treatment adherence, skills utilization and binge eating when used in conjunction with a remote behavioral treatment . This study is testing a novel approach to deliver evidence-based treatment for binge eating in a routine clinical setting. Your consent is being sought out in order to ensure that you understand the risks and responsibilities of participation. Your participation in this research study is completely voluntary. During the study, you will receive 12 weeks of remote self-help CBT program delivered through the smartphone application that will track eating patterns and maladaptive eating behaviors
Participation in the study will involve no cost to you. CBT includes elements that have been shown to help with binge eating disorder, and to improve quality of life and associated distress. It is expected that you will directly benefit from these treatment conditions and see reductions in binge eating because of improvements in treatment adherence and skills utilization. You might feel uncomfortable or anxious during the treatment process as you will be asked to change your long-standing behaviors and abstain from binge eating. You may decide not to take part in the research, and it will not be held against you. We can help you locate a treatment program if you wish to pursue treatment for binge eating disorder, or other eating concerns. There is no cost to you for participating in this study. You will receive up to $175 in compensation for participation in the study.

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, ask questions.
- Ask all the questions you want before you decide.

2. Why is this research being done?

The purpose of this study is to test the feasibility, acceptability and efficacy of two technology-based intervention systems (including Advanced Digital Data Sharing (DDS) with coaches or a smartphone-based just-in-time, adaptive interventions (JITAIs) system) for improving treatment adherence, skills utilization and binge eating when used in conjunction with a remote behavioral treatment (i.e., self-help cognitive behavior therapy [CBT] delivered via a smartphone application [app]). It is expected that Advanced DDS with coaches and smartphone based JITAIs

systems independently improve adherence to treatment and utilization of therapeutic skills during self-help CBT program. It is expected that improvements in treatment adherence and skills utilization will improve binge eating from self-help CBT program. We are seeking to develop a more effective remote self-help CBT treatment program for binge eating and this study is the first test of two novel and highly scalable technology-based intervention systems as augmentations to self-help CBT treatment program for binge eating. So, the study is being conducted to test a novel approach to deliver evidence-based treatment for binge eating in a routine clinical setting. About 76 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 for 7 months (4 months of treatment and 3 months of follow up assessment).

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

If you decide to participate in this study, you can expect the following: At the start of the study, you will be interviewed to determine if you are fully eligible to participate in the study. After we determine you are eligible for the study, you will complete the baseline assessment (pre-treatment) using a HIPAA-complaint Zoom software, which is a videoconferencing platform, with Drexel University WELL Center study staff. This baseline assessment will take approximately six hours. If you continue with the study, you will complete a total of 4 research assessments (pre-, mid-, post-treatment, and 3-months follow up), each assessment will take approximately four hours to complete, with a total of 24 hours of assessments throughout the clinical trial. All of these assessments will be conducted by study team remotely via HIPAA-complaint Zoom software. Research assessments will be audio-recorded. The recordings will be securely stored until the completion of study analyses. Assessments will involve the following:

- Completing questions regarding demographics, disordered eating, weight history, and other psychological symptoms.
- Completing an interview with our study staff where we will assess your eating disorder symptoms, eating behaviors, weight control behaviors, and other psychological symptoms.
- Getting your height and weight measured.
- Completing self-report measures that assess your thoughts and feelings about eating, shape and weight concerns.

Medical clearance by your primary care physician may be needed to participate in the study. If you report 3 or more times of purging/laxative use per week or worsening medical symptoms related to your eating symptoms, we will require you to go to your primary care provider and will require you to get medical clearance. We will require you to have regular appointments with your primary care physician (PCP) throughout the study. Throughout the study, the study staff will communicate with your PCP to ensure that it is medically safe for you to continue with the

study. Medical information will be obtained from the office of the primary care physician (PCP). This could happen at intake or at any time in your participation. That medical clearance may involve bloodwork or other laboratory tests at the discretion of your primary care provider. This may also include an assessment of Body Mass Index, and vitals (for example: pulse rate, temperature, blood pressure, and respiration rate). You will be responsible for costs associated with the medical assessment. You will be asked to sign a HIPAA authorization specifying that study personnel may obtain your PHI from the PCP's office during the study. Study staff will provide you with a medical clearance form via mail or email to be filled out by your primary care provider (PCP). If you do not have a PCP, we can help you locate one or refer you to one. We do not cover any costs for PCP visits. The medical clearance form will then be submitted to study staff prior to starting the study. If you refuse to obtain medical clearance or receive medical monitoring as requested by the study, you will not be eligible for participation in this study.

You will be assigned to one of the four treatment conditions including, 1) Self-help CBT program only, 2) Self-help CBT program plus Advanced Digital Data Sharing (DDS) with coaches, 3) Self-help CBT program plus just-in-time, adaptive interventions (JITAIs) system, and 4) Self-help CBT program plus Advanced DDS with coaches and JITAIs system. All treatment conditions involve receiving 12 weeks of self-help CBT treatment program delivered via smartphone app over the 4 months period. You will be expected to access the internet to receive internet-based self-guided CBT program using a unique and de-identified user ID and password. You will be expected to access the learning modules once each week for 12 consecutive weeks as you would attend an in-person session. Each session will last for approximately one hour. You will be expected to install a smartphone app on your mobile device. You will be required to record your eating patterns and maladaptive eating behaviors five times a day during 12 weeks of treatment. In the Self-help CBT program plus Advanced DDS with coaches condition, the data tracked on the smartphone app will be shared with coaches (i.e., individuals having a bachelor's degree in a health-related field) via a secured digital data portal. On weekly basis, coaches will review the tracked data and will send emails with suggestions to help you improve completion of internet-based self-help CBT program and compliance with smartphone app (i.e., treatment adherence) and use of therapeutic skills introduced in self-help CBT program (i.e., skills utilization). In the Self-help CBT program plus JITAIs condition, the smartphone app will deliver text messages whenever it will detect that you will benefit from receiving interventions to improve treatment adherence and skills utilization. In the Self-help CBT program plus Advanced DDS with coaches and JITAIs condition, you will receive weekly emails from coaches and will receive text messages on smartphone app to help you improve both treatment adherence and skills utilization. As such, all participants will be able to receive treatment. Treatment will be completed remotely via HIPAA-Compliant zoom software. We will ensure that the information received from the app is stored on secured servers, and that all stored data is de-identified. However, we cannot promise complete secrecy (see section 10 for more details).

For this study, you will receive up to $175 in compensation for completing the study. You will receive $20 for completing the baseline, $30 for completing mid treatment assessment, $50 for completing post-treatment assessment, and $75 for completing 3 months follow up assessment. You will receive the compensation for your participation after each assessment point through a remote-payment electronic system at Drexel, which is administered by JPMorgan Chase Bank. This system allows us to compensate you for your participation in the study through a secure electronic payment system (ACH) that is used by most major banks. This system securely sends direct payments from an account associated with this study to your account, immediately upon study completion. The use of this system 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 need to provide JPMorgan Chase Bank your participant number ID and your email and phone number. You will then be sent an invitation to receive payment either as an email or a text message. Once you accept the invitation the funds will be disposed to your account by the next business day. Drexel University and the researcher 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 through this system, you have the option of receiving a check from Drexel University. This option takes several weeks to process, requires you to complete a federal W9 form, and requires you to disclose your name and social security number to Drexel's Accounts Payable department. You will also need to provide your name and address to JPMorgan Chase Bank, who will be sending this check to you.

Alternatively, if you do not want a check, we can send you an electronic Amazon gift card to your provided email.

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.

5. Could being in this research hurt me?

The study interventions involve standard and scientifically proven self-help CBT treatment program for binge eating. This treatment program is purely behavioral in nature and are associated with minimal risks. However, when undergoing treatment for binge eating, you may feel uncomfortable or anxious, because you will be asked to stop binge eating and/or purging, a process that is difficult given the nature of the illness. During study interventions, you will learn skills to adaptively cope with emotional experiences that may come up due to abstinence from binge eating and purging. If it is determined that you are demonstrating discomfort/distress due to abstinence from binge eating and purging, they will invite you for an individual meeting with staff to assess your discomfort/distress and to determine whether or not referral to a higher level of care and/or another treatment would be the best decision for you. All efforts will be made to

minimize the risk to participants in this study, with medical monitoring occurring on a regular basis.

It is possible you might experience some distress during the assessment procedures. You will be asked to fill out questionnaires that ask about sensitive information about your eating behaviors and emotional experiences. You can choose to not answer any of these questions at any point. It may be the case that you report a clinically significant problem to us over zoom or on an online form. If a clinically significant problem is discovered, Dr. Srivastava will talk with research staff, and she may call you to discuss further. If there is a problem, there will be several steps taken to make sure the problem gets solved. You may be asked several questions about your mood and thoughts and may be encouraged to think about things in a different way. You may also be given a list of strategies to try at home to help you feel better. If needed or requested, you will be given an appropriate counseling referral.

Other potential risks include:

- another individual outside of research staff gaining access to the data on your mobile device due to theft or loss of your mobile device, interception of transmission.

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 proposed self-help CBT treatment program will help to improve binge eating and cooccurring conditions, and improvement in quality of life and associated distress. Thus, it is expected that you will directly benefit from the study intervention. All efforts will be made to minimize the risk to you in this study, with medical monitoring occurring on a regular basis and your data being securely stored. Indirect benefits include increased knowledge regarding treatment for binge eating.

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

Instead of being in this research, your choices may include cognitive behavioral therapy (CBT) with a clinician, other self-help CBTs, to receive treatment from the WELL clinic for a fee for service, and any other behavioral treatment for binge spectrum disorder and bulimia nervosa. If the research participant chooses not to participate, they are given the option to be added to our study database to be contacted for other studies they might be eligible for at the WELL Center in the future. They will also be offered referral lists for other resources or treatment providers if they are interested.

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

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

- You will be responsible for attending 12 weekly sessions of internet-based self-help CBT treatment program in addition to completing assessments at pre-treatment, mid-treatment , post-treatment and at a 3-month follow-up.
- Follow the investigators or researcher's instructions.
- Tell the investigator or researcher right away if you have any problems with accessing self-help CBT program.

- Tell the investigator researcher right away if you have any problems with your app or if you are not receiving prompts when you think you should be (i.e., Self-help CBT program plus Advanced Digital Data Sharing (DDS) with coaches, and Self-help CBT program plus Advanced DDS with coaches and JITAIs system).
- Respond to prompts from the smartphone app when you receive them.
- Attend all assessments via videoconferencing.
- Tell the investigator or researcher right away if you have any complications, injuries, or are pregnant or plan to become pregnant during the study.

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

There is no cost to you for participating in this study. In order for the smartphone-based self-help CBT program to work, you may need to use your data services. However, you will not be compensated for any data usage expenses associated with using this smartphone app on your personal device. If you are unwilling to accept this condition, please do not sign below on this consent form. The study team will not pay for any PCP visits or related fees.

10. What happens to the information collected for this research?

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

- The research sponsor
- 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
- National Institutes of Mental Health (NIMH)

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. You will be provided a unique and de-identified user ID and password to access the self-help CBT program (delivered via a smartphone app) so that information that you add to the treatment program does not reveal your personal information. Smartphone app will have its own sandbox environment and no data will be shared outside the app. In other words, the data collected by the smartphone application will not be shared with other smart devices, third parties or specified organizations. All the data you entered in the app will be saved on an encrypted back-end server, which will be linked to the unique research participant identifier assigned to you. No personal health information will be linked to this data collected from the smartphone application. This back-end server will only be accessed by the study team using a secure password. Your data from the smartphone app will be regularly downloaded from the encrypted and secure web server by study staff and subsequently removed from the web server. Efforts will be made to limit access to your personal information including research study records to people who have a need to review this information. All data downloaded from the Advanced Digital Data Sharing portal and smartphone app will be de-identified and identifiable information will be replaced with code numbers. Data files will not contain personal health information. Names will not be linked to data. All electronic files will be stored on a password-protected computer in locked offices and stored on an institutionally secured network. All paper surveys (if any) will be labeled with non-identifiable information and

stored in a locked filing cabinet in a limited access, password protected office at the Drexel University Center for Weight, Eating, and Lifestyle Science (WELL Center). We cannot promise complete secrecy. Organizations that may inspect and copy your information include the NIMH (the sponsor of the project), Institutional Review Board in Drexel University (IRB) and other representatives of IRB. If needed and upon receipt of HIPPA authorization by you, information pertaining to mental health diagnosis or treatment could be released by the study and/or research team. The de-identified data collected may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you. We may publish the results of this research. However, we will keep your name and other identifying information confidential, and this information will not be used or distributed for future studies. The research team will collect and retain any PHI from the medical records obtained through the HIPAA authorization. All PHI data that will be destroyed upon the completion of the study and all data will be erased or shredded in the standard 7 years. Federal law and state law provides additional protections of your personal and private health information. These are described in an attached document titled "Permission to use Private Identifiable Health Information for Research".

A description of the clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this website at any time. Data or specimens collected in this research might be deidentified and used for future research or distributed to another investigator for future research without your consent. Federal law and state law provides additional protections of your personal and private health information. These are described in an attached document titled "Permission to use Private Identifiable Health Information for Research". Participants will have access to their own personal survey and interview results upon request; however, researchers will not share data with each participant as part of study protocol. If participants request their data, they will be provided with a password protected excel file with their own response. A password will be sent in a separate email to ensure protection of data. If the research participant doesn't have access to a computer, they can be provided a paper copy of their responses.

11. Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think the research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page or talk to the primary investigator, Dr. Paakhi Srivastava, from the research team at the Center for Weight, Eating, and Lifestyle Science at (267) 815-6511. 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 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.
- You want to get information or provide input about this research.

12. 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: any acute life-threatening incident, hospitalization, you become pregnant, suicidal or homicidal ideation or serious self-harm behavior. Participants will be withdrawn from the study if they no longer meet study criteria. We will tell you about any new information that may affect your welfare or choice to stay in the research. If termination is found necessary, you will be contacted by the project coordinator immediately and the necessary precautions will be taken to ensure safety or medical attention as appropriate. You will then be provided with referrals to other programs or studies if applicable and the data will be destroyed/barred from use. We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

13. What happens if I agree to be in this research, but I change my mind later?
You may decide not to take part in the research, and it will not be held against you. If you decide to leave this research, contact the research team so that the investigator can withdraw you from the study. We can help you locate a treatment program if you wish to pursue treatment for bulimia nervosa, binge eating disorder, or other eating concerns. You will be given the option to be added to our study database to be contacted for other studies you might be eligible for at the WELL Center in the future. Should you choose not to be entered into the database, all your information will be destroyed.

14. 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 $175. In order for the smartphone-based self-help CBT program to work, you may need to use your data services. However, you will not be compensated for any data usage expenses associated with using this smartphone app on your personal device. If you are unwilling to accept this condition, please do not sign below on this consent form. Your compensation will be broken down as follows:

You will receive $20 for completing the baseline, $30 for completing mid treatment assessment, $50 for completing post-treatment assessment, and $75 for completing 3 months follow up assessment. You will receive the compensation for your participation after each assessment point through a remote-payment electronic system at Drexel, which is administered by JPMorgan Chase Bank. This system allows us to compensate you for your participation in the study through a secure electronic payment system (ACH) that is used by most major banks. This system securely sends direct payments from an account associated with this study to your account, immediately upon study completion. The use of this system 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 need to provide JPMorgan Chase Bank your participant number ID and your email and phone number. You will then be sent an invitation to receive payment either as an email or a text message. Once you accept the invitation the funds will be disposed to your account by the next business day. Drexel University and the researcher 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 through this system, you have the option of receiving a check from Drexel University. This option takes several weeks to process, requires you to complete a federal W9 form, and requires you to disclose your name and social security number to Drexel's Accounts Payable department. You will also need to provide your name and address to JPMorgan Chase Bank, who will be sending this check to you.

Alternatively, if you do not want a check, we can send you an electronic Amazon gift card to your provided email.

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.

Signature block for studies that only involve adult subjects able to consent

Your signature documents your consent to take part in this research.

Printed Name and Signature of adult subject capable of consent	Date
Printed name and Signature of person obtaining consent	Date

DREXEL WELL CENTER CLINICAL TRIALS ADDENDUM

Consent to Telehealth

The following information pertains specifically to the use of **videoconferencing** for research assessments. Use of videoconferencing is completely voluntary and is an option we can discuss if you are interested.

• ZOOM is a HIPAA compliant online communication tool that allows for face-to-face video telehealth appointments. For more information about ZOOM security and privacy, please see: Zoom's Notice of Privacy Practices at https://www.zoomcare.com/info/notice-of-privacy-policy

• ZOOM requires the use of a browser but does not require any software download.

• Appointments will be made via email or phone. Please be online at least five minutes prior to assessment, alone, in a quiet room, with the door closed.

I understand that ZOOM assessments will be audio recorded.

• Confidentiality should be treated like an in-person assessment: no outside distractions, turn off cell phones, close other programs on your computer, and be on time. Headphones may be helpful to further reduce distractions and add additional security.

*The option for in-person care will not be available in times when Drexel is closed. You will be referred to an emergency services provider should your care necessitate in-person services and we are closed.

I have been informed of and understand the risks and procedures involved with using the videoconferencing technology. I agree to the terms listed above and I hereby voluntarily consent to the use of this platform for research assessments with study personnel. I agree that the Drexel University WELL Center should not be held liable in the event that any outside party circumvents the administrative, physical, and technical safeguards in place and discovers personal or confidential information. This consent will last for the duration of your relationship with the study. I can withdraw my consent for a research assessment at any time.

ASSESSMENTS VIA ZOOM:

Yes _____

No_____

EMAIL TO BE USED FOR ZOOM LINK AND CORRESPONDENCE ABOUT SCHEDULING APPOINTMENTS:

_____

Patient Name: _____

Signature of Patient: _____Date: _____

Signature of Provider: _____Date: _____