Open Trial of a Behavioral Activation Telepsychology Intervention for People Who Inject Drugs

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University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

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IRB Study # 19-1458
Principal Investigator: Catherine Paquette
Principal Investigator Department: Psychology and Neuroscience
Principal Investigator Phone number: 919-962-9924
Principal Investigator Email Address: catherine.paquette@unc.edu
Faculty Advisor: Stacey Daughters
Faculty Advisor Contact Information: (919) 962-9924

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CONCISE SUMMARY

The purpose of this research study is to determine the usefulness of an investigational treatment that is being developed to assist people who use drugs in living a healthy lifestyle and working toward personal goals. Participants will complete 3 assessment appointments where they will answer questions about mood and lifestyle, including physical functioning, mental state, and drug use. Participants will also complete individual treatment sessions 2 times each week for 4 weeks, for a total of 8 sessions. Each assessment appointment visit will take 1.5 to 2 hours, and each treatment session will take about 1 hour. Total study duration is about two months. All assessments and treatment sessions will be conducted remotely.

The benefits to you from being in this study may include making progress toward your goals in treatment. The greatest risks of this study include the possibility of emotional distress while answering questions and loss of confidentiality.

If you are interested in learning more about this study, please continue to read below.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason, at any time, without penalty. Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to determine the usefulness of an investigational treatment that is being developed to assist people who use drugs in living a healthy lifestyle and working toward personal goals. The results of this study may be used to develop more appropriate and successful treatment

interventions for people who use drugs. Results will be determined based on information you share with research staff during each appointment.

Are there any reasons you should not be in this study?
You should not be in this study if you are unable to read and write and/or are unable to attend the treatment sessions.

How many people will take part in this study?
There will be approximately 33 people in this research study.

How long will your part in this study last?
Your participation in this study will last approximately 2 months. Specifically, your participation will total up to 15 hours over the 2-month span, including an initial appointment (2 hours), eight treatment sessions (8 hours), four brief weekly online questionnaires (30 minutes), a post-treatment appointment (1.5 hours), and follow-up appoint one month post-treatment (1.5 hours).

What will happen if you take part in the study?
Today you will complete an appointment session that includes a number of questions that will assess your mood and lifestyle. Some of the questions are of a sensitive nature, and pertain to personal information such as your current physical functioning, mental state, drug use history, and sexual behavior. You can choose not to answer any question. If at any time you have questions or concerns about the questionnaires you are urged to discuss these issues with the researcher. You will be answering some of these questions in an online questionnaire, and some in the form of an interview. We encourage you to complete the assessments in a private room.

Portions of the interview will be audio recorded to ensure the appointment is conducted properly. We will upload these files to a secure computer server and only use them for research training purposes. Your full name will not be audio recorded. During your appointments, the research assistant will be happy to answer any questions you may have. This researcher is not a staff member at the syringe exchange program and will not share any information you provide with the syringe exchange program staff. With your written permission, we may coordinate with the syringe exchange program staff to get messages to you between appointments. Under no circumstance will the researcher share your information with other participants of the exchange.

You will also be asked to participate in assessments to answer similar questions after your final treatment session. All assessments will be conducted remotely. If at any time you would like to withdraw from participation, you are free to do so.

Treatment

After you answer questions today, you will attend eight sessions of individual treatment, all held remotely. This treatment focuses on environment, lifestyle, and mood related changes in order to facilitate a healthy lifestyle and help you work toward personal goals. You may also be given voluntary assignments to complete between sessions. Each therapy session will be audio recorded and reviewed by the lead researcher to ensure that the treatment is being conducted properly. Audiotapes will be heard by study personnel only.

Follow-up Appointments

Your 2 follow-up appointment dates will be based on your final session of treatment. At these follow-up appointments we will ask you to do the same questionnaires you completed during your baseline

appointment. We will contact you to remind you of this appointment in advance. If we have difficulty contacting you, we may contact individuals that you list on your contact form. If we speak with your contacts, we will tell them that we are from UNC and calling to confirm an appointment. We will not share any additional information with any of your contacts.

Scheduling Appointments

We will contact you to remind you of your appointments in advance. If we have difficulty contacting you, we may contact individuals that you list on your contact form. If we speak with your contacts, we will tell them that we are from UNC and calling to confirm an appointment. We will not share any additional information with any of your contacts.

Your decision whether to participate in this study will not be shared with anyone outside of our research team.

Your decision to enroll in, continue or not continue participation in research will not be shared with any staff member or volunteer at the syringe exchange program.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. Through participation in our study, you may learn skills to help you live a healthy lifestyle and work toward your personal goals.

What are the possible risks or discomforts involved from being in this study?
During treatment, you will be asked to discuss your mood, thoughts, behaviors, and treatment goals. This may lead to feelings of emotional distress, which you should report to your therapist. There may also be uncommon or previously unknown risks. You should report any of these problems to the researcher.

There is also a minimal risk of a breach of confidentiality. We will take every feasible step to protect you from any breach of confidentiality (see below).

If you choose not to be in the study, what other treatment options do you have?
Whether or not you choose to participate in the study, we can provide you with a list of treatment providers in the area. Your participation in the syringe exchange program will not be impacted by your decision to participate in the research study.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?
We will do our best to keep your personal information confidential. To help protect your confidentiality, (1) your name will not be included on questionnaires and other collected data except for the pre-screening questionnaire, consent form, and contact form; (2) a personal identification number, instead of your name, will be placed on the questionnaires and other collected data; (3) through the use of an identification key, only certain members of the research team (the investigators and the study coordinator) will be able to link your survey to your identity and contact form; and (4) only these members of the research team will have access to the identification key. In addition, any identifiable data and identifying links will be destroyed 7 years after the conclusion of data collection for the study. Only de-identified data will be retained and may be used for future research without additional consent.

Participants will not be identified in any report or publication based on this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as to examine quality control or safety.

Audiotapes of treatment sessions and portions of the research appointments will be stored on password protected, secure servers at UNC. Only the research team will have access to these files. These tapes will be kept for 7 years before they are erased. As we do our best to protect your information, we ask that you also do your best to not reveal anything that you learn from your appointments with other participants.

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

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects 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 or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of harm to self or others or knowledge of child abuse.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time, for example, if you are unable to complete research visits or unable to attend the first treatment session.

Will you receive anything for being in this study?
You will be eligible to receive up to $180 for taking part in this study.

- $40 upon completion of your first appointment
- $40 upon completion of your post-treatment appointment
- $40 upon completion of your one-month follow-up appointment
- $5 for attending treatment sessions (up to $40 for attending all eight sessions)
- $5 for completing brief weekly feedback questionnaires (up to $20 for completing all four questionnaires)

You will have options for how you receive your compensation, including via electronic payment (e.g., Venmo/PayPal) or a reloadable Visa card which we can mail to you or you can pick up from the North Carolina Harm Reduction Coalition (NCHRC) needle exchange program. If you choose to receive compensation via a reloadable Visa card, we will need to share your name, address, phone number, and phone type with the UNC prepaid card system and Visa.

Will it cost you anything to be in this study?
There will be no costs to you associated with your participation.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, or concerns, you should contact the researchers listed on the first page of this form.

A description of this clinical trial will be available on 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.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

By typing my name here, I certify that I have read the information provided above, I have asked all the questions I have at this time, and I voluntarily agree to participate in this research study.

_____	_____
Typed Name of Research Participant	Date