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# Informed Consent Cover Page

**Official Title:** CoMBAT Opioid Use Disorder: A Pilot RCT of a Combined Medication and Behavioral Activation Treatment for People Living with Opioid Use Disorder.

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**BROWN UNIVERSITY**
**CONSENT FOR RESEARCH PARTICIPATION**

**CoMBAT Opioid Use Disorder: A Pilot RCT of a Combined Medication and Behavioral Activation Treatment for People Living with Opioid Use Disorder**
[Version 1.5, December 14, 2020]

**Key Information:**
You are invited to take part in a Brown University research study. Your participation is entirely voluntary. Your participation in this study will not affect any services you receive through Brown or any Brown-affiliated organization. If you are currently enrolled in any type of service or treatment in the community, including substance abuse counseling, you can keep using that service while in this study.

- **PURPOSE:** This study is about testing a new behavioral intervention for people who are receiving medication for opioid use disorder (such as Methadone and Buprenorphine/Suboxone) to help them stay on medication and reduce opioid use.
- **PROCEDURES:** You will be asked to complete three research assessment visits (in-person or remotely/online), provide a urine sample for drug testing at each visit, and meet with a trained counselor 2 times. Some people may be asked to meet with the trained counselor up to 8 additional times.
- **TIME INVOLVED:** The study will last about six months. Depending on the group you are assigned you may attend 5 to 13 study visits (including the visits with the counselor).
- **COMPENSATION:** You will receive up to $240 for your time.
- **RISKS:** There is some risk of feeling embarrassed or uncomfortable while being a part of this study, such as while talking about personal issues, or about your behavior related to drug use. You can refuse to answer any question and stop a study visit at any time. You can also request that the researcher refer you to an outside counselor or other means of support.
- **BENEFITS:** If you are randomized to an intervention, your participation in the intervention may be beneficial.
- **ALTERNATIVES TO PARTICIPATION:** If you decide not to participate in this study you may continue to receive counseling from your community treatment provider. The care you receive in the community (outside of Brown) will not be affected whether you choose to participate in this study or not. Research staff will also provide you with a list of local resources.

1. **Researcher(s):** Jaclyn White Hughto, PhD, MPH. Brown University School of Public Health. 121 South Main Street, Providence RI, 02912. Phone: 401-863-2198.

2. **What is this study about?** This study is funded by the National Institute of General Medical Sciences. This study will test a new behavioral intervention for people who are receiving medications for opioid use disorder, such as Methadone and Buprenorphine/Suboxone, to help them stay on medications and reduce or maintain reductions in opioid use. We will test two different intervention approaches. You will be randomly assigned to 1 of 2 intervention groups. Your chance of being in Group A or Group B is 50-50.

3. **What will I be asked to do?** The study will enroll up to 80 participants from Rhode Island and Massachusetts. If you are eligible and consent to participate in this study you will be asked to do the following:

Consent Visit: Study staff will go over the study details and expectations for participation. You will be able to ask questions and decide if you want to participate or not. If you are doing the study online and you decide you want to participate, we will mail you a package with the study materials needed for the baseline visit. If you are doing the study in-person, you will continue with the baseline visit.

Baseline Visit: If you agree to be in this study, you will complete a survey that asks questions psychological, social, and behavioral questions. Some of these questions are about medication taking, substance use, mental health, physical health (such as HIV status and related behaviors), and criminal history. You will have the chance to refuse to answer any question that you do not want to answer. This research visit lasts about 2.5 hours.

Health Navigation & Substance Abuse Counseling Sessions (2 sessions): If you enroll in the study, you will receive 2 health navigation and substance use counseling sessions with a trained therapist/counselor. These weekly counseling sessions will last about an hour each.

Randomization: After the second health navigation session, you will be randomly assigned to either Group A or Group B.

1. **Group A** – The CoMBAT opioid use intervention (10 sessions total): 2 health navigation and substance abuse counseling sessions, and 8 sessions of Behavioral Activation (BA) therapy. BA therapy is a type of therapy that focuses on helping people re-engage in enjoyable and meaningful life activities that do not involve drugs This therapy aims to help you stay on your medications, navigate life challenges, and find new pleasurable activities outside of drugs. In-person weekly individual counseling sessions that will last about 50 minutes each. You will also be asked to complete a brief (~10 minute survey).

2. **Group B** – Control/Treatment-as-Usual (TAU): All participants regardless of randomization will receive the two health navigation and substance abuse counseling sessions noted above. Group B participants will not have any additional therapy sessions after the last health navigation session and substance abuse counseling session. Group B will be asked to come back for 8 more weeks to complete a brief (~10 minute) survey, but will not receive additional counseling sessions.

Follow-up assessment visits (2 total): 3- and 6-months after your second counseling visit, you will do the same activities as your baseline visit. You will also be asked to complete a brief, about 20 minutes interview with research staff about your experience in the study. Each follow-up visit lasts about 2.5 hours.

**Drug Testing.** At each visit, you will be asked to provide your urine for drug testing. If you are completing the visit online you will be mailed a package with test kits and you will be asked to show your results to study staff over secure video chat. The test will determine the presence of methadone and buprenorphine as well as other drugs (opiates, fentanyl, oxycodone, cocaine, amphetamines, methamphetamines, ecstasy, barbiturates, benzodiazepines, propoxyphene, marijuana, and phencyclidine). If requested, results of the drug test results may be provided to you on the same day as your visit. The results of the test do not affect your eligibility to enroll in the study, the compensation you receive, or the number of visits you will receive. Results of this test are

strictly confidential and are not shared with your community healthcare provider or any other non-research personal and will not affect the care you receive outside of the study.

**Note.** All therapy sessions will be digitally recorded. To protect your confidentiality, your name will not be on the digital file. All data will be kept confidential and digital files will be uploaded after the research visit to a secure network. The recorded interview will be password protected and will only be accessible to study staff. The digital file will be destroyed upon completion of the study.

**4. Are there any different procedures if I am doing the visit online/remotely?**

If you are participating in this study online/remotely, you will complete each visit on a web-enabled phone, computer, or tablet in a private location of your choosing.

**Remote Baseline and 3 and 6 Month Follow-Up Visits.**

Baseline Only. If you are doing the visit in person, your drug test will allow us to confirm that you are taking Methadone or Suboxone/Subutex. If you are doing the visit remotely, we will have to confirm that you are currently prescribed Methadone or Suboxone/Subutex. This can be done by showing us your prescription or other documentation such as a letter from your provider. If you don't have your prescription or other documentation, we will send a completed and signed medical release form to your provider to confirm that you are a patient. If you do not sign the medical release form or provide any other proof that you are currently taking Methadone or Suboxone/Subutex, we will not be able to enroll you in the study.

Survey: For baseline and follow-up visits, you will complete the first half of the visit on secure video chat with a research staff member. The staff member will send you a link to connect to secure video chat on a web-enabled smartphone, tablet or computer. No password is required and you do not need to download any software to use SecureVideo. Once you are on SecureVideo chat, the staff person will ask you the survey questions. The research staff member will also send you a link to the second part of the survey and you will take the survey online on a web-enabled phone, computer, or tablet. When taking the survey on your own, please complete the survey all at once. If you have to exit out of the survey, your answers may not save and we will ask you to do the survey again.

Drug Testing. For drug testing, we will mail you your drug testing/toxicology test. If you are a patient at VICTA you can also pick up tests there, but please let a staff member know in advance if you plan to do this. After you provide the urine, we ask that you connect with a staff person by SecureVideo and show them the results of the test on the test cup. A staff member will send you a link to SecureVideo that you can access on a web-enabled phone or computer.

Brief Interview (6-Month Visit Only). If you are completing your 6-month visit remotely, you will be asked to complete a brief (about 15 minute) interview with a study staff member. This can be done over the phone or on SecureVideo using a link that we provide to you.

**Remote Weekly Visits.**

Survey: For weekly remote visits, you will be asked to complete a brief (about 10 minute) survey on a web-enabled device. A research staff member will send you a link to take the survey. Please

complete the survey all at once. If you have to exit out of the survey, your answers may not save and we will ask you to do the survey again.

Drug Testing. For drug testing, we will mail you your drug testing/toxicology test. If you are at patient at VICTA you can also pick up tests there, but please let a staff member know in advance if you plan to do this. After you provide the urine, we ask that you connect with a staff person by SecureVideo and show them the results of the test on the test cup. A staff member will send you a link to SecureVideo that you can access on a web-enabled phone or computer.

Counseling Sessions. If you are completing counseling sessions, we ask that you find a private location, where no one else can hear you, to participate in the session with your therapist. You will be asked to complete the visit on SecureVideo chat. A staff member will send you a link that you can access on a web-enabled device. No password is required and you do not need to download any software to use SecureVideo. While the sessions will take most people 1 hour in total, please schedule 1 hour and 30 minutes of your time for the sessions to make sure you have time to complete both the survey and the counseling session.

5. **Will I be paid?** If you decide to participate in this study you can receive up to $240 for your time.
   - $40 for the baseline visit
   - $50 for each of the two follow-up visits
   - $10 for each of the weekly visits (up to 10 weekly visits).
   - Transportation vouchers are also available to assist you in getting to Brown University for each visit if needed.

6. **How will I get paid?**

   If you are completing the visit in person, you will receive an American Express gift card for your baseline and follow-up visits and cash for your weekly visits.

   If you are completing the study remotely, you have the option of being mailed the American Express gift card (baseline and follow-up visits only); receiving your payment in the form of an Amazon gift card that is e-mailed to you; or receiving a reloadable, pre-paid Mastercard (ClinCard).

   ClinCard. If you choose to receive the ClinCard, we will add money to the card after each of your completed visits. You may use this card online or at any store that accepts Mastercard. We will provide you with information about how to use this card and whom to call if you have any questions. Please read the information sheet we provide you for details about the ways you can use the card, some of which may involve fees that will reduce the amount of money on the card.

   In order to activate the card, we will need you to provide use with your name, address, and date of birth. This information will be provided to Greenphire, an outside company the manages the card. Greenphire will use your information only as part of the payment system, and it will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

   If your card is lost or stolen, please call the study phone number and ask for a free replacement card. If you request a replacement card from Greenphire directly, you may be charged a fee.

If you earn $600 or more from Brown University in a single calendar year (January to December), either in a one study or across multiple studies, Brown will request your social security number to correctly identify you in the payment system and issue you an IRS 1099 Form. You may also be asked to complete a Form W9. This may affect your taxes. Only payments for being in research studies will be used to decide if you should receive the IRS form. Money for study-related parking, food, and other expenses are not included in this IRS disclosure.

7. **What are the risks?** Questions relating to substance use, depression, and anxiety can be upsetting. You may also feel uncomfortable providing urine for drug testing. If you feel uncomfortable with any study procedures, please share your feelings with study staff. As part of the study you will have access to a qualified counselors who can help you deal with any feelings you have. Due to the length of the first visit and 3 and 6 month follow-up visits, you may feel tired. You may ask to take a break at any time. You are also free to stop your participation in this study at any time.

   We will take several steps to protect your personal information. Although the risk is low, it is possible that your personal information may be given to someone who should not have it. If that happens you could face discrimination, stress and embarrassment. We can tell you more about how we will protect your personal information if you would like it.

8. **What are the benefits?** You may benefit from being in this research study. You will have counseling sessions that have been shown to help others cope with life challenges, improve mood, and reduce opioid use. You will also be provided with local substance use treatment, mental health, and other local resources. Your participation in this study will also further opioid use disorder treatment research, which other people manage opioid use disorder in the future.

9. **How will my information be protected?** Preserving your confidentiality is our top priority and we will do everything we can to protect your confidentiality. We will collect information that will identify you, such as your name and contact information. The identifiable information we collect will be kept separately for the data we collect during the research assessment. All data collected during the research assessment will be kept confidential and stored on REDCap, a data management system. REDCap can only be accessed by designated research staff who have been assigned REDCap user credentials. Your name and other identifiable data will be kept separately from the assessment data we collect, and all assessment data will be identified with an ID number only. A link between names and ID numbers will be kept separately. Your name will not be publicly disclosed at any time and your records will be strictly maintained according to current legal requirements. This applies to any written study records, survey assessments, and test results. Should you authorize the release of information from your medical record, identifying information will be removed before it is linked to your study assessment data.

   Additionally, counseling sessions and the exit interview will be audio recorded with a digital recorder. To protect your confidentiality, your name will not be recorded. Your audio files will be stored on a password protected server. The survey data you provide will not be stored with the digital file of your audio recordings. Your signed informed consent form will be stored separately from study documents, including the audio data that will be identified by participant ID only. We will maintain all study documentation for at least six years after the completion of the study. No individual identities will be used in any reports or publications that may result from this study. Study

data may become available to people other than study staff, but all identifying information that links you to the study will be removed.

Urine will only be collected for the purpose of drug/toxicology tests. The urine you provide will not be stored.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. 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 Government that is used for auditing or evaluating federally 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, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

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.

There are limits of confidentiality; most notably, the disclosure of suicidal thoughts, suicide attempts, or abuse or neglect. If you are under age 18, disclosure of violence or victimization relating to a family member/other individual will require reporting and/or notifying appropriate authorities. Additionally, if you inform study staff of any ongoing abuse or neglect involving a person under the age of 18, we will notify the authorities when indicated by state procedures and laws. Consistent with state-mandated abuse and/or neglect reporting requirements, should a report to the authorities be required, the information provided will be from the PIs. No mention of the study site or the participation in this particular research protocol will be disclosed.

10. **What if I want to stop?** You do not have to be in this study if you do not want to be. Even if you decide to be in this study, you can change your mind and stop at any time. If you decide to quit the study, it will not affect any care or services you receive at Brown or any Brown-affiliated organization.

11. **Will I be told of any new findings or information while I am participating in the study?** You will be told about any important new findings that may be helpful or harmful to you. We will also tell you about findings that might change your mind about being in the study.

12. **Why will I be taken off the study?** You may be removed from the study if we are not able to confirm that you are prescribed medications for opioid use disorder at the beginning of the study. You might also be taken off of the study if we cancel the study. You may also be asked to leave the study if you do not follow instructions or if you miss appointments. There may be other reasons to take you out of the study that we do not know at this time.

If any of the study activities seem too upsetting to you, the counselor can recommend that you do not continue. This could happen even if you want to continue. The researchers will make the decision and let you know if you need to leave the study. If you must leave the study because the researchers ask you, you will still be paid the full amount for the study visit.

13. **Who can I talk to if I have questions about this study?** If you have any questions about your participation in this study, you can call the Principal Investigator, Jaclyn White Hughto at 401-863-2918 or email her at: Jaclyn_Hughto@Brown.edu.

14. **Who can I talk to if I have questions about my rights as a participant?** If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050 or email them at IRB@Brown.edu.

15. **Consent to participate**

**In-Person Consent.** Your signature below shows that you have read and understood the information in this document, and that you agree to volunteer as a research participant for this study.

*I confirm that I have been informed about the purpose of the research study, the procedures that I will undergo, and the possible risks, discomforts, and benefits I may experience, and had all of my questions answered. Alternatives to my participation in the study have also been discussed. I understand that I am free not to participate in this research at all. I understand that I will be offered signed copy of this consent form. I may refuse to sign this form. By choosing to do so, I will not lose any rights or benefits to which I might otherwise be entitled. However, I will not be able to enroll in this research study without signing this form.*

*I agree to give my consent to participate as a subject in this research study. I give permission to Brown University to use and disclose my study data as described above.*

| Participant's Signature | Printed Name | Date |
|---|---|---|

| Investigator's Signature<br>(or Investigator's Representative) | Printed Name | Date |
|---|---|---|

**Remote Consent.** If you have listened to and understand this information that I have provided to you, please state whether you consent to the following statement:

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*I confirm that I have been informed about the purpose of the research study, the procedures that I will undergo, and the possible risks, discomforts, and benefits I may experience, and had all of my questions answered. Alternatives to my participation in the study have also been discussed. I understand that I am free not to participate in this research at all. I understand that I will offered a copy of this consent form. I may refuse to consent to this study. By choosing to do so, I will not lose any rights or benefits to which I might otherwise be entitled. However, I will not be able to enroll in this research study if I do not state that I agree to participate.*

*I agree to give my consent to participate as a subject in this research study. I give permission to Brown University to use and disclose my study data as described above.*

☐ **YES, participant provided verbal consent**

**OR**

☐ **NO, participant did not provide verbal consent**

| Investigator's Signature (or Investigator's Representative) | Printed Name | Date |
|---|---|---|