IRB Protocol #20000 26276
NCT05204576

COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

YALE UNIVERSITY
YALE UNIVERSITY SCHOOL OF MEDICINE
and
Liberation Programs
and
Connecticut Counseling Centers Inc.

Study Title: Computer Based Treatment for Cognitive Behavioral Therapy and Cooperative Pain Education and Self-Management --CBT4CBT-IMPACT

Principal Investigator (the person who is responsible for this research):

Alicia Heapy, PhD
950 Campbell Avenue
West Haven, CT 06516

Phone Number: 203-932-5711 X 2299

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to evaluate a computer learning program for people on methadone or buprenorphine with an opioid use disorder and chronic pain. You have been invited because you are seeking treatment at this clinic for a problem with opioid use and have chronic pain.
- Study procedures will include: If you are willing and eligible to participate in the study and sign the consent form, you will be interviewed by a member of the research team, asked to fill out questionnaires (this should take about 1.5 hours), and agree to provide a breath (if Covid procedures allow) and urine specimen for alcohol and drug testing. These questions will include information on your current and past alcohol and drug use, any alcohol or drug-related problems you may be having as well as any chronic pain issues you may be experiencing. If you are found eligible for this study, you will then be assigned to one of two treatments explained in detail below.
- The treatment will last twelve weeks. You will be asked to complete some forms and answer some questions before beginning treatment (this will take about 1.5 hours), each week (this will take about 15 minutes each time), and at the end of the 12 weeks (this will take about 2 hours). We will contact you for follow-up interviews at 1 month, 3 months, and 6 months after you finish the study, and these interviews will take about 1.5 hours each time.
- There will be 12 study “visits” or timepoints that are required plus 3 study “visits” or timepoints during follow up.
- There are some risks from participating in this study. There is the possibility of the loss of confidentiality from participation in this study that are explained below. We will make every effort to minimize this risk.
- The study may have no benefits to you.
- There are other choices available to you outside of this research. Participating in this study is voluntary. If you choose not to participate you will be referred to or will continue treatment at this clinic.

APPROVED BY THE YALE UNIVERSITY IRB 2/15/2024

- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Why is this study being offered to me?
We are asking you to take part in a research study because you are seeking treatment at this clinic for a problem with opioid use and you have chronic pain. We are looking for 160 participants to be part of this research study.

Who is paying for the study?
National Center for Complementary and Integrative Health (NCCIH)

What is the study about?
The purpose of this study is to look at the effects of using the computer program IMPACT versus Treatment-As-Usual for people taking either methadone or buprenorphine who have an Opioid Use Disorder and chronic pain at this clinic.

What are you asking me to do and how long will it take?
If you agree to take part in this study, this is what will happen: The main part of this study, the treatment, will last for 12 weeks, with follow-up visits 1 month, 3 months, and 6 months after the end of the treatment part of the study. All study procedures will be conducted either in-person or virtually via Zoom, RedCap or phone. If you are willing to participate in the study and sign the consent form, you will be interviewed by a member of the research team, asked to fill out questionnaires (this should take about 1.5 hours), and provide a urine specimen for alcohol and drug testing. By signing this form, you give permission for the research team to access your urine test results. These questions will include information on your current alcohol and drug use and alcohol and drug use history, as well as any pain-related problems you may be having.

If you are found eligible for this study, you will then be assigned to **one** of two treatments. We will decide what treatment you will receive by random selection. This means that your treatment will be decided by luck of the draw and not selected deliberately because of any special characteristics or problems you have. Each participant will be assigned by random selection to one of the two following treatments:

1. IMPACT

In this treatment you will work with a computerized program that teaches skills for managing your pain and cravings for opioids. Your will learn skills for improving sleep, stress and physical activity that positively impact both pain and craving. You will be taught how to use the computer program by a staff member and will be asked to spend about 9 hours using the program (approximately one hour per week) at the clinic or at home. Staff will be available while you are using the program at the clinic if you have any concerns or questions about the computer program. You will also be asked to complete a brief questionnaire about your opioid use in the past week either in person with the Research Assistant or virtually in RedCap. We will also ask you to provide breath and urine specimens for alcohol and drug testing per clinic schedule.

If you are randomized to this condition you will also be provided with a pedometer to help with your participation in the walking portion of the treatment. Study staff will measure your stride length, adjust the pedometer stride length setting accordingly, and provide a brief demonstration of pedometer use. We will only be recording your steps.

AND

Daily texts: Following randomization to IMPACT, you will receive a daily text with a link to a survey. The survey will ask you about your pain intensity, how much pain has interfered in your daily activities, pedometer-measured step counts, sleep, and opioid craving. Once you begin using the IMPACT program two additional questions regarding practice of the treatment skills and progress toward the weekly goals you set in treatment will be included. You will continue to receive daily texts for the 12-weeks of treatment. Your answers on the survey will be used by a coach to give you personalized weekly feedback message that you can listen to from the dashboard of the IMPACT computer program. Surveys via text will be no longer than 2 minutes each.

OR

2. Treatment As Usual (TAU) at this clinic

This is the same as the treatment you would normally receive at this clinic. This will be tailored to your needs, but generally includes individual and group therapy sessions and regular urine monitoring. Sessions will generally last for 1 hour one time per week for 12 weeks and include issues such as:

• Teaching about the treatment program at this clinic
• Teaching you important ideas about recovery
• Increasing your knowledge about specific problems you may have about your addiction or pain
• Demonstrating new ways of coping with skills designed to fit your lifestyle.

You will also be asked to complete a brief questionnaire about your drug use and pain level in the past week with the Research Assistant and to provide urine and breath specimens for alcohol and drug testing one time each week or per clinic schedule.

Cell phones for IMPACT surveys

All eligible participants will have the option of receiving a cell phone including a data plan for the duration of the study. If you already have a cell phone that can access the internet (smartphone) in Wi-Fi and/or a data plan and would prefer to use that phone for IMPACT surveys, you may. If you choose, it is expected you will use the provided cell phone for the surveys received via text and keeping in touch with the research assistant and viewing the web-based IMPACT program if assigned to that treatment. You will be asked to decide when signing this consent form if you choose to keep the cell phone as a form of payment for your weekly sessions valued at $180 **or** return the cell phone in good, working and damage-free condition to the research assistant and then receive up to $180 ($20 per week for sessions completed for the 12 weeks of treatment) for your participation. At the end of the 12 weeks the data plan will be turned off.

If you choose to keep the cell phone at the time of signing this consent form and the cell phone then is lost, broken, stolen or otherwise damaged you cannot then decide to take the payment of up to $180.

It is expected you will take care of the cell phone provided and use it responsibly. It is expected you will not use, retrieve, store, or send improper language, pictures, or other digital content including but not limited to illegal content. This cell phone will be assigned to you and if you do not abide by this user agreement the research team will not be held responsible.

Assessments
At the end of the 12-weeks you will be asked to fill out more questionnaires (which is a set of questions), provide a urine specimen for drug and alcohol testing, and be interviewed again: this will take about 2 hours. Again, these questions will focus on your current drug use and any pain-related problems you may be having. At the end of this part of the study, you may continue treatment at this clinic, or if you wish, to be referred for more treatment somewhere you are interested in.

We will ask you to provide the names and telephone numbers of several persons in your life who are likely to know your whereabouts, to help us locate you for interviews. These persons will be contacted only if we cannot locate you directly first; we will ask them only about where we may contact you (we will not ask about drug use or other problems); and we will not tell these persons any information about this study or your participation in it.

If you are randomized to the IMPACT Program, we may ask you at the Post-treatment interview if you would be interested in giving feedback about the program in the form of a Qualitative Interview. This would be an additional interview that would take place at a scheduled time and for which you will be paid $60 in the form of a gift card. A separate verbal consent will be given at the time and details reviewed to your satisfaction.

What are the risks and discomforts of participating?
We believe that there are very few risks to participating in this treatment. We would like you to tell us about any times you use alcohol or illegal drugs as well as your experience of pain while you are in the study. It is not illegal to report past substance use. Also, we know that stopping substance use can be quite difficult. In order to be helpful to you we simply need to know about your substance use. The urine drug tests for alcohol enables us to be certain of our results. The only way you might be dismissed from the study is if you repeatedly do not come to treatment or violate the rules of this clinical program. We would only ask that you do your best to stop using alcohol and drugs, be honest about yourself and your problems and to be available at your appointment times for both the research assistant and your counselor.

If you decide to be in this study, the researcher will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name and address. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator, Alicia Heapy, PhD. will keep a link that identifies you to your coded information, and this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify you will remain confidential. All personal information will be coded and stored in a locked cabinet and any data stored on a computer will be password protected to further protect your confidentiality

A risk to this study is the possibility of the loss of confidentiality. We will make every effort to minimize this risk. The web-based intervention is highly secure and ***does not collect any PHI***

identifiers nor specific information regarding illegal activities and has passed stringent Yale Information Technology Security Design Review (September 2011). It is accessible only through a username/password system monitored by Yale staff. Moreover, the design of the IMPACT program has closely followed recommended ethical and safety guidelines for use of computer assisted behavioral therapies developed by Sampson and Pyle, including (1) assurance of confidentiality, (2) determination of appropriateness of the specific form of training, in this case, CBT, which has been shown to be effective for a wide number of substance use disorders and populations, (3) adequate introduction to the computer program by staff to reduce possible anxiety about use of the system, and (4) provision of follow-up consultation with a clinician if needed.

Chess Health, an outside vendor, will build and maintain the information system that will be used for the daily survey data collection. Chess Health uses Amazon Web Services to host the system in their secure environment. The environment is in line with Yale/HIPAA rules of privacy and security. Chess Health will have your phone number in order to send you the link to the daily survey. At the conclusion of this study, electronic files containing personal or confidential data will be destroyed according to Yale IRB guidelines. Your phone number will not be connected to any other identifying information we collect about you in the study like your name. If you choose to use your personal cell phone your phone number will be stored for the length of the study. A phone may be provided for you for research purposes if you choose.

If you become uncomfortable for any reason or at any time in using the computer program, you should inform your counselor, the Project Coordinator, or Dr. Heapy immediately.

How will I know about new risks or important information about the study?
We will tell you if we learn any new information that could change your mind about taking part in this study.

How can the study possibly benefit me?
There is no direct benefit from taking part in this study. This program may help you control your drug use and pain however, there is no guarantee that you will benefit from participating in this program.

How can the study possibly benefit other people?
The benefits to science and other people may include a better understanding of opioid use disorder and pain treatment options for people taking either methadone or buprenorphine and may provide a general advancement of scientific knowledge.

Are there any costs to participation?
You will not have to pay for taking part in this study. The only costs include transportation and your time coming to the study visits.

Will I be paid for participation?
You will be paid for taking part in this study. You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments.

Activity	Compensation Available	Bonus for in-person	Total available	Form of Payment
Screening	$25	$0	$25	Cash/gift card
Baseline	$35	$0	$35	Cash/gift card
Weekly assessments **OR** Keep provided cell phone	$180 Total (@ $20 per session completed X 9) Valued at $180 w/ data plan for 12 weeks	$45 Total (@ $5 per session completed X 9)	$225	Cash/gift card Cell phone
Monthly assessments at weeks 4 and 8	$40 Total (@ $20 per session completed X2)	$40 Total (@ $20 per session completed X 2)	$80	Cash/gift card
Post treatment	$35	$20	$55	Cash/gift card
Follow up @ 1 month	$50	$20	$70	Cash/gift card
Follow up @ 3 months	$75	$20	$95	Cash/gift card
Follow up @ 6 months	$100	$20	$120	Cash/gift card
Total Available			$705	

What are my choices if I decide not to take part in this study?

Instead of participating in this study, you have some other choices. You could get treatment at this clinic without being in a study.

How will you keep my data safe and private?

We will keep information we collect about you confidential. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, we will tell somebody if you we learn that you are hurting a child or an older person or have concerns about your safety or suicidal risk. If we become aware of circumstances of risk directly related to clinical care such as an overdose or overnight hospitalization possibly related to your treatment at this clinic, we will inform the clinic director. Any of your identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission, with the following exceptions: We will disclose to appropriate authorities any reportable diseases, known or suspected abuse of a child or elderly person, or if you become a danger to yourself or others. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained.

We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the researcher will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name and address. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator, Alicia Heapy, PhD. will keep a link that identifies you to your coded information, and this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify you will remain confidential.

All personal information will be coded and stored in a locked cabinet and any data stored on a computer will be password protected to further protect your confidentiality The research team will only give this coded information to others to carry out this research study. The link to your personal information will be kept for the 1 year follow up period after which time the link will be destroyed and the data will become anonymous. The data will be kept in this anonymous form for a minimum of 3 years after the study has ended and then will be destroyed.

All Zoom conversations are conducted on secure and encrypted computers. All RedCap data is on a secure and encrypted database.

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we would ask you for your permission.

We will also share information about you with other researchers for future research, but we will not use your name or other identifiers. We will not ask you for any additional permission.
We will also share information about you with other researchers for future research, but we will not use your name or other identifiers. All identifiers will be removed from your private information. Your information may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you. We will not ask you for any additional permission.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. 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 NCCIH 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 of such as child abuse and neglect, or harm to self or others.

Data and Sample Storage and Sharing
Your study data will be stored securely at this clinic during the active part of the study and then in the Principal Investigators office: Alicia Heapy, PhD; 950 Campbell Avenue, West Haven, CT 06516 or at sites NIH selects for this study. Your data will be stored indefinitely. We will do our best to protect your personal information. Your name and other personally-identifying information will not be kept with the data. Your data will be stored with a code linking them to

you or they will have a code that links to your identifying information. If your data has a code, the key to the code will be kept at the Principal Investigators office: Alicia Heapy, PhD; 950 Campbell Avenue, West Haven, CT 06516 in a separate, secure area and will not be shared outside of the study.

This study is part of the NIH HEAL Initiative focused on understanding and developing new treatments for addiction and pain. Research gives us the best information and progresses more quickly when data is available from many studies and many individuals, and when many researchers can work with the data and samples and analyze them in different ways. Therefore, your data will be used for this and other NIH HEAL Initiative studies. Your stored data will also be made widely available to other researchers. The shared data may be used indefinitely for research not related to this study or the HEAL Initiative, without asking you for additional consent.

If you withdraw from this research study before it is done, we will keep and continue to use data that have already been collected.

Potential benefits of sharing of data and samples
There is no direct benefit to you from the storage and sharing of your data, but sharing may help researchers learn more about people on methadone or buprenorphine with an opioid use disorder and chronic pain and other diseases, which may help you or others in the future.

Risks of sharing data
Even though we will protect your privacy as much as possible, there is a very small chance that the data could be identified as yours. The risk of this happening is very small but may increase in the future as technology changes.

Research using data from this study may lead to new tests, drugs, or devices with commercial value. You will not receive any payment for any product developed from research using your data.

If you do not want your data used for other research, you should not participate in this study.

What Information Will You Collect About Me in this Study?
The information we are asking to use and share is called “Protected Health Information.” It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

- Research study records
- Medical and laboratory records of only those services provided in connection with this Study.
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research regarding
    - Laboratory, x-ray, and other test results
    - Diaries and questionnaires

- The diagnosis and treatment of a mental health condition
- Use of illegal drugs or the study of illegal behavior

How will you use and share my information?

We will use your information to conduct the study described in this consent form.
We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- National Institute of Health (NIH) who are the research sponsor
  National Center for Complementary and Integrative Health (NCCIH)
- Chess Health
- Health care providers who provide services to you in connection with this study.
- Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan.
- Principal Investigator of the study
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- Liberation Programs
- Connecticut Counseling Centers Inc.
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Why must I sign this document?

By signing this form, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

What if I change my mind?

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to Alicia Heapy, PhD; 950 Campbell Avenue, West Haven, CT 06516.

If you withdraw your permission, you will not be able to stay in this study but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to ensure the integrity of the study and/or study oversight.

Who will pay for treatment if I am injured or become ill due to participation in the study?

If you develop any mental or physical problems as a direct result of being in this study, we will refer you for treatment. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available. Your legal rights are not waived by signing this consent form.

What if I want to refuse or end participation before the study is over?

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

You would still receive standard therapy or, at your request, we could refer you to a clinic or doctor who can offer this treatment. Not participating or withdrawing later will not harm your relationship with your own doctors or with this institution.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part.

The researchers may withdraw you from participating in the research if necessary. Reasons for withdrawal may include your substance use getting continually worse so that you need more intensive care and non-compliance of research requirements as described above.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to ensure the integrity of the study and/or study oversight.

What will happen with my data if I stop participating?

If you sign this authorization, you may change your mind at any time, but the researchers may continue to use information collected before you changed your mind to complete the research. To withdraw, you can call a member of the research team at any time and tell them that you no longer want to take part. This will cancel any appointments in the future.

Withdrawing Your Authorization to Use and Disclose Your Health Information:

You may withdraw or take away your permission to use and disclose your health information at any time. You may withdraw your permission by telling the study staff or by writing to Alicia Heapy, PhD, 950 Campbell Avenue, West Haven, CT 06516.

If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to ensure the integrity of the study and/or study oversight.

Who should I contact if I have questions?
Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator at Alicia Heapy, PhD., at 203-932-5711 X2299

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

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.

Authorization and Permission

Your signature below indicates that you have read this consent document and that you agree to be in this study.

We will give you a copy of this form.

Please choose one of the following:

I choose to:
Not take the cell phone and receive weekly payments for assessments _____

OR

Keep the cell phone provided by the study as payment for weekly assessments _____

OR

Return the cell phone provided by the study in good working and damage-free condition at the end of the 12 weeks as outlined above and receive up to $240 for the weekly sessions I completed _____

Participant Printed Name	Participant Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date