INFORMED CONSENT FOR PARTICIPATION IN RESEARCH

Study Title: Cognitive Functioning in Opioid Use Disorder: Examining the Impacts of Computerized Working Memory Training and Non-Fatal Opioid Overdose

Key Information

Purpose: You have been invited to be evaluated as a potential participant in a research study at the NY State Psychiatric Institute. The purpose of this visit is to evaluate your condition in order to determine if you are a suitable candidate for a study evaluating the impacts of opioid overdose on cognitive functions (memory, planning, organization etc.).

Voluntary: Participation in this research study is entirely voluntary and you may discontinue research participation at any time.

Procedures: The evaluation will involve you meeting with our clinicians for a psychiatric and medical screening, which will include questions about your drug use, health, and any other problems you may be having.

Duration: After the initial screening visit(s), you will be told whether you may be eligible for this research study. The screening process may take between a few days to a few weeks depending on the frequency of your visits and the availability of our clinic staff.

Risks: There is risk of COVID-19 during in-office visits and during travel for research purposes. We have minimized in-office visits to lessen this risk.

Benefits: This evaluation is not designed to benefit you directly.

Alternative Treatment: If you do not wish to be evaluated here, or to participate in this study, then you will be offered appropriate referrals. If you are not eligible, or if you are not interested in taking part in research treatment, then the clinicians will assist you in finding treatment elsewhere.

Purpose of Study

The main purpose of this study is to understand the impacts of opioid overdose on cognitive functions (memory, planning, organization etc) and to examine the usefulness of a computerized memory training program for those with opioid use disorder. You are confirming that you currently receive buprenorphine/naloxone (suboxone) and are not dependent on any other drug with the exception of opioids, nicotine, and/or caffeine. If you are a woman, you are also confirming that you are not pregnant.

Voluntary

Participation in this research study is voluntary. If you decide not to participate, or if you later decide to stop participating, you will not lose any benefits to which you are otherwise entitled. A decision not to participate or withdraw your participation will not affect your current or future treatment at the New York State Psychiatric Institute (NYSPI) or Columbia University Irving Medical Center (CUIMC).

Alternatives to Study Participation

This is not a treatment study. Data are being collected for research purposes. Referrals for treatment are available at any time. You do not have to participate in this study to get a referral for psychiatric or medical care. If you are interested in treatment, an appropriate outpatient treatment will be arranged. Available treatments for opioid use disorder include methadone, buprenorphine, buprenorphine/naloxone, and naltrexone maintenance.

Study Procedures

You have been selected as a potential research volunteer. In order to participate in the study, you must first pass medical and psychiatric screening. This will include answering a general health questionnaire and other questionnaires relating to drug use and completing an interview with a psychologist or nurse (45-60 minutes). Screening is expected to take approximately 3 visits to complete, which may take 1-2 weeks depending on your availability and the availability of our clinic staff. Some of your visits may be conducted remotely using the telephone or HIPAA-compliant video teleconferencing. Remote visits will include a clinical interview with a psychologist (including questions about your psychiatric, drug use and overdose history; 45-60 minutes) and a detailed medical history (10-20 minutes).If you are determined to be eligible and decide to participate, you will be asked to come to NYPSI for more screening procedures that will include review of this screening form (15-30 minutes), collection of vital signs (heart rate, blood pressure; 5-10 minutes) and a urine sample (5-10 minutes), a physical examination (30-45 minutes), and collection of detailed information about your current suboxone program and provider (10-15 minutes). You will also be tested for COVID-19 during screening using a nasal swab (5-10 minutes).

Risks

Confidentiality: You will be asked to disclose identifying and protected health information in order to participate in this study. We will do everything we can to keep others from learning about your participation in the research (see confidentiality section below).

COVID-19 Exposure: There is a risk of COVID-19 exposure while traveling to and from NYSPI, during in-office visits. The risk related to travel can be reduced by taking the recommended precautions. You should exercise caution when traveling in public and follow public health guidelines, such as wearing masks in public and avoiding crowds. It is important for you to stay informed about public health recommendations and guidelines regarding COVID-19, such as those issued by the Centers for Disease Control (CDC.gov) and local government guidelines and directives. If you have questions about how you will travel for appointments, or do not feel safe traveling, please let us know, and know that you can call to reschedule visits.

Nasal Swab: The nasal swab we use to test you for COVID-19 may be uncomfortable.

Benefits

The study is not designed to benefit you personally. The benefits of this research relate primarily to the general scientific value of gaining a better understanding of opioid use disorder.

Confidentiality

The records of your participation, including research forms, will be kept in locked cabinets at NYSPI and will be available only to Substance Abuse Division clinical research staff, and to Federal, State and institutional regulatory personnel (who may review records as part of routine audits). Your name and other personal identifying information will be stored in an electronically secure data base at New York State Psychiatric Institute. Confidentiality will be maintained during remote visit through the use of HIPAA-Compliant videoconferencing and web-based platforms such as FaceTime, Webex, and RedCap. We will also use encrypted email communications. Your private information or biospecimens cannot be used for future research studies or distributed to another investigator for future research studies, with or without identifiers.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

A description of this 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.

Compensation

As a result of participating in this screening, you will receive up to $20 per screening visit. If you do not qualify for an in-person screening, the compensation you've earned for completing the remote screening procedures will be sent to you in the form of an Amazon gift card or can be wired to you.

In Case of Injury

Federal regulations require that we inform participants about our institution's policy with regard to compensation and payment for treatment of research-related injuries.

If you believe that you have sustained an injury as a result of participating in a research study, you may contact the Principal Investigator, Dr. Rachel Luba, at 646-774-6496 so that you can review the matter and identify the medical resources that may be available to you.

Questions

The investigators will answer to the best of his/her ability any questions that you may have now or in the future about the research procedures, or about your response to the procedures. You may contact the Principal Investigator, Dr. Rachel Luba, who can be reached at (646) 774-6495, if you have any questions. You will be given a copy of this consent form to take home with you. If you have any questions about your rights as a research participant, want to provide feedback, or have a complaint, you may call the NYSPI Institutional Review Board (IRB). An IRB is a committee that protects the rights of participants in research studies. You may call the IRB Main Office at (646) 774-7155 during regular office hours.

Documentation of Verbal Consent

Verbal Consent Obtained □**Yes** □**No**

Printed Name of Person Designated to Obtain Remote Consent

_____

Signature_____**Date**_____

An electronic copy of this consent form can be emailed to you.

INFORMED CONSENT FOR PARTICIPATION IN RESEARCH

STUDY TITLE: Cognitive Functioning in Opioid Use Disorder: Examining the Impacts of Computerized Working Memory Training and Non-Fatal Opioid Overdose

Study ID:	IRB # 8185	
Principal Investigator:	Rachel Luba, Ph.D.	
Medical Director:	Jeanne M Manubay, MD	
Study Site:	New York State Psychiatric Institute	
	1051 Riverside Drive, Unit 120	
	New York, NY 10032	
Study Contacts:	Dr. Rachel Luba	646-774-6495
Telephone:	646-774-6243	
Participant Number:	_____	

For questions about your rights as a research participant, contact NYSPI IRB at 646-774-7155.

Key Information

Purpose: You have been invited to be evaluated as a potential participant in a research study at the NY State Psychiatric Institute. The purpose of this study is to evaluate the impacts of opioid overdose on cognitive functions (memory, planning, organization etc.) and examine the usefulness of a computerized memory training program.

Voluntary: Participation in this research study is entirely voluntary and you may discontinue research participation at any time.

Procedures: If you are eligible to participate, you will be asked to come into the clinic for several outpatient sessions (described below) and to complete 20 sessions of computerized memory training from your home computer, tablet, or smart phone for 1-month.

Duration: After the initial outpatient assessment visit, you will complete 1 month of computerized training sessions from your home. Shortly after training (within 1 week) you will be asked to return to the clinic for an outpatient session lasting 1.5 hours. You will be asked to return for subsequent outpatient sessions 1-month and 3-months after you complete the training.

Risks: There is risk of COVID-19 during in-office visits and during travel for research purposes. We have minimized in-office visits to lessen this risk.

Benefits: This study is not designed to benefit you directly.

Alternative Treatment: If you do not wish to participate in this study, you will be offered appropriate referrals. If you are not eligible to participate then the clinicians will assist you in finding treatment and/or appropriate referrals elsewhere.

Purpose and Overview

You are being asked to take part in a research study. The main purpose of this study is to understand the possible impacts of opioid overdose on cognitive functions (memory, planning, organization etc). Further, the current study will examine the usefulness of a computerized memory training program for those with opioid use disorder. You are confirming that you currently receive buprenorphine/naloxone (suboxone) and are not dependent on any other drug with the exception of nicotine, and/or caffeine. You are also confirming that if you are a woman, that you are not pregnant.

You are being asked to take part in this research study because you have been diagnosed with opioid use disorder (OUD) and you are stable on a buprenorphine/naloxone (suboxone) therapy. Your participation in this study will last a total of about 3 months. The study will be conducted on an outpatient basis.

The current study will examine the usefulness of a computerized memory training program for those with opioid use disorder. If you enroll in this study, you will be asked to complete computer tasks that measure cognitive functions. After enrolling in this study, you will be assigned to complete 20 sessions of a computerized memory task for one month. You will be expected to complete five training sessions per week for the duration of the study. Assignment to training sessions will be random (like flipping a coin) and you will either complete 20 sessions that are the same level of difficulty, or 20 sessions that change in difficulty over time. Neither you nor the researchers will know which condition you've been assigned to**.** Each training session takes between 30 and 45 minutes. These sessions will be completed from your home computer, tablet, or mobile device. You will receive training on accessing the computer task before starting the study.

Voluntary

Your participation is entirely voluntary, meaning that you can say yes or no. If you decide not to participate, or if you later decide to stop participating, you will not lose any benefits to which you are otherwise entitled. A decision not to participate or withdraw your participation will not affect your current or future treatment at the New York State Psychiatric Institute or Columbia University Irving Medical Center. After signing this consent form, you are free to change your mind—at any time—and leave the study if you wish, without giving a reason. If you decide not to take part, or if you decide to stop being in the study, there will be no penalty, and you will not lose any benefits which you would otherwise have. You will not give up any legal rights by signing this consent form.

Alternative Treatments/Alternatives to Participation

Counseling about different treatment options and referrals for psychiatric or medical treatment are available at any time before, during, or after participation in this study.

Procedures

The study consists of an in-person pre-training assessment visit (1.5 hours), one month of computerized training sessions (completed remotely, from your home device), an in-person post-training assessment visit (1.5 hours), and in-person 1-month and 3-month follow-up visits (approximately 1.5 hours minutes each). The baseline, post-training, and follow-up visit will include computerized tests of cognitive function and decision-making (45 minutes), and completion of brief questionnaires measuring your quality of life and daily functioning (10-15 minutes). You will also be asked to complete an assessment of recent substance use (5-10 minutes)

and to provide a urine sample (5 minutes). Following the baseline assessment visit, you will be assigned to complete 20 computerized training sessions over the course of 1 month.

Collection of Information from your Suboxone Provider

In order to participate, you will be asked to provide your consent for our staff to contact your current suboxone provider in order to confirm your participation in a suboxone program. You will be asked to provide the name and phone number of your current provider's office, and to sign a form indicating that you give your consent to our team to contact this provider. Our team will send a copy of this form to your provider to let them know it's okay to share information with us. We will ask your provider to share information about your current dose and how long you've been taking that dose.

Baseline Assessment Visit

After you complete screening procedures, you will be asked to come into the clinic to complete a baseline assessment visit. This visit will include completion of several computer-based tasks that measure cognition and decision making. You will also be asked to complete several short questionnaires that measure your daily functioning and quality of life. You will be asked to provide a urine sample, and to report on any drug use in the past month. This visit is expected to take 1.5 hours.

Computerized Memory Training

Following the baseline assessment, you will be randomly assigned (like flipping a coin) to complete one of two types of training sessions. You will either complete 20 sessions that are the same level of difficulty, or 20 sessions that change in difficulty over time. Neither you nor the investigator will know which type of training you've been assigned to**.** You will be trained on accessing the training program from your home computer, tablet, or mobile device and provided a unique code to login to the program. You will be expected to complete five sessions per week for 4 weeks. You will receive a phone call from the investigator or research staff at the start of each week to remind you about the training sessions, and assist you with any technical difficulties you may have.

Post-Training Assessment Visit

Approximately one week after you complete all of the computerized memory training tasks, you will be asked to come into the clinic to complete a post-training assessment visit. This visit will include completion of several computer-based tasks that measure cognition and decision making. As with your baseline assessment, you will also be asked to complete several short questionnaires that measure your daily functioning and quality of life. You will be asked to provide a urine sample, and to report on any drug use in the past month. This visit is expected to take 1.5 hours.

1-month and 3-month Follow-up Visits

Approximately 1 month and 3 months after you complete the computerized training tasks, you will be asked to return to the clinic to provide a urine sample and to complete approximately 45 minutes of computerized tasks. Just prior to these visits, you will receive an email to complete several short questionnaires measuring your daily functioning, quality of life, and recent drug use. If you prefer to complete these questionnaires when you come into the clinic in person, or over the phone, this can be arranged.

Risks and Inconveniences

The risks and inconveniences of this study are expected to be minimal.

Confidentiality: You will be asked to disclose identifying and protected health information in order to participate in this study. We will do everything we can to keep others from learning about your participation in the research (see confidentiality section below).

Discomfort/Boredom: You may find it uncomfortable and/or tiring to answer questions of a personal nature during screening, at post-training, and follow up. You may refuse to answer questions or ask to stop the screening or study process at any time. We will make every effort to foster a safe, confidential, non-judgmental environment for you to answer questions and complete assessments in a comfortable manner. During the computerized training period of the study, you will be asked to complete five 30-45 minute training sessions per week. You may find the computerized training to be boring or cumbersome, and may encounter some technical difficulties associated with running the software during training, which could cause some frustration. Support will be available if you experience technical difficulties. Your participation is entirely voluntary and you can withdraw from the study at any time, if you feel that discomfort or boredom outweighs any benefits of participating.

Coronavirus 2019 (COVID-19): There is a risk of COVID-19 exposure while traveling to and from NYSPI, during in-office visits. The risk related to travel can be reduced by taking the recommended precautions. You should exercise caution when traveling in public and follow public health guidelines, such as wearing masks in public and avoiding crowds. It is important for you to stay informed about public health recommendations and guidelines regarding COVID-19, such as those issued by the Centers for Disease Control (CDC.gov) and local government guidelines and directives. If you have questions about how you will travel for appointments, or do not feel safe traveling, please let us know, and know that you can call to reschedule visits.

Nasal Swab: The nasal swab we use to test you for COVID-19 may be uncomfortable.

Benefits

The study is not designed to benefit you personally. The benefits of this research relate primarily to the general scientific value of gaining a better understanding of opioid use disorder.

Confidentiality

We will do everything we can to keep others from learning about your participation in the research.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The

Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

A description of this 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.

Records will only be available to research staff, and to Federal, State and Institutional regulatory personnel (who may review records as part of routine audits). Your name and other personal identifying information will be stored in an electronically secure database at NYSPI. Your private information or biospecimens cannot be used for future research studies or distributed to another investigator for future research studies, with or without identifiers.

Signed consent forms and other forms containing identifying information will be kept in a locked file, and all interviews, assessments, etc. will be coded with initials and numbers. Your name and other personal identifying information will be stored in an electronically secure database at NYSPI. Electronic data are also coded and are stored on computers that are password protected. Any study data with identifying information will be encrypted before being sent by email, and anything we send to you via email will be encrypted. Confidentiality of remote communication is protected through the use of secure telecommunication (e.g. Webex, Facetime, or telephone) in combination with digital data collection procedures (through remote access to secure systems).

Study Compensation

Compensation is provided for your time and effort. As a result of participating in this research, you will receive $20 for each screening visit, $45 for the baseline and post-training assessment visits, and $20 for each follow-up visits. This money will be paid in cash at the end of each day. You will be compensated $10 for each day you complete a computerized training session, plus a bonus of $10/ day if you complete all five sessions in one week. You will be paid in cash, or your payments can also be wired to you using a service like Western Union.

Total payments will be approximately $590.00.

In Case of Injury

Federal regulations require that we inform participants about our institution's policy with regard to compensation and payment for treatment of research-related injuries.

If you believe that you have sustained an injury as a result of participating in a research study, you may contact the Principal Investigator, Dr. Rachel Luba, at 646-774-6496 so that you can review the matter and identify the medical resources that may be available to you.

Questions

The investigators will answer to the best of his/her ability any questions that you may have now or in the future

about the research procedures, or about your response to the procedures. You may contact the Principal Investigator, Dr. Rachel Luba, who can be reached at (646) 774-6495, if you have any questions. If you have any questions about your rights as a research participant, want to provide feedback, or have a complaint, you may call the NYSPI Institutional Review Board (IRB). An IRB is a committee that protects the rights of participants in research studies. You may call the IRB Office at (646) 774-7155 during regular office hours.

Documentation of Consent

I voluntarily agree to participate in the research study described above.

Print name: _____

Signature:_____

Date: _____

I have discussed the proposed research with this participant including the risks, benefits, and alternatives to participation (including the alternative of not participating in the research). The participant has had an opportunity to ask questions and in my opinion is capable of freely consenting to participate in this research.

Print name (Person designated to Obtain Consent): _____

Signature: _____

Date: _____

You will be given a copy of this consent form to take with you.