**Participant Information Sheet/Consent Form**

**Health/Social Science Research** -*Adult providing own consent*

[SITE NAME]

|  |  |
| --- | --- |
| **Title** | A pilot randomised controlled trial (RCT) of personalised approach bias modification for methamphetamine use disorder |
| **Short title** | Training the brain to avoid methamphetamine |
| **Protocol Number** | 1 |
| **Project Sponsor** | National Centre for Clinical Research on Emerging Drugs (NCCRED) |
| **Principal Investigator** | A/Prof. Victoria Manning |

**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in this research project, which is called ‘*A pilot randomised controlled trial (RCT) of personalised approach bias modification for methamphetamine use disorder’.* You have been invited because you are undergoing residential rehabilitation treatment (rehab) for methamphetamine use at [SITE]. The research project looks at whether a computerised “brain-training” program designed to reduce “*approach bias*” can help people stop using methamphetamine*.* “Approach bias” means the tendency to move towards things that we find attractive – for example, things associated with methamphetamine. Based on research on other drugs, reducing approach bias through “approach bias modification” (ABM) might help prevent relapse.

This Participant Information Sheet tells you about the research project. It explains the processes involved in taking part, to help you decide if you want to take part in the research. After reading this information, you can ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with someone else, like a relative, friend, or health worker.

Since participation in this research is voluntary, you don’t have to participate if you don’t want to. If you decide you want to take part in the research project, you will be asked to sign the consent form. By signing it you are telling us that you:

• Understand what you have read

• Consent to take part in the research project described

• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

**2 What is the purpose of this research?**

The aims of this project are to determine:

* whether the brain-training reduces people’s approach bias towards methamphetamine-related images.
* whether the brain-training reduces methamphetamine craving and other methamphetamine dependence symptoms.
* whether the brain-training helps prevent relapse to methamphetamine use after leaving rehab.

We have previously tested this form of brain-training for people withdrawing from alcohol and for people withdrawing from methamphetamine, and found promising results. However, this will be the first “controlled trial”, where we compare people who receive ABM brain-training to people who receive a different form of brain training that is not designed to change approach bias, during methamphetamine treatment. If our results show that the brain-training is effective, it could be made more widely available for people experiencing problems with methamphetamine use.

**3 What happens if I participate in this research?**

*Questionnaires*

If you consent to participate in the research, the researcher will first complete some questionnaires:

* The first questionnaire asks some basic questions about you, including questions about mental health diagnoses, and history of treatment for drug use.
* The second questionnaire asks some more specific questions about methamphetamine use disorder symptoms.
* The third one is about recent use of methamphetamine, as well as alcohol, tobacco, and other drugs.
* You will also be asked to provide contact details to allow us to do the follow-up phone interviews.
* The researcher will then ask you to fill in two other short questionnaires about cravings and dependence on methamphetamine.

Together, these questionnaires take approximately 30 minutes to complete.

*Computer tests*

After the questionnaires (or on a later day, depending on your schedule and how much you feel like doing in one day), we will need you to do two computer tests:

* The first involves rating 50 images related to methamphetamine to tell us how relevant these images are to your experience of methamphetamine use, and then rating 50 other “positive” images to tell us how relevant they are to your goals and interests.
* The second is a simple test to measure your “approach bias” and involves using a joystick to react to a series of images (some methamphetamine-related images, and some positive images) on a computer screen.

It will take about 20 minutes to complete both tests.

*Training tasks*

Following this, you will start the first “brain-training” session. You will have a 50% chance of being assigned to do ABM brain-training and a 50% chance of doing a similar “placebo” training task that may influence attention, but which is not designed to change approach bias. This type of study is called a ‘randomised controlled trial’, which means you will be randomly put in one of these two groups. This is so we can compare the results of people who do ABM (the ABM group) to the results of people who do the other training task (the control group).

The computer will automatically (randomly) assign you to either the ABM group or the control group. The researcher will have no influence over which group you are assigned to, and will not be able to tell you which group you have been assigned to. You will also not know which group you have been assigned to. This is so your response to the training isn’t influenced by knowing which group you’re in.

The training session takes about 15 minutes. It involves responding to methamphetamine-related pictures and positive pictures on a computer screen by using a joystick to move them. We would like you to complete 3 sessions of training each week for 2 weeks (i.e., 6 sessions total). To do this, a researcher will come once every 2 or 3 days to do a 15-minute training session with you, until 6 sessions have been completed.

Before and after each training session, the researcher will ask you to answer a short question about your methamphetamine cravings. After the last session of training, you will also be asked to complete the questionnaire about methamphetamine cravings and the computer test of approach bias for a second time, along with another short questionnaire about your impressions of the brain-training task.

After you leave [SITE], the researcher will obtain additional information about you from your health and medication records held at [SITE]. This includes information about medical diagnoses from your clinical admission assessment and about the medications you were prescribed while you were at [SITE]. By signing the consent form you agree to the study team accessing only those health records that are directly relevant to your participation in this research project.

*Follow-ups*

Once you leave [SITE] you will be asked to participate in two phone interviews that will take approximately 20 minutes each. This will be done by a different researcher than the ones who did the training. The follow-up researcher will not know whether you were in the ABM group or the control group. This is to avoid them being biased by knowing what group you were in.

The first follow-up phone call will be 4 weeks after you leave [SITE], and the second will be 3 months after you leave. Each follow-up will include:

* A questionnaire about methamphetamine and other drug use
* A questionnaire about methamphetamine cravings.
* Questionnaires about methamphetamine dependence symptoms.

To help us accurately measure the effects of the ABM training, we ask that you complete the follow-up phone interviews. It is really important that we find out whether or not the brain-training helped people who did it, so we know whether it could help many other people undergoing treatment for methamphetamine problems. As such we would like you to do the follow-up phone calls regardless of whether you remain abstinent or use methamphetamine again. We will not tell anyone outside of the research team whether you have remained abstinent or have started using methamphetamine again.

We have included a table below to summarise what the research project involves for you:

|  |  |  |  |
| --- | --- | --- | --- |
| **When** | **Type of session** | **What’s involved** | **How long it takes** |
| About 1 week after you start residential treatment at [SITE] | First questionnaire session | Completing consent form; Questionnaires about demographics, drug use, and cravings; collecting contact details | 30 minutes |
| Second week of residential treatment at [SITE] | First brain-training session | Picture rating; approach bias test; brain-training | 35 minutes |
| Second brain-training session | brain-training | 15 minutes |
| Third brain-training session | brain-training | 15 minutes |
| Third week of residential treatment at [SITE] | Fourth brain-training session | brain-training | 15 minutes |
| Fifth brain-training session | brain-training | 15 minutes |
| Sixth brain-training session | brain-training; approach bias test; craving questionnaire; rating the brain-training; Receive $60 gift card | 30 minutes |
| 4 weeks after you leave [SITE] | 4-week follow-up | Questionnaires over the phone about drug use, cravings, and dependence; we send a $20 gift card | 20 minutes |
| 3 months after you leave [SITE] | 3-month follow-up | Questionnaires over the phone about drug use, cravings, and dependence; we send a $20 gift card | 20 minutes |

*Reimbursement*

There are no additional costs to you associated with participating in this research project. You will be given a $60 supermarket gift card if you complete the brain-training, and we will send you a $20 gift card each time you complete a telephone follow-up. Therefore, you can receive a total of $100 worth of gift cards if you complete the brain-training and both follow-ups.

**4 What happens when the research project ends?**

We will not offer continuing brain-training to you after you have completed the 6 sessions that are part of this project. Once we have finished the study, we will publish a summary of our results on the Turning Point website, written in non-technical language. No individuals will be identified in any reporting of this study.

We will be recruiting participants for this study for up to a year, so we may not complete data collection and analysis until over a year after you finish participating. Therefore the summary of our results may not be available for more than a year from now. The results of this research will also be used by the researchers to publish research papers about our findings in scientific and clinical journals and conferences.

**5 Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to participate, but then change your mind later, you are free to withdraw at any time prior to the analysis of the data.

If you decide to withdraw while you are still in rehab, please notify any of the researchers involved in running the brain-training sessions here. You can also tell the treatment staff at [SITE] and they can help you withdraw. If you do withdraw, please complete and sign a ‘Withdrawal of Consent’ form; this will be provided to you by the research team. If you decide to withdraw after leaving rehab (i.e., if you don’t want to participate in further follow-ups), you can contact the research team to let them know, using the contact details at the end of this form.

After you withdraw, the researchers will not collect additional personal information from you. However, personal information already collected before you withdrew will be retained and will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

Your decision whether to take part or not will not affect your relationship with the service providing your residential rehabilitation treatment, or any other aspect of your treatment here. Nor will it affect any relationship you have either now, or in the future, with any of the other institutions conducting this research (Eastern Health, Monash University, SHARC, Malvern Private Hospital, Albert Road Clinic, or the University of Melbourne). If you decide to participate, but then decide to withdraw later, that also has no impact on these relationships or treatment.

**6 What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research because we don’t know yet whether ABM is effective for treating methamphetamine use. However, if the ABM brain-training turns out to be effective, participating might help you to stop using methamphetamine (depending on which group you are in). Your participation in the study will help determine whether or not the brain-training should be made available in the future to others wanting to reduce or stop using methamphetamine.

**7 What are the possible risks and disadvantages of taking part?**

The computer tests and the training task involve viewing images of methamphetamine and objects related to methamphetamine use (like glass pipes and needles). The questionnaires include questions about methamphetamine cravings, mental health, and use of methamphetamine, alcohol, and other drugs. Sometimes people find these tests or questionnaires upsetting, or find that they trigger craving for methamphetamine. We believe this risk is small, but if you feel distressed or experience increased cravings, please let the researcher know if you would like them to seek support for you from [SITE] staff. Remember that you can also leave the study at any time.

**8 Could this research project be stopped unexpectedly?**

Although unlikely, this research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as the rehabilitation service closing or equipment breaking.

**Part 2 How is the research project being conducted?**

**9 What will happen to information about me?**

By signing the consent form you consent to the research team collecting and using personal information about you only for this research project. Any information obtained in connection with this research project that can identify you will remain confidential. Only the researchers involved in the project will have access to the data provided by you during the research project. It will not be disclosed without your permission, except as required by law. A serious and imminent threat to harm yourself or others may be subject to reporting to a third person. Any information concerning the protective safety of children is subject to reporting to relevant authorities.

If you decide to participate in this study, you will be assigned a participant number. All questionnaires and other paper and electronic files containing your data will be labeled with this number. We will not label these questionnaires or files with your name or other information which could directly identify you.

A document detailing which number corresponds with your name, and any other details that could identify you, will be kept separate from the rest of the data on a password-protected computer hard drive accessible only to researchers directly involved in this study. This “re-identification” document will be deleted 2 years after the conclusion of this study to protect your confidentiality. However the data (which will not contain any identifying information) may be used in other analyses not described in this information sheet, and may be combined with data from other studies for this purpose. If we decide to do this, we will seek approval from the Eastern Health Human Research Ethics Committee before doing so.

Public presentations about this research (e.g., in written reports and at conferences) will only include numerical data and statistical analyses. They will not include descriptions of any individual participant’s personal history or any other information which may identify you. Seven years after we finish publishing any findings arising from these data, the Principal Researcher or Turning Point management will dispose of all data by shredding paper records and deleting computer files (in accordance with Turning Point’s policy on data storage and management).

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. However, be aware that once the re-identification document has been destroyed, 2 years after the conclusion of the project, information collected about you may not be able to be identified. Access to information about you after this point may not be possible. Please inform the research team member named at the end of this document if you would like to access your information.

**10 What if I experience harm while participating in this project?**

Ifyou suffer any distress or psychological injury as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support from your treatment team at [SITE]. If you experience problems related to the project, or would like to make a complaint about any aspect of the project, see the contact details at the end of this information sheet.

**11 Who is organising and funding the research?**

This research has been initiated by the chief investigator, Associate Professor Victoria Manning. This research project is being conducted by Monash University, in cooperation with researchers from Turning Point, Self Help Addiction Resource Centre (SHARC), Malvern Private Hospital, Albert Road Clinic, and the University of Melbourne. Funding for this project has been provided by the National Centre for Clinical Research on Emerging Drugs (NCCRED).

**12 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). This research project has been approved by the HREC of Eastern Health. This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007) – Updated 2015. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**13 Who to contact for further information or to make a complaint**

The person you may need to contact will depend on the nature of your query:

* If you want any further information concerning this project, or if you have any problems which may be related to your involvement in the project, you may phone the lead principal investigator, A/Prof. Victoria Manning on (03) 8413 8724 or contact her by email at victoria.manning@monash.edu
* For complaints about the study, or the way it is being conducted, you may also contact the Eastern Health Human Research Ethics Committee on (03) 9895 3398 or email them at ethics@easternhealth.org.au

**Consent Form**

[SITE]

|  |  |
| --- | --- |
| **Title** | A pilot randomised controlled trial (RCT) of personalised approach bias modification for methamphetamine use disorder |
| **Short title** | Training the brain to avoid methamphetamine |
| **Protocol Number** | 1 |
| **Project Sponsor** | National Centre for Clinical Research on Emerging Drugs (NCCRED) |
| **Coordinating Principal Investigator** | A/Prof Victoria Manning |

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand. I understand the purposes, procedures and risks of the research described in the project. I have had an opportunity to ask questions and I am satisfied with the answers I have received. I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future care. I understand that I will be given a signed copy of this document to keep.

|  |
| --- |
|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
|  |

**Optional**: I also give my consent for members of the research team to contact me for up to 2 years after this project ends about any additional research that I may be eligible to participate in. I understand that I do not have to agree to this to take part in the current project, and that I have no obligation to participate in any future studies that I am contacted about if I do agree to be contacted.

🞎**yes** 🞎 **no**

**Declaration by Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

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|  |
|  | Name of Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

**Form for Withdrawal of Participation**

[SITE]

|  |  |
| --- | --- |
| **Title** | Can novel computerised brain training reduce relapse among methamphetamine users? |
| **Short title** | Training the brain to avoid methamphetamine |
| **Protocol Number** | 1 |
| **Project Sponsor** | Eastern Health  |
| **Coordinating Principal Investigator** | A/Prof Victoria Manning |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine care, or any other aspects of my relationships with the organisations running this study.

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| --- |
|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
|  |

In the event that the participant’s decision to withdraw is communicated verbally, a researcher must provide a description of the circumstances below.

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**Declaration by Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

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| --- |
|  |
|  | Name of Researcher (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

† An appropriately qualified member of the research team must provide information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.