

**Participant Information Sheet/Consent Form**

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

De Paul House

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| **Title** | Can novel computerised brain training reduce relapse among methamphetamine users? |
| **Short title** | Brain training for methamphetamine dependence |
| **Protocol Number** | SVHM 4 |
| **Project Sponsor** | Eastern Health |
| **Principal Investigator** | Dr. Victoria Manning |

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

**1 Introduction**

You are invited to take part in this research project, which is called ‘*Can novel computerised brain training reduce relapse among methamphetamine users?’* You have been invited because you are undergoing inpatient withdrawal for methamphetamine use (detox) at De Paul House. The research project looks at whether computerised “brain-training” programs designed to change *approach bias* can help people increase their abstinence from methamphetamines. *Approach bias* is a psychological term. It refers to our tendency to move towards things that we find attractive.

We hope that using computer task that’s meant to help reduce approach bias towards methamphetamine will make it easier for people to resist the temptation to use methamphetamine after they leave detox. This Participant Information Sheet tells you about the research project. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. 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 a relative, friend or local health worker.

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

• Understand what you have read

• Consent to take part in the research project

• Consent to be involved in the research 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?**

Recent research suggests that a training task called “cognitive bias modification” (CBM), that is meant to reduce approach bias, can help people who are trying to stop drinking alcohol to avoid relapse. However, no-one has tested whether CBM works for people who are trying to stop using methamphetamine. This project has three aims:

1. We don’t know whether this approach is practical, so we want to see if most patients can complete the CBM training before they leave detox.

2. We don’t know whether patients will find the CBM training task acceptable (i.e. enjoyable or interesting), so we want to find out by asking patients who complete the training.

3. We don’t know if this approach will help reduce risk of relapse after leaving detox, so we want to see how many people remain abstinent after doing the “brain-training”.

If our results suggest that the CBM training intervention is practical, acceptable, and effective, this may lead to it being a widely used intervention for people with substance use disorders. This study is being funded by the Eastern Health Foundation. The results of this research will be used by Turning Point in the publication of a research paper. This research has been initiated by the researcher, Dr. Victoria Manning, Principal Researcher, and is being conducted by researchers from St. Vincent’s Hospital Melbourne, Eastern Health, Monash University, and Deakin University.

**3 What does participation in this research involve?**

If you consent to participate in the research, the researcher will first do three short questionnaires to get some information about you and confirm that you are eligible to participate. The first questionnaire asks some basic questions about you, including questions about your current living situation, mental health diagnoses, and history of treatment. 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, other drugs, and medications. The researcher will then ask you to complete two other short questionnaires about cravings and dependence on methamphetamine. They will also ask you to do a short test of thinking ability. Together, these questionnaires and tests are likely to take approximately 15 minutes.

You will then be asked to complete a 5-minute computer game that measures your tendency to take risks. Following this, you will start the CBM training session. This takes about 15 minutes, and involves responding to pictures on a computer screen, some of which will be methamphetamine related, by using a joystick to move them. You will repeat the training once per day for each of the next 3 days (i.e. on 4 consecutive days in total). Before and after each training session, the researcher will ask you to answer a short question about your methamphetamine cravings.

On the 4th day, after the last session of training, you will also be asked to complete the questionnaire about methamphetamine cravings and the computer game that tests risk-taking for a second time, along with another short questionnaire about your impressions of the training task. You will also be asked to provide contact details to allow us to do the follow-up phone interviews. After you leave De Paul House, the researcher will also obtain records about your medical history from your clinical intake interview and about the medications you were prescribed while you were at De Paul House.

Once you leave De Paul House you will be asked to participate in two phone interviews that will take approximately 10 minutes each. They will be conducted two weeks and three months following your departure from De Paul House. Each follow-up will include questionnaires about methamphetamine, alcohol, tobacco, medication, and other drug use, and methamphetamine cravings.

Participation in the follow-up interviews is voluntary. However, to help us accurately measure the effects of the CBM training, we encourage you to complete the follow-up interviews regardless of whether you remain abstinent or return to using methamphetamine. We will not tell De Paul House, or any other people outside the research team whether you have remained abstinent or have started using methamphetamine again.

There are no additional costs to you associated with participating in this research project. You will be given a $30 supermarket gift card if you complete the dual training. We will mail you a $10 gift card each time you complete a telephone follow-up (you can receive a total of $50 for participation in all follow-up interviews).

**4 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. Even after giving consent, you are not required to answer any questions that you don’t want to. Your decision whether to take part or not will not affect your relationship with the service providing your inpatient withdrawal treatment. Nor will it affect any relationship you have either now, or in the future, with any of the other institutions conducting this research (St Vincent’s Hospital Melbourne, Eastern Health, Monash University, and Deakin University).

If you change your mind about taking part in the research you are free to withdraw at any time prior to the analysis of the data. If you decide to withdraw, please notify the researchers. Their details are at the end of this form. Otherwise, you can tell the clinical staff at De Paul House and they can help you withdraw. If you decide to withdraw from the research, this will not affect your relationship with your clinician or your treatment at De Paul House. Nor will it affect any relationship you have either now, or in the future, with any of the other institutions conducting this research.

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

We cannot guarantee or promise that you will receive any benefits from this research. However, possible benefits of participating in CBM training may include improving treatment outcomes for methamphetamine problems.

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

The CBM training tasks involve viewing images of methamphetamine and objects related to methamphetamine use. The questionnaires include questions about methamphetamine cravings and recent use of methamphetamine, alcohol, and other drugs. There is some risk that the tests or questionnaires may therefore be upsetting or increase craving for methamphetamine. We believe this risk is small, but if you feel distressed or experience increased cravings, please let the researcher know so they can provide support or arrange support from De Paul House staff. You can also leave the study at any time.

**7 What if I withdraw from this research project?**

If you decide to withdraw from the project, please notify a member of the research team. If you do withdraw, please complete and sign a ‘Withdrawal of Consent’ form; this will be provided to you by the research team. After you withdraw, the researchers will not collect additional personal information from you. However, personal information already collected before you withdrew will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw 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.

**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 service closing or equipment breaking.

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

After you leave De Paul House, you will be contacted two weeks and three months later to answer some follow up questions about methamphetamine and other drug use and methamphetamine cravings. Total duration of your involvement in the study is therefore 3 months. However, 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.

Once we have finished the study, we will make a summary report available on the Turning Point website. It will be written in non-technical language, and provide a summary of the key findings of the study. No individuals will be identified in any reporting of this study.

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

**10 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. 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.

Information collected from you will be de-identified. If you decide to participate in this study, you will be assigned a participant number and all questionnaires and other paper and electronic files containing your data will be labeled with this number, rather than your name or other information which could directly identify you. Only the researchers involved in the project will have access to any data provided by you during the research project. Researchers will obtain additional information about you from your health and medication records held at De Paul House for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

A document detailing which number corresponds with you, and any other details that could identify you, will be kept on a password-protected computer hard drive accessible only to researchers directly involved in this study. This document will be deleted at 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 St Vincent’s Hospital Melbourne Human Research Ethics Committee before doing so.

We intend to publish the findings of this study in scientific journals and to present the findings at scientific conferences. In any publication or presentation of this study, information will be provided in such a way that you cannot be identified. Publicly presented data will only include numerical data and statistical analyses. They will not include descriptions of your 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, you must be aware that once the re-identification document has been destroyed at the conclusion of the project, information collected about you may not be able to be identified. Access to information about you after this point will not be possible. Please inform the research team member named at the end of this document if you would like to access your information.

**11 Complaints and compensation**

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 treating team at De Paul House. If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact any of the researchers of this study. For complaints about the study, or the way it is being conducted, you may also contact the St. Vincent’s Hospital Melbourne Human Research Ethics Committee, which provides governance oversight for this study at De Paul House. Their contact details are provided at the end of this information sheet.

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

This research project is being conducted by St. Vincent’s Hospital Melbourne, Turning Point, Deakin University and Monash University, with funding provided by Eastern Health Foundation.

**13 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). The ethical aspects of this research project have been approved by the HREC of St. Vincent’s Hospital Melbourne. This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

**14 Further information and who to contact**

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, Dr. Victoria Manning on (03) 8413 8724 or contact her by email at victoriam@turningpoint.org.au

**Complaints:**

If you have any complaints about any aspect of the study or the way in which it is being conducted you may contact the Patient Liaison Officer at St Vincent’s Hospital (Melbourne) on Telephone: (03) 9231 3108. You will need to tell the Patient Liaison Officer the name of the person who is noted above as principal investigator.

**Research Participant Rights:**

If you have any questions about your rights as a research participant, then you may contact the Executive Officer, Research at St Vincent’s Hospital (Melbourne) on Telephone: (03) 9231 3930.



**Consent Form**

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| **Short title** | Brain training for methamphetamine dependence |
| **Protocol Number** | SVHM 4 |
| **Project Sponsor** | Eastern Health |
| **Principal investigator** | Dr. Victoria Manning |
| **Location** | De Paul House |

**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.

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

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**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 my relationships with the researchers or Turning Point.

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

In the event that the participant’s decision to withdraw is communicated verbally, the Senior 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.