**Participant Information Sheet/Consent Form**

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

|  |  |
| --- | --- |
| **Title** | A randomised controlled trial of cognitive bias modification training during early recovery from alcohol dependence |
| **Short title** | An RCT of CBM during alcohol withdrawal |
| **Protocol Number** | 4 |
| **Project Sponsor** | National Health and Medical Research Council |
| **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 ‘*A randomised controlled trial of cognitive bias modification training during early recovery from alcohol dependence’.* You have been invited because you are undergoing inpatient withdrawal for alcohol use disorder at [site].

The research project tests a computerised training program called “cognitive bias modification” (CBM), designed to change a person’s *approach bias*. *Approach bias* is a psychological term. It describes how people are more keen to move towards things they find attractive than they are to move towards other things. Many researchers believe that when people develop alcohol use disorders, they often develop a strong *approach bias* towards alcohol and other things (like images, people, and places) that are related to alcohol. This makes it more difficult to resist the urge to approach alcohol. CBM is meant to reduce approach bias towards images of alcohol, in the hopes that this will help participants avoid drinking once they leave [site].

This participant information sheet tells you about the research project and explains what it would involve for you if you decide to take part. Knowing this will help you decide whether or not you want to participate in the research. Please read this information carefully. Ask questions about anything you don’t understand or that you 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 health care 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, you will be asked to sign the consent form. By signing the consent form, you are saying that you:

* Understand what you have read.
* Consent to take part in the research.
* Consent to the use of your personal and health information as described later in this information sheet.

You will be given a copy of the participant information sheet and consent form to keep.

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

The aims of this research are:

(1) To determine if Cognitive Bias Modification (CBM) reduces drinking after leaving detoxification. Previous studies have found that CBM increases people’s chances of staying abstinent from alcohol. However, most of these studies have tested CBM training in people who aren’t doing inpatient withdrawal, or who have already left treatment. We want to test whether giving a short course of CBM *while people are still in inpatient withdrawal* reduces their risk of relapse after they leave inpatient treatment. If this project finds that CBM is effective, this may lead to CBM being used widely for people with substance use disorders.

(2) To understand whether the strength of someone’s approach bias to alcohol cues before they start CBM affects how well CBM works. We want to see if CBM has stronger or weaker benefits depending on whether or not someone has strong approach bias in the first place. This will help us understand how CBM works and whether it works better for some kinds of people than for others.

(3) To test whether CBM helps the health system save money by reducing people’s need for later treatment. If CBM is effective at helping people cease or reduce their alcohol use, we think that people who receive CBM will be less likely to need repeated inpatient treatments for alcohol use and less likely to need acute health services, like ambulances or emergency departments. We want to find out how much people use these kinds of health services after receiving CBM, to see if CBM actually helps the health care system save money.

**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 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 alcohol use disorder symptoms. The third one is about recent use of alcohol, tobacco, drugs, and medications. If you are confirmed to be eligible, the researcher will then do two short questionnaires about alcohol cravings. Altogether, the questionnaires are likely to take around 25 minutes.

You will then do three computerised tests to measure your approach bias towards alcohol, your tendency to take risks, and to measure how attracted you are to pictures of alcoholic and non-alcoholic beverages. These tests involve reacting to images on the computer screen. These tests take about 15 minutes altogether.

Following this, you will start the first training session. You will have a 50% chance of being assigned to do CBM training and a 50% chance of doing a similar 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 two groups to ensure that both the CBM and control groups have similar characteristics. This is so we can compare the results of people who do CBM (the CBM group) to the results of people who don’t have training to change their approach bias (the control group).The computer will automatically (randomly) assign you to either the CBM 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 task takes approximately 15 minutes. It is like a simple computer game where you use a joystick to react to pictures that appear on the screen, according to instructions that will be provided to you. You will repeat the task once per day for each of the next 3 days (i.e. on 4 days in a row total). Before and after each training session, the researcher will ask you to answer a short question about your alcohol cravings. On days 2 and 3, the researcher will also ask you some additional short questionnaires. On day 2, they will ask you about your use of drug treatment and health services over the past year and on day 3 they will do a short questionnaire about alcohol dependence severity.

After you have finished the last training session on the 4th day, you will be asked to repeat the tests of approach bias, risk-taking, and attraction to pictures of beverages. The researcher will also repeat the questionnaires about alcohol cravings and ask you to complete 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 [site] 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 [site].

We will contact you over the phone to do follow-up questionnaires at 4 different time points: 2 weeks, 3 months, 6 months, and 12 months after you left [site]. Each follow-up will take approximately 15 minutes and will include questionnaires about alcohol, tobacco, medication, and drug use, alcohol cravings, and substance use treatment and health service use. This will be done by a different researcher than the one who did the CBM training.

The researcher who does the follow-up interviews will not know whether you were in the CBM group or the control group. This is to avoid them being biased by knowing what group you were in. Participation in the follow-up interviews is voluntary. However, to help us accurately measure the effects of CBM, we encourage you to complete the follow-up interviews regardless of whether you remain abstinent or return to drinking alcohol. We will not tell [site], or any other people outside the research team whether you have remained abstinent or have started drinking again.

There are no additional costs to you if you participate in this research project. You will be given a $30 supermarket gift card if you complete the CBM training. We will mail you a $10 gift card each time you complete a telephone follow-up. You can therefore receive a total of $70 if you complete 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 your clinician or your treatment at [site]. 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 [site] 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 [site]. 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 CBM training may include being less likely to relapse to drinking.

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

The computerised tests and training tasks involve viewing images of alcoholic beverages. The questionnaires include questions about alcohol cravings, alcohol problems, and recent use of alcohol and drugs. There is some risk that the tests or questionnaires may upset you or increase your craving for alcohol. 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 [site] staff. You are free to leave the research at any time if any questionnaires or tests are distressing to you.

**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 [site], you will be contacted two weeks, three months, six months, and 12 months later to answer some follow up questions about alcohol and other drug use, alcohol cravings, and health service use. Total duration of your involvement in the study is therefore 12 months. However, we will be recruiting participants for this study for up to 2 years, so we may not complete this project until several years 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 for the research project. Any information obtained for 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 reported to a third person. Any information about safety and protection of children is subject to reporting to relevant authorities.

Information collected from you will be *de-identified*. This means that you will be given a participant number and all questionnaires and other paper and electronic files containing your data will be labeled only with this number, not 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 medical records held at [site] only 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 participant number corresponds with your name and contact details will be kept on a password-protected computer hard drive accessible only to researchers directly involved in this study. This will be kept so we can contact you for the follow-up questionnaires. This document will be deleted at the end of this study to protect your confidentiality. However the questionnaire and test 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.

We intend to publish the findings of this study in scientific journals and to present the findings at scientific conferences. Publicly presented data will only include numerical data and statistical analyses about the whole group of participants. It will not include individual descriptions of your personal history or any other information which may identify you. Seven years after we finish publishing the study’s findings, 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**

If you suffer any distress or 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 [site]. 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 might also want to contact the St Vincent's Hospital Melbourne Human Research Ethics Committee. Their contact details are provided at the end of this information sheet.

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

This study is being funded by the Australian Government through the National Health and Medical Research Council (NHMRC). This research has been initiated by Dr. Victoria Manning. The research is being conducted by Monash University, Deakin University, Eastern Health, and St Vincent’s Hospital.

**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 St Vincent's Hospital Melbourne HREC.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 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) 9412 9951 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 St. Vincent’s Hospital Melbourne HREC by phoning (03) 9231 2394 or emailing research.ethics@svhm.org.au

**Research Participant Rights:**

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

**Consent Form**

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**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 with [site], St Vincent’s Hospital Melbourne, Eastern Health, Monash University, or Deakin University.

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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.