Participant Information Sheet

Ambulance Patient

Health/Social Science Research - *Adult providing own consent over the telephone*

Title	Improving access to care: a national ambulance approach to improve help-seeking and the mental health of men
Short Title	Beyond the Emergency
Protocol Number	HREC Ref 15/301
Project Sponsor	The Movember Foundation
Principal Investigators	Professor Dan Lubman Professor Terence McCann
Associate Investigator	Dr Michael Savic Ms Fiona Blee Ms Nyssa Ferguson Ms Kate Emond
Location	National

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project, which is called *Improving access to care: a national ambulance approach to improve help-seeking and the mental health of men*. You have been invited because you are a male aged 18 years or over who recently had contact with an ambulance service for a possible mental health issue.

This Participant Information Sheet/Consent Form tells you about the research project and 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, and ask questions about anything that you don't understand or want to know more about.

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 for verbal consent over the telephone. By consenting 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
• Consent for the telephone interview to be audio-recorded

2 What is the purpose of this research?

This project aims to: 1) better understand men's reasons for, and experiences of, accessing ambulance services for mental health issues; and 2) examine paramedics' attitudes, confidence, and experience of mental health presentations amongst males.

Men frequently experience mental health issues, but are often reluctant to seek professional help. The ambulance service is a key emergency service accessed by men across Australia, with around 1.2 million attendances to male patients annually. However, this contact does not necessarily result in ongoing mental health care.

You have been invited because you are a male aged 18 years or over who recently had contact with an ambulance service for a possible mental health issue. This could include symptoms of anxiety, depression or psychosis, concerns about alcohol or drug use, self-injury or suicidal thoughts/attempt. You do not have to be diagnosed with a mental health issue to participate.

The information obtained in this project will provide a more comprehensive understanding of men's mental health help-seeking behaviour, as well as the experiences and needs of paramedics in providing support to patients with mental health issues. In addition, it will inform the development of interventions and training to ensure paramedics can better link men into appropriate mental health care.

This research has been funded by The Movember Foundation's Australian Mental Health Initiative.

3 What does participation in this research involve?

Participation will involve a 60-minute (approximate) telephone interview about your recent experiences of using an ambulance service. You will be called on a nominated phone number at a time that suits you. You will be asked about your reasons for using ambulance services, what you thought of the care you received, and what kinds of services or initiatives you think might help people facing similar situations to seek help for mental health and related issues. The interview will be audio recorded.

You will be asked for verbal consent to participate in the research prior to the interview commencing.

You will be reimbursed $30 for your participation in the form of a supermarket voucher.

The research will be monitored primarily by an advisory group which consists of key experts and stakeholders who meet to monitor the progress of the research project and provide expert input on project design and dissemination. Furthermore, the Associate Investigators will hold regular meetings to provide a forum for interviewers to feed back any issues in relation to the conduct and progress of the project. The team also have established timelines and other project management practices to ensure ongoing monitoring of project progress.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way.

4 Other relevant information about the research project

We intend to recruit two groups of people to participate in this study. One group involves men who have presented to ambulance services with mental health issues. We intend to recruit 100 participants into this group. The other group consists of paramedics currently employed by a participating ambulance service. We intend to recruit 2000 paramedics to the on-line survey and 60 paramedics to the qualitative telephone interviews. Including interviews with 100 men who have presented to ambulance services, the total sample for the research project will be 2160.

Ambulance services from all Australian states and territories excluding Western Australia are participating in the study.

The advisory committee overseeing the project is made up of researchers and ambulance service workers from a number of organisations.

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 take part and later change your mind, you are free to withdraw from the project at any stage. Your choice to participate in the study or not will not affect any current or future care from ambulance services that you may need.

If you do decide to take part you will be directed to a Participant Information and Consent Form which you can read over and may ask any questions to clarify information. You will then be asked for verbal consent over the telephone.

6 What are the possible benefits of taking part?

We cannot guarantee that you will receive any benefits from this research. However this research will inform the development and implementation of training to paramedics, as well as a help-seeking resource for men experiencing mental health problems. It is hoped that this will lead to improvements to men's engagement with appropriate treatment services, and treatment outcomes. However, in this project, we will not be administering any treatments to you or changing any treatments that you are already receiving hence it is unlikely that you will receive any direct benefits from this research.

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

You may feel that some of the questions we ask are stressful or upsetting (for example, recalling experiences with mental health issues). Should you become distressed you will be given the option to receive a phone call from experienced psychiatrist Professor Dan Lubman. We will also provide the details of Lifeline's 24 Hour Crisis Support Service 13 11 14 which provides free 24-hour, 7-day counselling.

If you do not wish to answer a question, you may let us know and we will move to the next question. You may also stop your participation in this research immediately at any time you wish.

8 What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team. There are no requirements related to withdrawing from the project. If you do withdraw, you will be asked to complete and sign a 'Withdrawal of Consent' form; this will be provided to you by the research team.

If you decide to leave the research project, the researchers will not collect additional personal information from you and your contact details will be deleted from the database., Information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law, however this information will be de-identified. 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.

9 What happens when the research project ends?

The results of this project will be presented in reports and publications in the future and will be available from Turning Point (Eastern Health). You are welcome to contact the researcher at Turning Point (details listed below) if you would like information about the results.

Part 2 How is the research project being conducted?

10 What will happen to information about me?

The information you provide for this project will remain confidential. Research information is stored without your name on it and your anonymity is assured. After 7 years, all data will be disposed of through shredding of paper records and deletion of computer files by the Principal Researcher, or by Turning Point (Eastern Health) management.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that participants cannot be identified. For example, information presented will be the collected results for the whole group. If there is any information from a particular person that we report, for example a story or a way you describe your experience, we will not identify you but we will use a pseudonym (name that is not your real one).

Any information obtained for the purpose of this research project that can indentify you will be treated as confidential and securely stored. It will be disclosed only with your permission or as required by law, or where there may be an immediate risk of harm to yourself or others.

In accordance with relevant Australian and/or state/territory specific privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. 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 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 can contact the Eastern Health HREC on 99822470.

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). The ethical aspects of this research project have been approved by the Eastern Health HREC and relevant state, territory and ambulance service ethics committees.

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.

13 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 contact a researcher on the project:

Research contact person

Name	Ms Fiona Blee
Position	Trial manager and health promotion worker
Telephone	03 9412 9952
Email	Fiona.Blee@turningpoint.org.au

Consent Form (Ambulance Patient) –

Adult providing own consent over the telephone

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Location	*National*

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 give consent for the interview to be audio-recorded Yes ☐ No ☐

Name of Participant (please print)

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.

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 (Ambulance Patient) –

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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.

Name of Participant (please print)

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

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.

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.