



Patient Information Sheet

- Title of Study:** *Psychological Treatment for Alcohol-Related Liver Disease* (Metro South Health Research Support Scheme Project Grant)
- Study Address:** Alcohol and Drug Assessment Unit (ADAU)
Princess Alexandra Hospital
199 Ipswich Road; Woolloongabba, Brisbane, Queensland, 4102
- Researchers:** Jason Connor, PhD (Clinical Psychologist, ADAU), Paul Clark, MD (Hepatologists/Gastroenterologist), Dr Gerald Feeney, MD (Medical Director, ADAU), Matthew Gullo, PhD (Clinical Psychologist, ADAU), Gerald Holtman, MD (Director, Gastroenterology & Hepatology), Graeme MacDonald, MD (Hepatologists/Gastroenterologist), Jason Coates, PhD (Psychologist, ADAU).
- Telephone:** 07 31765191

1. Background

You are being invited to participate in this study because you are starting an alcohol abstinence program at the Alcohol and Drug Assessment Unit (ADAU), Princess Alexandra Hospital. This program is effective in treating alcohol problems.

We have recently updated this program, based on recent research, to better suit the needs of patients with Alcohol-Related Liver Disease and Alcoholic Hepatitis. The new program is more flexible options (for example we can do telephone consultations with patients who live far away) and it is structured to better suit the challenges of liver disease. To ensure patients are responding better to the new program we are conducting a study comparing the results of the new program against the old one.

In addition, we are using this opportunity to better understand the genetic factors which contribute to Alcohol-Related Liver Disease. Based on recent research we suspect a gene called PNPLA3 is related to Alcohol-Related Liver Disease. This study aims to test this finding. By better understanding how an individual's genetic make-up contributes to Alcohol-Related Liver Disease and treatment of alcohol problems we may be able to improve future treatments.

2. What happens if I decide to participate?

If you decide to be a part of this study you are allowing us to include your treatment outcomes in a dataset which we will compare to patients treated in the past.

If you would like to be involved in the genetic study, you will be invited to provide a small amount of saliva ('spit') for genetic testing. We can obtain DNA from your spit sample. DNA is the chemical structure that carries your genetic information. This is what makes you different from everyone else (for example, eye and hair colour). The DNA will be used to look at new genes that may be related to alcohol problems and treatment outcomes. This information may improve future treatment for alcohol problems. The collection of the DNA sample is painless. It involves spitting into a container. Participation is completely voluntary. Regardless of if you wish to provide a saliva sample or not, you will still be enrolled in the ADAU alcohol abstinence program.

3. What will happen to my data?

We expect the study to last two years. Your assessment and questionnaire data will be used in treatment. As is standard clinical practice, it will be kept in a locked filing cabinet and in a password protected computer

program for seven years after the study is completed. To make sure your information is confidential no identifying information (like your name) will be included in the dataset and it will only be seen by people involved in this research.

If you agree to provide a saliva sample, it will be de-identified (no names on it). This means that it will be impossible for any person outside ADAU to ever individually link genetic data with your name. Saliva will be sent to the Australian Genome Research Facility for analysis and frozen at the Queensland University of Technology for seven years after the study. It will then be completely destroyed.

As is standard practice, your results from the assessments and questionnaires you complete as part of the alcohol abstinence program can be provided to you. You will not receive results from the genetic tests as this information is for research purposes only. It currently does not provide any good clinical information about your treatment.

4. Do I have to take part in this research project?

You do not have to participate in this study- (it is completely voluntary). If you agree to take part but change your mind at a later time you are free to withdraw your consent. Regardless of your decision to take part or not to take part, or even drop out, you will be treated the same by ADAU.

You will be asked to agree (or not) to three things. The attached “Consent Form” explains these options as well.

Part 1. You will be asked if you will allow your treatment outcomes to be compared to those of patients treated in the past.

Part 2. You will be asked if you want to donate DNA (by spitting in a container) so we can look at possible genetic reasons for alcohol problems, alcohol-related liver disease, and responses to treatment for alcohol problems.

Part 3. You will also be asked if we can store your de-identified (no names) DNA for up to 15 years after study completion. Science is changing very quickly and it is likely that new genes may be discovered in the future that may help in the treatment of alcohol problems. We will ask for ethical approval if we want to look at any new genes. After the 15 years, your sample will be completely destroyed.

You may agree to all of these options, or only one.

5. What are the possible risks and benefits?

There may be no immediate benefit to you for being in this study. At this stage we are unsure if our new program is better than our usual treatment. We would not expect it to worse, but it could be. We believe there are no risks for you in this study beyond what you would normally experience with our standard treatment. There are no immediate clinical benefits to you if agree to donate DNA. However, it will give researchers more information to eventually get a better understanding of the how a person’s genetic differences make them vulnerable to alcohol-related problems.

6. What will happen to information about me?

Any information obtained in this research that can identify you is confidential. At the end of the 24-month study, your data will be de-identified so it is impossible to link your information and your name. This means if any material is published in scientific books, it will never be able to identify you. Clinical information already collected by ADAU will remain there as usual.

7. Is this research project approved?

This study has been reviewed and approved by the Hospital’s Ethics Committee. If you wish to discuss this with someone not directly involved in the study- for example questions on your rights as a patient, or if you have a complaint- please contact the Hospital Ethics Manager on (07) 3443 8049.

If you want further information concerning this project or if you have any problems which may be related to your involvement in the project (for example, feelings of distress), you can contact Jason Coates on 07 31765191



Consent Form

Title of Study: *Psychological Treatment for Alcoholic Hepatitis* (Metro South Health Research Support Scheme Project Grant)

Study Address: Alcohol and Drug Assessment Unit (ADAU)
Princess Alexandra Hospital
199 Ipswich Road; Woolloongabba, Brisbane, Queensland, 4102

Researchers: Jason Connor, PhD (Clinical Psychologist, ADAU), Paul Clark, MD (Hepatologists/Gastroenterologist), Dr Gerald Feeney, MD (Medical Director, ADAU), Matthew Gullo, PhD (Clinical Psychologist, ADAU), Gerald Holtman, MD (Director, Gastroenterology & Hepatology), Graeme MacDonald, MD (Hepatologists/Gastroenterologist), Jason Coates, PhD (Psychologist, ADAU).

Telephone: 07 31765191

I have read and I understand the *Psychological Treatment for Alcoholic Hepatitis* Information Sheet (or it has been read to me).

This study has been explained to me and I have had an opportunity to ask questions. I am happy with the answers I have been given.

I freely agree to be involved in this study as described in the Participant Information Sheet. I give my permission to (please tick):

Part 1. Participate in a study which allows my information from this updated treatment protocol to be compared to patients treated in the past.

YES NO

Part 2. Provide a saliva ('spit') sample to look at genes that may be responsible for alcohol-related problems.

YES NO

Part 3. Store my de-identified (no names that can link information) DNA for up to 15 years after the study so future genetic research may be conducted following appropriate ethical approval by the Hospital.

YES NO

After all the below signatures have been provided, I will receive a copy of all these pages of the document for my records.

Patient's Name

Signature of Patient

Date

Declaration by researcher: I have given a verbal explanation of the research project, its procedures and risks and I believe that the patient has understood that explanation.

Printed Name of Researcher/ADAU Clinical Staff

Signature of Researcher

Date



Withdrawal of Consent

Title of Study: *Psychological Treatment for Alcoholic Hepatitis* (National Health and Medical Research Council of Australia Grant)

Study Address: Alcohol and Drug Assessment Unit (ADAU)
Princess Alexandra Hospital
199 Ipswich Road; Woolloongabba, Brisbane, Queensland, 4102

Researchers: Jason Connor, PhD (Clinical Psychologist, ADAU), Paul Clark, MD (Hepatologists/Gastroenterologist), Dr Gerald Feeney, MD (Medical Director, ADAU), Matthew Gullo, PhD (Clinical Psychologist, ADAU), Gerald Holtman, MD (Director, Gastroenterology & Hepatology), Graeme MacDonald, MD (Hepatologists/Gastroenterologist), Jason Coates, PhD (Psychologist, ADAU).

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I would like to WITHDRAW my consent (agreement) to be involved in the research described above. I understand that my withdrawal WILL NOT have any impact on future treatment or any relationship I have with the ADAU or with other staff members from the Princess Alexandra Hospital.

Patient's Signature:..... **Date:**.....

Print Name:

Please return this withdrawal form to:

Jason Coates, PhD, MPsych(Clin), MAPS
Psychologist
Alcohol and Drug Assessment Unit (ADAU)
Princess Alexandra Hospital
199 Ipswich Road; Woolloongabba, Brisbane, Queensland, 4102