

**Assessing the impact and effectiveness of
alcohol care teams (ACTs) targeting adults with alcohol dependence
admitted to NHS Hospitals in England**

The ProACTIVE Prospective Patient Study



Participant Information Sheet

We would like to invite you to take part in a research study which is evaluating alcohol care teams in England. The organisation responsible for this research (the “Sponsor”) is the University of Hull. Alcohol care teams provide specialist care for people with alcohol-related problems who attend accident and emergency or have been admitted as an inpatient to hospital. We hope this research will help to improve the future care of people with alcohol-related difficulties when they attend hospital.

It is entirely up to you whether or not you decide to take part. Before you decide, we would like you to understand why the research is being done and what it would involve for you. One of our team will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. Please feel free to talk to others about the study if you wish.

The first part of the Participant Information Sheet tells you the purpose of the study and what will happen to you if you take part. Then we give you more detailed information about the organisation of the study.

What is the purpose of the study?

Not all hospitals have an alcohol care team, but they are becoming increasingly common. At the moment, there is limited evidence about the impact of alcohol care teams on the people who receive care from these teams. The purpose of this study is to find out whether people who receive care in a hospital with an alcohol care team differ from people who receive care in a hospital without an alcohol care team, in terms of their alcohol consumption, health, wellbeing, and use of services, six months after their admission to hospital.

To do this, we are working with three hospitals which have established alcohol care teams and three hospitals which do not have established alcohol care teams. We will compare the outcomes of people with alcohol-related problems who attended the hospitals with alcohol care teams to those who attended the hospitals with no alcohol care team. This will help to assess how effective alcohol care teams are in improving patient outcomes compared to hospitals without these teams and could lead to better care in future.

What will taking part involve?

If you decide to take part, a researcher will arrange a time to meet with you in a private area in the hospital in which you are currently an inpatient. During the first part of this meeting, the researcher will go through this information sheet with you and answer any remaining questions you might have. If you are still happy to take part, you will be asked to sign a consent form.

***Checking you are eligible to take part***

We will first ask you some questions about the extent of your difficulties with alcohol. We are looking for people who experience specific types of problems with alcohol because these are the people that alcohol care teams aim to help. Following completion of this first questionnaire, you might be asked to continue and complete the remaining questionnaires, or you might be thanked for your time and not asked to continue. This questionnaire is just for research purposes. If you are not asked to continue, this will not impact your care at the hospital in any way.

If you are eligible to take part

We will ask you to complete a series of questionnaires with the researcher. These will include questions about you and your home environment, how much alcohol you have drunk on each day in the last month, problems associated with drinking alcohol that you might experience, how you have been feeling recently, and the health and social care services you have recently used. We have found that these questionnaires take around one hour to complete. You will be able to take as many breaks as you need during the meeting with the researcher.

Optional consent to access your medical records

In addition to completing the questionnaires with a researcher, you will be asked if you consent to us accessing your medical records to find out any other diagnoses you have been given during this hospital admission. It is up to you whether you consent for us to look at your medical records and you can still take part in this research without giving consent to this. If you do consent, we will only look at the records for your current admission.

***Follow-up interview***

We will invite you to take part in a follow-up interview around six months after you complete the first set of questionnaires in hospital. We will contact you around one month before your interview is due, to arrange a time for your follow-up interview. You can decide if this interview happens on the telephone, via video call or in person. During this interview we will repeat the same questionnaires but will focus on your more recent experiences.

What are the benefits of taking part?

There may not be any direct benefits of taking part for you, but we hope that this research will help us find out whether alcohol care teams have an impact on the lives of people with alcohol-related problems that are admitted to hospital. We hope that this information will help policy makers decide how best to support people with alcohol-related difficulties admitted to hospital and will improve people's care in the future.

What are the disadvantages and risks of taking part?

Some people may find talking about their feelings, experiences and past or current drinking upsetting. You will not have to answer any questions that you do not want to answer and if you become upset, you will be able to take a break or stop the interview completely.

You may find answering the questions tiring. You can take as many breaks as you need during the research interviews and, if you need to, you will have the option to finish answering the questions at another time.

There are contact details on the last page of this information sheet of organisations you can contact for support.

How will we contact you for your follow-up interview?

If you decide to take part, we will ask you for your contact details. This could be your telephone number, email address and/or your address. We will use these contact details to get in touch with you about your follow-up interview. If your contact details change, you can contact us with your new information at: ProACTIVE@hull.ac.uk or on 01482 463297. In case your contact details change, and you have not had the chance to let us know, you can also provide the contact details of a friend or family member that we can contact if we are unable to reach you with the details you provided to us. This is completely optional, and you are able to take part in this research without providing a friend or family member's contact details. If you do wish to provide these details, we ask that you let this person know that you have done so.

Why am I being invited to take part?

You are being invited to take part because you are currently an inpatient in one of the hospitals taking part in this research. A member of your clinical team has identified that you may be eligible to take part.

Can I take part in similar research studies?

This research project is part of a large programme of research looking at many aspects of alcohol care teams. If you take part in this study, you will be asked if you are happy to be contacted about other related research studies. It is up to you whether or not you consent to this. If you do consent, we may use the contact details you have provided to us to contact you about related research projects.

Will my expenses be covered?

We will reimburse any extra travel expenses that you have to pay in order to take part in the follow-up interview for this research. In addition, you will receive a £10 voucher at the end of your follow-up interview to thank you for your participation in this research study.

What will happen if I don't want to carry on with the study?

If you decide not to take part, or if you decide to take part but then change your mind, this will not affect the care that you receive from the hospital or any other health or care service.

If you change your mind about taking part in the research before your interview, we will not contact you again. If you change your mind about taking part after your interview, we will use the information we have collected up to that point, and we will not contact you again.

Will my information be kept confidential?

Yes. Before you take part in the interview, you will need to sign an electronic consent form. You will then be allocated a unique identification number and this number will be used on the questionnaires and any other study documents. Only authorised researchers will know that this number links to you.

The University of Hull will manage the data collected about you using computer databases and file storage systems that comply with national data protection guidelines and security standards. The computers we use are encrypted. This means that if anyone found the computer, they would not be able to access details about you.

All information which is collected from you will be treated as strictly confidential and only members of the research team will have access



to it. This research is separate from your clinical care. No information that you share with the researcher will be shared with your clinical team unless you indicate that you or someone else is at serious risk of harm. When we speak with you for your follow-up interview, you may no longer be under the care of the hospital team; therefore we ask for your consent to contact your GP in case you indicate that you are at risk of harm. We will not contact your GP without informing you first.

What will happen to the results of this study?

The findings of this research will be written up in a report for policy makers, so they can make decisions about providing care for people with alcohol-related difficulties who are admitted to hospital. Results of the study will also be written up in articles for clinical and academic journals and the findings will be shared at conferences. The results will also be written up in a report for everyone that was involved in the study and will be available at <https://www.hull.ac.uk/work-with-us/research/institutes/health-trials/study/proactive>. All of the responses to the questionnaires will be combined and you will not be identifiable in any of the outputs from this study.

Who is organising and funding this study?

This research has been funded by the National Institute for Health Research and is supported by the University of Hull.

How have patients and the public been involved in this study?

A plan of how this study will be conducted has been reviewed by the Patient and Public Involvement Coordinator for the ProACTIVE study. This participant information sheet was reviewed by ProACTIVE Public Advisory Group and recommended changes were considered and changed where possible to make this document clearer. The

ProACTIVE Public Advisory Group is a group of people with lived experience of problematic relationships with alcohol who advise on this research project aiming to make it better for people who take part.

What if any issues arise?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this via the Chief Investigator, Professor Thomas Phillips or the NHS Patient Advice and Liaison Service (PALS) (details are given below).

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Hull or <enter site NHS Trust>, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Who has reviewed this study?

This study has been reviewed by the London - Hampstead Research Ethics Committee and received a favourable opinion.

Further information and contact details

For further information or to take part, please contact <local researcher> on: Telephone: XXXXX XXXXXX, Email: XXXXX@XXXXXX

If you are unhappy with any aspect of the study and the researcher is unable to help, please contact:

- Professor Thomas Phillips (Chief Investigator): ProACTIVE@hull.ac.uk
- The University of Hull (Sponsor of this research): coo@hull.ac.uk
- Patient Advice and Liaison Service: <Local PALS>

SECTION 2 – GENERAL DATA PROTECTION REGULATION (GDPR) 2018

GDPR stands for the General Data Protection Regulation. In the UK we follow the GDPR rules and have a law called the Data Protection Act. All research using patient data must follow UK laws and rules.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your:

- Name
- Contact details
- Postcode
- Name and contact details of one or more friends or family members (optional)
- Age
- Gender
- Ethnicity
- Medical records (where you have given consent)

If you consent to us looking at your medical records for this admission, we will also collect your NHS number to ensure we are looking at the correct person and details of other diagnosed conditions.

People will use this information to do the research or to check your research records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. Data will be stored for ten years in line with the University of Hull's guidelines. We will write our reports in a way that no one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason. If you stop being part of the study, we will retain any data about you that we have already collected.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where are your data stored?

Your personal data will be processed and stored by the HHTU using REDCap Cloud and BOX.com. It will only be accessible by authorised staff and study researchers. Data will be collected using REDCap Cloud.

Further information about how we use your information and how it is stored can be found on the ProACTIVE Prospective Patient Study privacy notice here:

<https://www.hull.ac.uk/work-with-us/research/institutes/health-trials/study/proactive> or by contacting the ProACTIVE study team via ProACTIVE@hull.ac.uk

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- or leaflet available from www.hra.nhs.uk/patientdataandresearch

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- by asking one of the research team
- by contacting the University's data protection officer at data.protection@hull.ac.uk
- by ringing us on 01482 463297.

Places where you can access support:

Below are the details of some local and national services that can offer you guidance and support if you need help with your drinking or your mental health.

HELP FOR ALCOHOL PROBLEMS

Local services:

<Local services to be added by research sites>

National services:

Drinkline: A free, confidential helpline for people who are concerned about their drinking, or someone else's. Call 0300 123 1110 (weekdays 9am–8pm, weekends 11am–4pm)

Alcoholics Anonymous: Their helpline is open 24/7 on 0800 9177 650. If you would prefer, you can also email them at help@aamail.org or live chat via their website at www.alcoholics-anonymous.org.uk.

SMART: You can join a SMART Recovery meeting online here: <https://smartrecovery.org.uk/online-meetings/> SMART holds both face-to-face and online meetings which support people in managing problematic addictive behaviour. The SMART Recovery Programme has women's only meetings and those specifically for members of the LGBTQ+ community.

HELP FOR MENTAL HEALTH

Local services:

<Local services to be added by research sites>

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National services:

Samaritans: To talk about anything that is upsetting you, you can contact Samaritans 24 hours a day, 365 days a year. You can call 116 123 (free from any phone), email jo@samaritans.org or visit some branches in person: <https://www.samaritans.org/branches/>

Mind: Provide information, support, local support services <https://www.mind.org.uk/about-us/local-minds/>, they have an information line; 0300 123 3393 (9am-6pm Monday to Friday)

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Information for locator:

Your friend or family member has consented to take part in a research study called ProACTIVE. This study involves the research team contacting your friend or family member six months after the first meeting. They have provided us with your contact details in case we are unable to contact them.

We will hold your details securely at the University of Hull and only authorised researchers will have access to them. If you do not wish us to hold these details or to contact you, please contact us at XXXXX or ProACTIVE@hull.ac.uk

Thank you,

Prof Tom Phillips, University of Hull.