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King's College Hospital NHS
NHS Foundation Trust

KING'S College LONDON

PARTICIPANT INFORMATION SHEET

Assertive outreach treatment for alcohol related frequent attenders: a randomised controlled trial

Invitation to take part in a research project

Thank you for taking time to read this information. We would like to invite you to take part in our research study funded by Guy's and St. Thomas' Charity and the National Institute for Health Research, and is led by King's College London.

Before you decide to take part we would like you to understand why the research is being done and what it would involve for you. Please take the time to read this information carefully and discuss it with your friends, relatives or your GP. Deciding not to take part will not affect your healthcare. Please ask if anything is not clear or if you would like any further information.

Why are we doing this research?

It has been found that people who have frequent hospital admissions because of alcohol related problems have varied and complex problems related to their drinking and wider social and medical circumstances. For example physical and mental illness, social isolation, unstable housing or homelessness and unemployment. We want to see if a new approach called Assertive Outreach Treatment (AOT) is preferred by clients, if it increases engagement with services and if it helps to address both drinking and other problems. To do this we are asking 200 people to take part in this study to compare experiences of people who get usual support for their alcohol drinking with those who attend an assertive outreach service.

Key features that make AOT different from the usual support that is offered to people with drinking problems includes:

1) Having a range of professionals within the team so most of the client's care needs (alcohol dependence, other drug use, mental health and physical health problems) can be met within the team instead of being referred to external agencies. A dedicated care co-ordinator arranges all of the client's care which clients may find more convenient and effective.
2) The content of sessions to be client led. For example, instead of focussing on alcohol drinking, if the client prefers, support can be given with physical and mental health, housing issues, leisure, and seeking employment/education.
3) The majority of appointments are held in a location chosen by the client, which may be at home or in their local neighbourhood, instead of in clinics.
4) 'Assertive engagement'- the team will make several attempts to keep in contact with the client. This may be by making phone calls, sending text messages or visiting the client's home address.

5) Frequent and regular contact with the client- usually at least once a week. This is possible because the clinician has a much smaller caseload (maximum of 15 clients) compared to traditional alcohol services.
6) Extended care- AOT is provided over a period of up to 1 year.

Why have I been invited to take part?

All clients who have been admitted to hospital three or more times in the last year, with at least one alcohol-related admission, are being asked if they would like to take part in this research. It is entirely your decision if you would like to take part in this study.

Do I have to take part?

No, you do not have to take part, taking part is completely voluntary. Deciding not to take part will not affect your healthcare. If you do take part you are free to withdraw at any time without giving a reason.

What will taking part involve?

If you are happy to participate, one of the researchers would like to meet you. This would involve going over the study details again, and asking you to sign a consent form to show you have agreed to take part. This meeting will take approximately 1 hour and you will be given £10 to thank you for participating. At this meeting you will be asked some questions about:

- Your alcohol drinking (including how much and how often you drink, and problems you may have experienced because of your alcohol use)
- Any drug use
- Use of health and social services
- Quality of life

After this meeting you will be placed at random by a computer system into one of two groups. The clinical team would make contact with you to let you know what group you are in, and to discuss the next steps. You will have an equal chance of being in either of the groups. The groups are:

1. **Assertive outreach treatment (AOT)**
   You will receive support from the assertive outreach team. This will involve regular contact with your care co-ordinator and support over 12 months. The appointments will take place in your preferred location (home, local neighbourhood or at the service). You will still receive your usual care from your specialist alcohol team and GP.

2. **Usual care**
   If you are placed in this group you will not receive assertive outreach treatment, but will continue to receive usual care provided from your specialist alcohol team and GP. If you are not engaged with a specialist alcohol team and would like their support we will help you identify a service appropriate for your needs and support you in contacting them.

Everyone will be invited to meet with a researcher after 6 months and 12 months to repeat the questionnaires used in the first appointment. These meetings will take approximately one hour and you will receive £10 to thank you for completing each meeting with the researcher. At the first appointment we will ask for the contact details of someone (family or friend) who we can contact to help us contact you for these follow up meetings if we are not able to contact you directly. It is important that you do not talk to the researcher about the treatment you have been receiving, this is to make sure what you tell them doesn't influence the way in which they complete the questionnaires. The researcher will remind you of this at the beginning of each follow-up meeting.

This method of investigating whether a new treatment is more effective than current treatment is called a randomised controlled trial. By everyone being randomised, and having an equal chance of being in the assertive outreach group or the usual care group, we are able to control for any other differences between groups. This allows us to compare experiences between both groups and have confidence in deciding whether the new approach improves outcomes for this group of patients.

As this trial is being carried out as part of a research team at King's College London, there may be other studies that take place in the future. If you are happy to be contacted by the research team about any potential upcoming studies, please sign the consent form.

What are the possible advantages of taking part?

We cannot promise that this study will help you, but you may receive assertive outreach treatment. The results of our research could also help to develop new treatments for people who are frequently admitted to hospital for alcohol related problems.

We do not expect there to be any disadvantages of participating in the study.

Will my participation be kept confidential?

Yes. What is said in the interview is regarded as strictly confidential and will be held securely until the research is finished. If you disclose any information that may result in you or anyone else being put at risk of harm we may have to inform the appropriate authorities. If this situation arises we will discuss all possible options for ourselves and you before deciding whether or not to take any action. The UK Data Protection Act 1998 will apply to all information gathered within the interviews and held on password-locked computer files and locked cabinets within King's College London. We will share some of the information you provide with the clinical AOT team, to help them in providing appropriate care and to avoid repeating some of the clinical assessment procedures. Information stored as part of the research will be protected by using a code number to identify data about you, and by keeping the list that links codes to people's identity locked separately from the trial data. No data will be able to be linked back to any individual taking part in the interview.

Please note that your GP will be told that you are taking part in this study. This is a standard procedure in clinical trials.

Who has reviewed the research?

The research has been reviewed and approved by a NHS Research Ethics Committee to ensure that participant's will not be negatively impacted by being involved in this research project.

What will happen with the results of the study?

The results of this research will be reported to Guy's and St. Thomas' Charity, and disseminated through publications in scientific journals and conferences. All data used will remain confidential and anonymous meaning there is no chance of you being identified by the study. The researcher will ask you at your first meeting if you would like a summary of the findings which we can send you when the study is finished.

Who should I contact for further information?

If you have any questions or require more information about this study, please contact me using the following details:

Stephanie Fincham-Campbell: stephanie.fincham-campbell@kcl.ac.uk
020 7848 0437

Jackie Dunne: jacklyn.dunne@kcl.ac.uk
020 7848 0717

Section of Alcohol Research, National Addiction Centre, Institute of Psychiatry, Psychology and Neuroscience, 4 Windsor Walk, London, SE5 8BB

What if something goes wrong?

In the event that something does go wrong and you are harmed during the research you may have grounds for legal action for compensation against King's College London and South London and Maudsley NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

If you wish to make a complaint about the conduct of the study you can contact King's College London using the details below for further advice and information:

Professor Colin Drummond (Principal Investigator)

Section of Alcohol Research, National Addiction Centre, Institute of Psychiatry, Psychology and Neuroscience, 4 Windsor Walk, London, SE5 8BB Tel: 020 7848 0449, Fax: 020 7848 0839

Thank you for reading this information sheet and for considering taking part in this research.