PARTICIPANT INFORMATION SHEET

PROP study

Agent for recovery: the opportunity for enhancing social inclusion afforded by prolonged release buprenorphine formulations

IRAS Ref Number: 305675

Study Researcher

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Supervised by Dr Andrew Radley

We're inviting you to take part in a research study

We would like to invite you to take part in this research study to investigate the effects of your opioid substitution therapy (OST) on your life.

Before you choose whether or not to take part, we want you to understand why we are doing the study and also what it will involve if you agree to take part. Please take time to read this information carefully. You can ask us any questions and, if you want, discuss it with others. We'll do our best to explain and give you any information you ask for. You don't have to decide straight away. A member of the research team will contact you about a week after you get this information to discuss it with you.

Why are we doing this study?

A new type of OST has become available. It doesn't need to be taken every day. Instead it is given weekly or monthly. We want to find out what effect this type of treatment has on people's lives, compared to the lives of people who take the daily therapy.

Why am I being invited?

We are inviting you to take part because you are taking OST and attending a Drug and Alcohol Recovery Service in Tayside so you may be suitable for the study. A total of 60 people in Tayside will be recruited to this study.

Do I have to take part?

No. It is up to you to decide. If you do choose to take part you can also stop the study at any time. You don't have to give a reason for not taking part or for stopping and it won't affect your current or future medical care or your relationship with any healthcare staff looking after you.

What will happen to me if I take part?

This study involves three appointments with researchers from the University of Dundee. These appointments could be face-to-face or by telephone call. At the first appointment the researcher will discuss the study with you and make sure you are happy to take part. They will ask you some questions about your life, including your living arrangements, employment, financial situation.

They will also ask you about your medical history, including your past and current drug use. They will ask you to complete some questionnaires about how you are feeling and how well you are in control of what happens to you in your life. The researcher will be able to help you with filling out the questionnaires. The researcher will also interview you about your OST and how it affects you in your life. This interview will be recorded. This first appointment will take about 60 minutes.

The second appointment will be 3-15 months after the first one. It will be very similar to the first appointment. The researcher will ask similar questions, you will fill out the questionnaires again, in case anything has changed, and you will have another recorded interview. This appointment will take about 50 minutes.

The final appointment will be 1-2 years after the first appointment. It will be very similar to the first two appointments. The researcher will ask similar questions, you will fill out the questionnaires again, in case anything has changed, and you will have another recorded interview. This appointment will take about 50 minutes.

What are the possible benefits of taking part?

The study may not benefit you directly but we hope it will give us a better understanding of the effect of different types of OST on people's lives and help us choose the right type for people in the future.

What are the discomforts and risks of taking part?

It is possible that some of the questions in the questionnaires or in the interview will cause you distress or make you feel uncomfortable. The researcher will be trained to try and make sure that this doesn't happen, and to be able to tell if you are becoming upset. If however you do become upset the interview will be stopped.

Expenses and payments

In thanks for your co-operation in this study, the researchers will be pleased to offer you a £10 supermarket voucher after interview 1 and after interview 2 and £20 after interview 3. The voucher can be spent at the supermarket as some compensation for your time.

Covid-19

The researchers will follow all current NHS Tayside checks and procedures related to Covid-19.

Will my personal information be kept confidential?

Identifiable information about you and your collected study data including the recordings of your interviews will be stored locally and designated members of the research team will have access to this information. No one outside the research team will have access to your identifiable information. Anonymised coded study data will also be securely stored on a password-protected database. Your data will be stored securely for 5 years after the end of study, after which it will be destroyed.

What will happen to the result at the end of the study?

The results will be examined by the researchers who have organised the study and a short report will be produced. You will not be identified in this report. The results will be shared with the funder of the study, Camurus. The results will be presented at scientific meetings and published in scientific journals. Again, you will not be identified in any presentation or journal article. You will be asked if you would like to receive a copy of the published reports. You will also be given the opportunity to discuss the results with the researchers.

Who is organising and funding this research?

This study is being sponsored by NHS Tayside. It is being funded by Camurus pharmaceutical company. The study has been organised by Dr Andrew Radley, University of Dundee and NHS Tayside.

What if something goes wrong?

If you're concerned about taking part in the study, you have the right to discuss your concern with a researcher involved in carrying out the study or a doctor involved in your care.

If you have a complaint about your participation in the study, first of all you should talk to a researcher involved in the study. You can also make a formal complaint. You can make a complaint to a senior member of the research team or to the Complaints Officer for NHS Tayside:

Complaints and Feedback Team, Ninewells Hospital, Dundee, DD1 9SY.

Telephone: 0800 027 5507

Email: feedback.tayside@nhs.net

If you think you have come to harm due to taking part in the study there aren't any automatic arrangements to get financial compensation. You might have the right to make a claim for compensation. If you wish to make a claim, you should think about getting independent legal advice but you might have to pay for your legal costs.

Insurance

NHS Tayside Health Board are Sponsoring the study. Tayside Health Board is a member of the NHS Scotland Clinical Negligence and Other Risks Insurance Scheme (CNORIS) which gives legal liability cover of NHS Tayside for this study.

If you apply for health, life, travel or income protection insurance you may be asked questions about your health. These questions might include questions about any medical conditions you currently have or have had in the past. We don't expect that taking part in the study will adversely affect your ability to buy insurance. Some insurers may use this information to limit the amount of cover, apply exclusions or increase the cost of insurance. Your insurer may take in to account any medical conditions you have, including

any which are diagnosed as part of a research study, when deciding whether to offer insurance to you.

Who has reviewed this study?

This study has been reviewed and approved by North West - Greater Manchester East Research Ethics Committee who are responsible for reviewing research which is carried out in humans. The Research Ethics committee doesn't have any objections to this study going ahead.

Data Protection Privacy Notice

How will we use information about you?

We'll need to use information about you for this research trial.

This information will include your initials, NHS number, name and contact details. Staff will use this information to do the research or to check your records to make sure that the research is being done properly.

People who don't 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'll keep all information about you safe and secure.

Once we've finished the trial, we'll keep some of the data so we can check the results. We'll 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 trial at any time, without giving a reason, but we'll keep information 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 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/
- http://www.ahspartnership.org.uk/tasc/for-the-public/how-we-use-your-information
- https://www.dundee.ac.uk/information-governance/dataprotection/
- http://www.nhstayside.scot.nhs.uk/YourRights/PROD_298457/index.htm

or by contacting Research Governance, Tayside Medical Science Centre (TASC), 01382 383900 email tascgovernance@dundee.ac.uk

Contact details

Thank you for reading this information sheet and considering taking part in this trial. If you would like more information or want to ask questions about the trial please contact the trial team on the number/addresses below:

Researcher: Sarah Donaldson on 07967323195 or 2395494@dundee.ac.uk

Chief Investigator: Dr Andrew Radley on Andrew.Radley@nhs.scot

You can contact us Monday – Friday between 09:00-17:00.

Outside of those hours, if you need health advice you can contact your out of hours GP service/NHS24 via 111.