Participant Information Sheet for Staff Involved in the Delivery and Support of Opiate Substitution Therapy (OST) by NHS Tayside.

Study title: Agent for recovery: The opportunity for enhancing social inclusion afforded by prolonged release buprenorphine formulations. "Prolonged release opioid for recovery (PROP)"

Study Researcher:
Sarah Donaldson, School of Medicine, University of Dundee and NHS Tayside

We are inviting you to take part in a research study

Before you choose whether or not to take part, we want you to understand why we are doing the study. We also want to tell you what it will involve if you agree to take part. Please take time to read this information carefully. You can ask us any questions you have and talk to other people about it if you want. We will do our best to answer your questions and give you any more information you ask for. You do not have to decide straight away.

Why are we doing this study?

A prolonged release buprenorphine treatment (Buvidal) is now available for treatment of opiate dependence. We want to find out what effect this type of treatment has on people's lives, compared to the lives of people who take sublingual/oral lyophilisate buprenorphine on a daily basis.

Why am I being invited?

We are inviting you to take part because you are a member of the multidisciplinary team providing care for patients receiving prolonged release buprenorphine (Buvidal). We require an estimated 10 staff to take part in this study. We would like to understand if prolonged release buprenorphine (Buvidal) changes the therapeutic relationships with staff members that allow a greater focus on achieving holistic gains in wellbeing that goes beyond health-related domains?

Do I have to take part?

No. It is up to you to choose, taking part in this study is entirely up to you. You can choose to take part or choose not to take part. If you choose to take part you can stop the study at any time. You do not have to give a reason for not taking part or for stopping. If you do not want to take part or want to stop the study your legal rights or relationship with your employer will not be affected.

What will happen to me if I take part involve?

If you are interested in participating, you will be asked to complete the staff contact slip. Our researcher will then contact you and will explain the study to you. If all your questions have been answered to your satisfaction, the researcher will ask for your informed consent to take part in a research focus group. If you prefer, you can take part in an interview instead. The focus group/individual interview will last approximately 45 minutes. These will be conducted in private interview areas across a range of possible locations with the researcher including the telephone or MS Teams. The interview date, time and place will be arranged between you and the researcher at the time of consent. All questions will be read to you and explained to you. With your permission we would like to audio record the focus group (or interview) to help make sure we have an accurate record of what you said. Please know that all audio-recorded interviews will be anonymised, so that no one can identify you.

What are the possible benefits of taking part?

Evaluation of new OST treatment options and the impact that they may have in improving the social inclusion and wellbeing of patients is important and will help health services do the best they can to care for people affected by substance use. You may like to feel that you have made a contribution to this.

What are the possible disadvantages and risks of taking part?

You may find that talking about your experiences is upsetting. If this happens, you might like to take a break from the focus group (or interview) after which, the researcher will ask you if you are prepared to continue. If you require additional support, the researcher will offer you a list of local services that may help.

The study could potentially expose areas of practice that may benefit from improvement. Please know that the research team are not evaluating the professional performance of individual staff members. Our focus is on how the programme works more generally.

Covid-19

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

Who is organising and funding this research?

This study is being sponsored by the NHS Tayside. It is being funded by Camurus. The study is being organised by Dr Andrew Radley at NHS Tayside.

What will happen with the information collected about me?

Identifiable information about you and the information collected about you during the study will be stored by NHS Tayside. Only specified members of the research team will have access to this information. Your anonymised coded study information will be stored securely on a password-protected database(s) in NHS Tayside. Specified members of the data management team will also have access to your identifiable information to manage your information and maintain the database. Your information will be kept securely for five years after the end of the study. After five years it will be destroyed. Information which identifies you will not be published or shared. Your study information with any information which identifies you removed may be shared with other researchers in the UK/EU/other.

What if something goes wrong?

If you are concerned about your participation in the study you have the right to discuss your concern with a researcher involved in carrying out the study. If you have a complaint about your participation in the study, you should talk to a researcher involved in this 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
NHS Tayside
Ninewells Hospital
Dundee DD1 9SY
Freephone: 0800 027 5507
Email: feedback.tayside@nhs.net

If you think you have come to harm due to taking part in the study there are not 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 the legal costs.

Insurance

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 have or have had in the past. You might also be asked if you have had any genetic tests or about taking part in this study. We do not 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 into 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?

The North West - Greater Manchester East Research Ethics Committee which has responsibility for scrutinising all proposals for medical research on humans, has examined the proposal and has raised no objections from the point of view of research ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from NHS Tayside whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

Contact details for further information.

Sarah Donaldson, School of Medicine, University of Dundee, Ninewells Hospital and Specialist Pharmacist in Substance Use, NHS Tayside. Tel: 01382 660 111 ext 22596 or 07967323195, Email: 2395494@dundee.ac.uk or Sarah.Donaldson@nhs.scot
If you would like more information or want to ask questions about the study please contact the study team using the contact details above.
You can contact us Monday – Thursday between 09:00-15:00 and Friday between 9.00am and 12.00.

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, 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.