Participant Information Sheet: RESCU-2

Study title: Feasibility of Virtual Safe Drug Consumption Technology, Using Respiratory Monitoring to Reduce Drug Harm

Study Researcher: Professor John Dillon

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 will be involved 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 information you ask for. You do not have to decide straight away.

Why are we doing this study?

The United Kingdom is currently experiencing an opiate drug overdose crisis and we are committed to helping people who are at risk of opiate drug overdose. When someone experiences an overdose, their breathing is slowed to a dangerous, and sometimes fatal level. In the hospital, doctors and nurses can easily monitor patients' breathing. However, monitoring someone's breathing in the community, e.g., in a homeless accommodation, hasn't been possible until now. Technology is available that consists of a small, discreet sensor that sticks to the chest area and monitors chest movement and has the potential to detect when a person is experiencing abnormal breathing relating to an overdose. This device has the potential to alert individuals, household members, friends and family, or emergency services, who can come and give lifesaving naloxone. We want to conduct this study to understand if wearing the device is possible for people who are at risk of overdose, as well as to collect information to understand their normal breathing patterns.

What is being tested?

We are testing if wearing the device is possible for people by looking at the amount of time that data is collected when participants are wearing the sensor and by interviewing participants about their thoughts and feelings about wearing the device. We also want to collect data that can be used to understand normal breathing

patterns and patterns that might trigger an emergency response if someone is experiencing an overdose.

Why have I been contacted?

You have been asked to take part in this study because you are part of a population that is at risk of experiencing opiate drug overdose.

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, the medical care you get and your relationship with the accommodation staff looking after you will not be affected.

All information about you and the information collected about you during the study will be anonymised (your name and other identifying information will be removed) and stored securely. Only specified members of the research team, regulatory authorities or Sponsor rep will have access to this information, and your anonymity will be protected.

The only time confidentiality would need to be broken would be if you disclose information about serious criminal activity or there is concern that you or somebody else is in danger.

What will happen to me if I take part?

At your first visit, the study will be carefully explained to you, by a staff member who works in the accommodation. You will have as much time as you need to think about your participation and following that, if you are happy to take part, you will be asked to sign a consent form.

The study will involve wearing the device overnight if you are only staying a short time or up to 4 weeks if you are staying longer. There is an option to wear the device for longer than 4 weeks, if the accommodation staff suggest it and you agree. The study will last for 1 year, this would be the longest time you would be asked to wear the device for. At your first study visit, after agreeing to take part, the staff member will take a brief medical history and take your height and weight measurements to calculate your BMI, as this can impact your breathing pattern. The staff will ask you

for some information about yourself and ask you to complete a questionnaire about your drug use. The information you provide in this questionnaire will be recorded anonymously with your participant number instead of your name and will be used to demonstrate rates of drug use to overdose risk so that the way the device works can be more effective. You will then be given instructions on how to wear the sensor on your chest area, and they will explain where the tablet which collects data from the sensor on your chest movement is located in your room. You will also be supplied with and instructed on using a paper diary to record when you are taking your drugs and prescription medication. An accommodation worker will check in on you at least once in an evening to make sure you are wearing the device, it is working correctly and you are safe.

You will be required to wear the sensor continuously while you are in the accommodation but should remove it and leave it in your room if you are going out. If you forget and leave the sensor on when you go out, the sensor light will flash red until it comes back into range of the tablet. If you are leaving the accommodation permanently, please return the device to an accommodation worker. You should swap the side of your chest the device is on once a week.

Your data will not be monitored during the study. All analysis will be carried out after the study is completed.

After each 4 week period (or after your first evening if you are a short stay resident), you will be asked to complete a satisfaction survey to highlight any issues with wearing the sensor.

During your last study visit, you will return the device, tablet and diary. You will be asked if you would like to take part in an interview and/or focus group about your experiences, thoughts and feelings on wearing the device. You may also be asked about your thoughts on the development of an intervention pathway (creating the most effective way to refer people and encourage people to wear the device) using the device to trigger an emergency response if someone is experiencing an overdose.

Will taking part in the study affect my usual care?

The research will not change the regular treatments you receive.

What will happen when the study finishes?

We will collect and compare all the information to see how possible it is for people who use drugs to wear the device and look at participants' normal chest movement patterns. We will also use the information collected through the interviews and focus groups to understand participants' thoughts and feelings about wearing the device and how we can potentially use it in future to design an intervention pathway that could trigger an emergency response if a person is experiencing an overdose. Should you complete an interview, this will be audio recorded by the researcher, anonymised and transcribed by a researcher at King's College London. The audio recordings will be destroyed after transcription.

What are the possible benefits of taking part?

The study may not immediately benefit you, but if the results of the study are positive, we can potentially design a future study in which we would develop an intervention pathway that uses the device to potentially trigger an emergency response if a person is experiencing an overdose.

For taking part in the study, you will be offered £25 per week over the four weeks you wear the device, if we can see you have been wearing it and the tablet is still in your room and working. If you are a short-stay participant, you will receive £5 each time you return the device and tablet the morning after use – up to a maximum total of £25. If you take part in an interview, you will receive £20. If you take part in a focus group, you will receive £10. Where possible, payment will be made by using the Cash Out system. You will receive a text message you can show at any shop with a PayPoint sign and they will give you the cash value. If you do not have a mobile telephone, you will be paid in cash or receive a shopping voucher of the same value.

What are the possible disadvantages and risks of taking part?

There are no anticipated discomforts, risks, or side effects from taking part in this study. The sensor is small and discreet, causing no discomfort. You can go about your daily life as normal. The device is water resistant and can be worn when showering or taking a bath. You can wear the device without noticing it.

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

Participation in this study is entirely voluntary. You do not have to participate if you do not want to. You are free to refuse to take part or to withdraw from the study at

any time without having to give a reason and without this affecting your future medical care or your relationship with medical or accommodation staff looking after you. If you decide to withdraw, or the Chief Investigator or a clinician advises you to withdraw from the study, we will retain and analyse the data already collected.

Who is organising and funding this research?

This study is being sponsored by the University of Dundee. It is being funded by the Scottish Government and Scottish Health and Industry Partnership Group. The study is being organised by Professor John Dillon, Consultant in Hepatology and Gastroenterology. The devices and monitors are provided by PneumoWave Ltd. King's College London will perform the analysis.

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 University of Dundee. Only specified members of the research team will have access to this information.

Your identifiable information will be held by the accommodation and your anonymised coded study information will be stored securely on a password-protected database(s) in the University of Dundee or Kings College London, depending on if you live in Scotland or England. Specified members of the data management team will also have access to your identifiable information to manage your information and maintain the database. Anonymised data will also be transferred to PneumoWave Ltd and King's College London for data analysis.

Your information will be kept securely for ten years after the end of the study. After ten years, your identifiable information will be removed and the rest of the information will be kept for research purposes. If you would like to be informed about future studies that you might be interested to participate we will ask you to sign a consent to allow us to hold your contact details.

Information which identifies you will not be published or shared.

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 trial or a doctor involved in your care.

If you have a complaint about your participation in the trial first of all you should talk to a researcher involved in the trial. You can also make a formal complaint. You can make a complaint to a senior member of the research team or to the study sponsor:

TASC Governance, Ninewells Hospital, Dundee, DD1 9SY.

Telephone: 01382 383297

Email: tascgovernance@dunde.ac.uk

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 your legal costs.

Insurance

The University of Dundee are Sponsoring the study. The University of Dundee holds Clinical Trials indemnity cover which covers the University's legal liability for harm caused to participants.

Who has reviewed this study?

This trial has been given a favourable review by the University of Dundee, School of Medicine and Life Sciences Research Ethics Committee who are responsible for reviewing research which is conducted in humans. The Research Ethics committee does not have any objections to this study going ahead.

Contact details for further information

[Site Specific Support Accommodation Details]

Thank you for taking time to read this information and for considering taking part in this trial.

If you would like more information or want to ask questions about the study please contact the trial team using the contact details above.

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

Data Protection Privacy Notice

How will personal information be used?

University of Dundee are the Sponsors for this study, based in the United Kingdom and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. University of Dundee will keep identifiable information about you for 5 years after the study has finished.

We will need to use information from you for this research project. This information will include your name, initials and contact details. People 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 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.
Your rights to access, change or move your information are limited, as we need to manage your information in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To protect your rights, we will use the minimum amount of information which is personably identifiable as possible.

University of Dundee will collect information from you for this study according to our instructions.

University of Dundee will use your name and contact details to contact you about the study. They will use this information to make sure that relevant information about the study is recorded for your care and to check the quality of the study.

The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

The supported accommodation will keep identifiable information about you from this study for 5 years after the study has finished.

University of Dundee will collect information about you for this study from the study questionnaires. This information will include your name, contact details and health information. Health information which is regarded as a special category of information. We will only use this information to conduct this study.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

Lawful reason for using your information

It is lawful for the University to use your personal data for the purposes of this study. The legal reason for using your information is that using it is necessary for the research which is carried out in the public interest.

It is lawful for the University to use your sensitive personal data (if applicable) for the purposes of this study. The reason we use sensitive personal information such as data concerning health is that using it is necessary for scientific research purposes. Legally we must ensure we have technical and organisational processes in place to respect your rights when we use your information.

You can find out more about how we will use your information at http://www.ahspartnership.org.uk/tasc/for-the-public/how-we-use-your-information and https://www.dundee.ac.uk/information-governance/dataprotection/ and at http://www.nhstayside.scot.nhs.uk/YourRights/PROD_298457/index.htm

If you wish to complain about the use of your information please email dataprotection@dundee.ac.uk or, you may wish to contact the Information Commissioner's Office.

Study Results

The results of this study will be published and available in due course, following the completion of the study analysis. A newsletter with results of the study will be made available to participants, if you are still in contact with the supported accommodation. Newsletters will be distributed to staff in the supported accommodation, and you can request a copy of the study results from them. You can also request a copy of the study results from the study investigators, whose contact details can be found in this leaflet.