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Participant Information Sheet: A randomised, controlled feasibility study of the SCEPTRE intervention to support smoking cessation and prevent lapse to tobacco use following a smoke free mental health inpatient stay

We would like to invite you to take part in our research study called SCEPTRE. This information sheet will explain why the research is being done and what taking part will involve.

What is the SCEPTRE Research Programme?

Researchers from the University of York are conducting the SCEPTRE research programme. SCEPTRE stands for Promoting **S**moking **CE**ssation and **P**revenTing **RE**lapse to tobacco use following a smokefree mental health in-patient stay.

Why is the research being done?

The smoking rate among people with a mental health condition is two to three times higher than in people who do not have a mental health condition. We know around 14% of adults in England smoke, but this rate increases up to 70% of people with conditions such as schizophrenia and those hospitalised for severe mental health conditions.

People with mental health conditions are motivated and able to quit. and a smokefree hospital stay can positively impact a person's smoking, motivations, and beliefs. Although staying in a smokefree environment may lead to temporary abstinence or quitting smoking, the chances of relapse after discharge from hospital are high. Smokers tend to relapse quickly, with most returning to smoking on the same day of discharge. Therefore, we have created a support package for people with a mental health condition following discharge from a smokefree hospital stay.

We want to find out if is possible to deliver the SCEPTRE support package, if it is acceptable to people with mental health conditions, and if the support helps people to change their smoking behaviour. The study's findings will allow us to make any changes to the support package before testing whether the support works on a larger scale.

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What is the SCEPTRE support package?

We have created a package to support people with mental health conditions to maintain the positive changes they have made to their smoking behaviour while in hospital. The support package will last for 12 weeks after you have been discharged and will be provided by a mental health worker trained to provide personalised support to assist you in meeting your smoking behaviour change goals. The chart below shows the types of support you will be offered.

Before you are discharged

Reflection and evaluation session: Exploring your smoking behaviour plans, motivations and goals with a trained mental health worker. This will also include discussion of NRT and/or e-cigarettes. This can split into two sessions depending

Core parts of the support package – After you are discharged

Personalised resource folder – 'My-Try folder': You will be given a folder containing practical information and motivational content to support you to meet your smoking behaviour change goals.

Telephone support: You will receive 1 support call each day for the first 5 days after discharge and then weekly calls. Each call will last up to 20 minutes each.

Optional parts of the support package – After you are discharged

Smoke Free App: You will have access to a paid subscription for 12 weeks.

Text-message support: Depending on your goals, you will receive up to 30 text messages during the first two weeks after discharge.

How has the SCEPTRE support package been designed?

People with lived experience of mental health conditions and quitting smoking, carers and family members, and mental health professionals have helped to design the SCEPTRE support package. We have also used the results of other studies that have worked well to help people with mental health conditions to change their smoking behaviours.

Why am I being asked to take part?

A staff member on your ward thinks you may be suitable for the study as you have said that you might be interested in either remaining smokefree when you are discharged or making changes to your smoking by stopping smoking, cutting down, or using an e-cigarette.

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Do I have to take part?

No, taking part is completely voluntary. It is entirely up to you whether to be involved, and you are free to change your mind at any time.

If you do decide to take part, you will be given this information sheet to keep and you will be asked to sign a consent form to confirm your decision.

What will happen to me if I take part?

If you are eligible to take part and are happy to proceed, a research team member will visit your ward to explain the study and answer any questions you may have. They will ask you to complete a consent form to show that you understand what is involved and are happy to participate.

The research team member will then ask you to complete a questionnaire with them. This will take approximately 30 minutes and ask questions about your smoking, mental health, general physical health, and the health services you use.

The first questionnaire will be completed whilst you are on the ward where we will also ask you to provide us with a sample of your breath to check how much carbon monoxide (CO) is in your body. If you smoke, you will have more CO than a non-smoker. The CO test that we carry out is a safe procedure. We will thoroughly clean the small hand-held device and provide a clean plastic straw, which you'll use to blow into the machine. The test takes less than 30 seconds to complete.

All participants in the study will have a random chance of receiving the SCEPTRE support package. This means a computer programme will choose if someone receives the support or their usual care. 'Usual care' might mean receiving advice to quit smoking on discharge, offering a short supply of Nicotine Replacement Therapy (NRT) products (smoking cessation medication), or a referral to a local stop-smoking service. 'Usual care' is different in each NHS Trust. Your NHS Trust and care team decides what 'usual care' involves. The research team at the University of York do not make decisions about your usual care.

A member of the research team will let you know if you have been allocated to receive the SCEPTRE support package and what this means for you or if you will receive your 'usual care'.

You will be asked to complete a questionnaire three months and six months after joining the study. The questionnaires can be completed by email where we send you a secure link to the questionnaire, or with a member of the research team in person, or via telephone or video call. The questionnaires will take approximately 30 minutes to complete and will ask about your smoking habits, mental and physical health, and the health services you use. We may ask your GP to confirm your contact details if we do not receive a response after 3 attempts to contact you to complete the questionnaires.

If you tell us that you have not smoked, you will be asked to provide another sample of your breath so that we can measure the CO in your body. A member of the research team will arrange to visit you to complete the test.

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We will send you a £15 shopping voucher for each completed follow-up questionnaire.

Feedback on the study

You may be asked if you would like to participate in a discussion with a researcher about your experiences in the study. The session will take place over the phone or by video call and will be arranged at a convenient time. It will last approximately 25 minutes. If you prefer, a relative or friend can be with you.

With your permission, interviews will be digitally audio-recorded using a secure device and transcribed by an independent transcription service. We may use anonymous direct quotes from the interview in publications. Your personal details will be kept confidential and removed from the recordings when we write these up, and your name will not appear in any written reports of the research. You can still give us your feedback, even if you do not wish to be recorded.

We will only ask a small number of people to give us their feedback, which is voluntary. If you do not wish to give us your feedback, you can still take part in the study

Recommending family members and friends

If you are allocated to receive the SCEPTRE support package, a research team member will ask if you know of a family member or friend who may also like to participate in the study.

If you suggest a family member or friend, they will be contacted by the research team to ask whether they would be happy to take part in a short interview about their views on the support you have received.

If you are unable to suggest a family member or friend who is willing to participate, this won't stop you from being able to take part.

What if I no longer want to take part?

If you agree to participate but change your mind later, you can withdraw from the study without giving a reason and your future care and treatment will not be affected.

If you leave the study, we would still like to keep and use the information we have collected from you, as this is valuable to the study. 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.

What are the benefits of taking part?

If you are allocated to receive the SCEPTRE support package, this will benefit you by providing personalised support to change smoking behaviours following a smokefree stay

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in a mental health hospital. By positively changing your smoking behaviours, this may have both physical and mental health benefits for you.

If you choose to take part in the feedback session at the end of the study, sharing your views and opinions will help us improve the SCEPTRE support package for other mental health patients.

Are there any risks to taking part?

We will ask some questions about your mental health and experiences staying in a smokefree mental health ward. While most people do not mind answering these questions, others may feel uncomfortable answering them. You don't have to answer any questions you do not want to.

How is my information used?

We will inform your mental health consultant and GP if you agree to participate.

Information collected about you during the research and from your health records will be held securely on paper or electronically at the study site and York Trials Unit, the centre organising the research. Information will be kept strictly confidential. We will keep your information safe and secure, in full compliance with the General Data Protection Regulations (GDPR).

Your name and contact details will be stored securely at the University of York to allow us to contact you about study questionnaires, ensure that relevant information about the study is recorded for your care, and oversee study quality. Your details will not be passed to anyone outside of the research team.

Very rarely, we may need to share confidential information, but this only happens in exceptional circumstances, such as when an individual has been or is at risk of harm.

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

If you agree to participate in this study, you can participate in future research using your data saved from this study.

We will keep this information for up to 10 years after the end of the study and then destroy your personal details so that they can no longer be linked to the information we collected.

Who is the Data Controller?

Sheffield Health and Social Care NHS Foundation Trust and the University of York will be joint data controllers.

Where can I find out more about how my information is used?

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You can find out more about how we use your information:

- At www.hra.nhs.uk/information-about-patients/
- A leaflet available from www.hra.nhs.uk/patientdataandresearch
- By asking one of the research team (contact details are provided at the end of this information sheet)
- By sending an email to the Sponsor's Data Protection Officer: DPO@shsc.nhs.uk.
- By writing to the Sponsor's Data Protection Offer at the following address:

The Data Protection Officer
Information Department
Sheffield Health and Social Care
Fulwood House
Old Fulwood Road
Sheffield
S10 3TH

What if there is a problem?

If you are concerned about any aspect of this study, you should ask to speak to a research team member who will do their best to answer your questions.

If you have any complaints or cause for concern, please contact:

Dr Elena Ratschen, the Chief Investigator of this study on elena.ratschen@york.ac.uk

You can also contact the Patient Advice and Liaison Service PALS team via email or telephone:

<insert local PALS email address> or telephone: <insert phone number>

What happens at the end of my time in the study?

When your time in the study ends, you will continue to receive standard or usual care.

What will happen to the results of this study?

If you would like to receive a copy of the results, these will be made available to you once the study has finished, which we anticipate will be in spring 2025.

We will publish our results in medical journals and present them at conferences. You will not be identified in any publication or presentation from this study.

What if new information becomes available?

Sometimes, during a trial, new information about treatments being studied becomes available.

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If this happens, your nurse or doctor will tell you about it and discuss with you if you want to continue in the study and if it is appropriate for you to continue to do so.

If you decide to withdraw from the study, your care will continue in line with routine practice. You will be asked to sign an updated consent form if you decide to continue.

Who has reviewed this research study?

An independent group of people looks at all NHS research, called a Research Ethics Committee to protect participants' safety, rights, well-being and dignity. This study has been reviewed and been given a favourable opinion by **[insert REC here].**

Who is organising and funding this study?

Researchers from the Department of Health Sciences at the University of York are conducting the research, and the Sponsor is Sheffield Health and Social Care NHS Foundation Trust. The National Institute for Health and Care Research (NIHR) funds the research programme.

I want to take part; what do I need to do?

If you are interested in taking part, please discuss this study with the person who gave you this information sheet. If you decide to take part you will be given a copy of this information sheet to keep and asked to sign a consent form to confirm your decision.

I do not wish to participate; what must I do?

If you do not wish to take part, you do not need to do anything. Thank you for reading this information.

I am unsure and would like more information; who should I contact?

If you do not understand anything on this information sheet or would like further information, please get in touch with the person who gave you this information sheet using the contact details provided below.

Who can I contact about this study?

If you have any questions or would like more information, please get in touch with:

INSERT TRUST RESEARCH TEAM CONTACT DETAILS

Thank you for taking the time to read this information sheet.

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