

# Promoting smoking cessation following a smoke-free mental health stay

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		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 02/03/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/09/2023	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The proportion of people with mental illness who smoke tobacco is very high compared to the general population. It can reach figures over 70% among those with schizophrenia and in hospitalised patients with severe mental illness, compared to only 15% in the general population. As people with mental illness are usually heavily addicted to tobacco, smoking causes large amounts of disease and deaths in this group, often from heart and lung disease and cancer. Smoking has been recognised as the single largest cause of health inequalities for people with mental illness. People with mental illness lose up to 20 years of life mainly to the consequences of smoking. Although mental health patients often want to quit and can do so successfully, smoking is rarely addressed in mental health care. In many mental health settings in England, a historic 'smoking culture' can still be found. Guidance from the National Institute of Health and Care Excellence (NICE) recommends that mental health settings become entirely smoke-free and mental health patients should have access to evidence-based stop smoking treatment. For many patients, receiving treatment in a smoke-free inpatient environment will be a rare experience of abstaining from tobacco in their lives. Currently, there are no strategies to help maintain or achieve a smoke-free lifestyle and avoid relapse after discharge. This means that most patients will return to old smoking behaviours within days of discharge. Researchers have developed an intervention to support mental health inpatients after discharge in maintaining or achieving abstinence from tobacco smoking, building on existing evidence, behaviour change theory, and working closely with service users and mental healthcare professionals. Therefore, the aim of this pilot study is to test the intervention, manuals, and research materials for fitness of purpose, and conceptual and logistic flaws on pilot acute mental health wards in each of the participating trusts.

### Who can participate?

Patients aged 18 years or older admitted to an acute inpatient mental health setting in the participating trusts who report smoking cigarettes or tobacco at least weekly and express an interest in maintaining abstinence or positively changing their smoking behaviour following discharge. Carers aged 18 years or older who currently have a relative or friend admitted to the included mental health inpatient wards are also eligible to participate.

### What does the study involve?

The study will implement the SCEPTRE package (the intervention to be tested). All participants recruited will receive the intervention in addition to usual care. At the start of the study a questionnaire will be administered to participants to collect sociodemographic information, mental and physical health status, and smoking-related characteristics before admission and during their inpatient stay. After the intervention participants will complete a questionnaire to collect information on their mental and physical health status and smoking-related characteristics since discharge. All participants (patients, carers and those delivering the intervention) will be offered the opportunity to take part in an interview after the intervention to explore their experiences of taking part in the study and their perceptions of the intervention.

### What are the possible benefits and risks of participating?

Individual participants may benefit from this study directly as the SCEPTRE package provides tailored support to the individual to positively change their smoking behaviours, which may have subsequent physical and mental health benefits. The researchers are aware that mental health inpatients represent a vulnerable group, and that transition from an acute inpatient ward to the community can be a vulnerable period in the care pathway. As a result of this, a risk assessment has been conducted in collaboration with mental health clinicians in each trust and relevant standard operating procedures and policies in relation to risk (suicide risk and non-suicidal risk) have been developed. Furthermore, safeguarding procedures and a pathway to obtain rapid and appropriate assistance for participants at risk of suicide or serious harm have been implemented. However, the researchers do not anticipate any material ethical issues since they will only offer interventions recommended in recent guidance issued by the NICE. Participants will not be denied any form of care that is currently available in the NHS by participating in this study.

### Where is the study run from?

University of York (UK)

### When is the study starting and how long is it expected to run for?

February 2020 to August 2022

### Who is funding the study?

National Institute for Health Research Programme Grants for Applied Research (NIHR) (UK)

### Who is the main contact?

1. Dr Elena Ratschen, [elena.ratschen@york.ac.uk](mailto:elena.ratschen@york.ac.uk)
2. Dr Lisa Huddleston, [lisa.huddleston@york.ac.uk](mailto:lisa.huddleston@york.ac.uk)

## Contact information

### Type(s)

Scientific

### Contact name

Dr Emily Shoemith

### ORCID ID

<https://orcid.org/0000-0002-2420-4919>

### Contact details

Department of Health Sciences  
Faculty of Sciences  
University of York  
Heslington  
United Kingdom  
YO10 4DD  
+44 (0)1904 32 1765  
Emily.shoesmith@york.ac.uk

**Type(s)**

Scientific

**Contact name**

Dr Lisa Huddleston

**ORCID ID**

<https://orcid.org/0000-0002-8054-4475>

**Contact details**

Department of Health Sciences  
Faculty of Sciences  
University of York  
Heslington  
United Kingdom  
YO10 4DD  
+44 (0)1904 32 1949  
lisa.huddleston@york.ac.uk

**Type(s)**

Principal investigator

**Contact name**

Dr Elena Ratschen

**ORCID ID**

<https://orcid.org/0000-0003-4128-9608>

**Contact details**

Department of Health Sciences  
Faculty of Sciences  
University of York  
Heslington  
United Kingdom  
YO10 4DD  
+44 (0)1904 32 1678  
elena.ratschen@york.ac.uk

**Additional identifiers**

Clinical Trials Information System (CTIS)

Nil known

## **Integrated Research Application System (IRAS)**

300176

### **Protocol serial number**

CPMS 51596, IRAS 300176

## **Study information**

### **Scientific Title**

Promoting Smoking CEssation and Preventing RELapse to tobacco use following a smoke-free mental health inpatient stay (SCEPTRE programme): a pilot study

### **Acronym**

SCEPTRE

### **Study objectives**

The study does not have a hypothesis but the overarching aim is to develop and test the feasibility, effectiveness and cost-effectiveness of a co-produced intervention to sustain or enhance smoking behaviour change and prevent smoking relapse for hospital inpatients with severe mental illness after discharge. Specifically for this small pilot study, the aims are to assess:

1. The usability of the intervention manual and study instruments
2. Patient, carer and staff acceptability (interest in participation, consent and engagement)
3. Acceptability and feasibility of the intervention delivery and receipt

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 17/12/2021, South Central - Hampshire B Research Ethics Committee (Health Research Authority, Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)20 7104 8064; hampshireb.rec@hra.nhs.uk), REC ref: 21/SC/0384

### **Study design**

Interventional; Non-randomized; Design type: Treatment, Prevention, Education or Self-Management, Psychological & Behavioural, Complex Intervention, Qualitative

### **Primary study design**

Interventional

### **Study type(s)**

Prevention

### **Health condition(s) or problem(s) studied**

Smoking cessation following a smokefree mental health stay

### **Interventions**

The intervention consists of components that aim to support smoking-related behavioural change among patients following discharge from a smoke-free mental health setting. The

intervention will be delivered by a mental health worker – named the My-Try Specialist (MTS) - who has received enhanced training and ongoing support in supporting people with mental illness to remain smoke-free following discharge or, where they have not been abstinent during admission, to achieve positive change to their smoking-related behaviours post-discharge.

The aim of the MTS role is to provide tailored behavioural and social support and information to patients to enable the continued change in smoking behaviours following discharge from a smoke-free mental health ward. Intervention components include:

1. Pre-discharge reflection and evaluation
2. Personalised resource folder (My-Try folder)
3. Nicotine Replacement Therapy (NRT)/e-cigarette selection and advice
4. Tailored in-person support (via telephone or video call)
5. Opt-out text-based support
6. Opt-out opportunity for peer interaction (moderated remotely)

The study will involve a recruitment period of 6–8 weeks, with no long-term follow-up, and the intervention will last for a period of 12 weeks.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

The usability of the manual and research measures, participant and staff acceptability (including interest in participation, consent, and engagement), and feedback relating to the research participation process and the intervention (as a whole and in terms of single components), assessed using interviews conducted with participants and staff members within 1-week post-intervention

## **Key secondary outcome(s)**

1. Mental health assessed using Recovering Quality of Life (ReQoL-10), Patient Health Questionnaire (PHQ-8), Generalized Anxiety Disorder (GAD-2) at baseline and 1-week post-intervention
2. Physical health assessed using self-reported physical health state, body mass index (BMI) at baseline and 1-week post-intervention
3. Smoking history and behaviour, including nicotine dependence (Fagerstrom Test of Nicotine Dependence), level of motivation to quit (Motivation to Quit Questionnaire) and intentions to quit post-discharge, assessed using a questionnaire at baseline and 1-week post-intervention

## **Completion date**

22/08/2022

# **Eligibility**

## **Key inclusion criteria**

Patients:

1. Adults aged 18 years and older (no maximum age)
2. Present admission to an acute inpatient mental health setting
3. Planned discharge to own residence or step-down setting
4. Tobacco smokers at the time of admission who express an interest in maintaining abstinence (if smokefree at time of assessment) or positively changing their smoking behaviour following discharge (including harm reduction and e-cigarette approaches)

5. Patients living in the catchment area of the Trust where they are admitted
6. Able to understand and communicate in English
7. Able to provide informed consent

**Carers:**

1. Adults aged 18 years and older (no maximum age)
2. Carers, family members or friends of patients who are currently admitted to an acute inpatient mental health setting
3. Carers, family members or friends of patients who are self-identified tobacco smokers at time of admission who express an interest in maintaining abstinence (if smokefree at time of assessment) or positively changing their smoking behaviour following discharge (including harm reduction and e-cigarette approaches)
4. Carers, family members or friends of patients who have consented to receiving the SCEPTRE intervention
5. Carers, family members or friends who are in regular contact with the patient and therefore able to provide feedback about the SCEPTRE intervention, what worked well for the patient, and what needs to be improved
6. Able to understand and communicate in English
7. Able to provide informed consent

**Participant type(s)**

Mixed

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

4

**Key exclusion criteria**

**Patients:**

1. Admitted under the care of older adult, learning disability, psychiatric intensive-care unit (PICU) or forensic mental health services
2. Patients with co-morbid drug or alcohol problems (dual diagnosis)
3. Patients who are pregnant or breastfeeding
4. Patients may also be excluded for any other reason at the discretion of their regular treating clinician.

**Carers:**

Carers may be excluded for any other reason at the discretion of their regular treating clinician

**Date of first enrolment**

14/03/2022

**Date of final enrolment**

20/05/2022

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Foss Park Hospital**

Haxby Road

York

United Kingdom

YO31 8TA

**Study participating centre**

**Roseberry Park Hospital**

Marion Road

Middlesbrough

United Kingdom

TS4 3AF

**Study participating centre**

**Becklin Centre**

Alma Street

Leeds

United Kingdom

LS9 7BE

## **Sponsor information**

**Organisation**

Sheffield Health and Social Care NHS Foundation Trust

**ROR**

<https://ror.org/05cn4v910>

# Funder(s)

## Funder type

Government

## Funder Name

NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR200607

# Results and Publications

## Individual participant data (IPD) sharing plan

The data will be uploaded to OSF once we have collated all the final findings (including anonymised data from baseline/post-intervention questionnaires and qualitative interviews). We will be able to provide the link once this has been uploaded, but final data collection has not been completed yet. This will be made publically available once the data has been analysed and the intervention for the next stage has been refined. The datasets will also be included in the subsequent results publication

## IPD sharing plan summary

Stored in non-publicly available repository, Published as a supplement to the results publication

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>			15/09/2023	No	No
<a href="#">HRA research summary</a>			26/07/2023	No	No
<a href="#">Protocol file</a>	version 2.0	03/12/2021	02/03/2022	No	No