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Promoting smoking cessation following a smoke-free mental health stay

Submission date
02/03/2022

Recruitment status
No longer recruiting

Registration date
02/03/2022

Overall study status
Completed

Last Edited
15/09/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 in 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?
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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)
300176

ClinicalTrials.gov (NCT)
Nil known

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
Marton Road
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United Kingdom
TS4 3AF

Study participating centre
Becklin Centre
Alma Street
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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?
Basic results			15/09/2023	No	No
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2.0	03/12/2021	02/03/2022	No	No