Promoting Smoking CEssation and PreventTing RElapse to tobacco use following a smokefree mental health inpatient stay

Protocol

SCEPTRE Pilot Study

Version 2.0

FULL/LONG TITLE OF THE STUDY	Promoting Smoking CEssation and PrevenTing RElapse to tobacco use following a smokefree mental health inpatient stay (SCEPTRE programme): a pilot study
SHORT STUDY TITLE / ACRONYM	SCEPTRE Pilot
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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: Date:
...../...../.....
.....

Name (please print):

.....

Position:
.....

Chief Investigator:

Signature: Date:
..../...../.....

Name: (please print):

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KEY STUDY CONTACTS

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Programme Manager	Dr Lisa Huddlestone
Sponsor	Sheffield Health and Social Care NHS Foundation Trust (SHSCT)
Joint-sponsor(s)/co-sponsor(s)	N/A
Funder(s)	NIHR Programme Grant for Applied Research
Key Protocol Contributors	Dr Lisa Huddlestone Dr Emily Shoesmith
Committees	SCEPTRE Programme Management Committee SCEPTRE Programme Steering Committee SCEPTRE Patient & Public Involvement Panel

STUDY SUMMARY

Study title	Promoting Smoking CEssation and PrevenTing RElapse to tobacco use following a smokefree mental health inpatient stay (SCEPTRE programme): a pilot study
Internal ref. no. (or short title)	SCEPTRE Pilot Study
Study design	Non-randomised mixed-methods pilot study
Study participants	12 to 24 participants (8 – 16 patients; 4 – 8 carers)
Planned size of sample (if applicable)	N/A
Follow up duration (if applicable)	N/A
Planned study period	6 – 8 weeks recruitment period; 12 weeks intervention delivery
Research question/aim(s)	To assess: 1. Usability of the intervention manual and study instruments 2. Patient, carer, and staff acceptability (interest in participation, consent, engagement) 3. Acceptability and feasibility of intervention delivery and receipt (as a whole and individual components)

LIST OF ABBREVIATIONS

AE	Adverse Event
BMI	Body Mass Index
CI	Chief Investigator
CO	Carbon Monoxide
CRN	Clinical Research Network
GAD-7	Generalised Anxiety Disorder 2-item
GCP	Good Clinical Practice
GDPR	General Data Protection Regulations
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
IQR	Interquartile Range
LYPFT	Leeds & York Partnership Foundation Trust
MRC	Medical Research Council
MTS	My-Try Specialist
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NRT	Nicotine Replacement Therapy
PHQ-8	Patient Health Questionnaire-8
PID	Patient Identifiable Data
PIS	Participant Information Sheet
PMC	Programme Management Committee
PPI	Patient and Public Involvement
PSC	Programme Steering Committee
REC	Research Ethics Committee
ReQoL	Recovering Quality of Life
SAE	Serious Adverse Event
SD	Standard Deviation
SHSCT	Sheffield Health and Social Care NHS Trust
SMG	Study Management Group
SMI	Severe Mental Illness
SOP	Standard Operating Procedure
TEWV	Tees, Esk, and Wear Valleys NHS Partnership Foundation Trust

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES, GROUPS AND INDIVIDUALS

Study Management Group (SMG)

The SMG will meet fortnightly to discuss all aspects of the study and report directly to the PMG. All Trust investigators and members of the study team are invited, and the meeting will be chaired by the Programme Manager (Dr Huddlestone). Study targets/milestones and progress will be reviewed, and risk assessment and troubleshooting undertaken.

Programme Management Committee (PMC)

The PMC will meet 6-weekly to discuss all aspects of the pilot study and report directly to the PSC. All investigators and other members of the study team, where appropriate, are invited and the meeting will be chaired by the Chief Investigator (Dr Ratschen).

Programme Steering Committee (PSC)

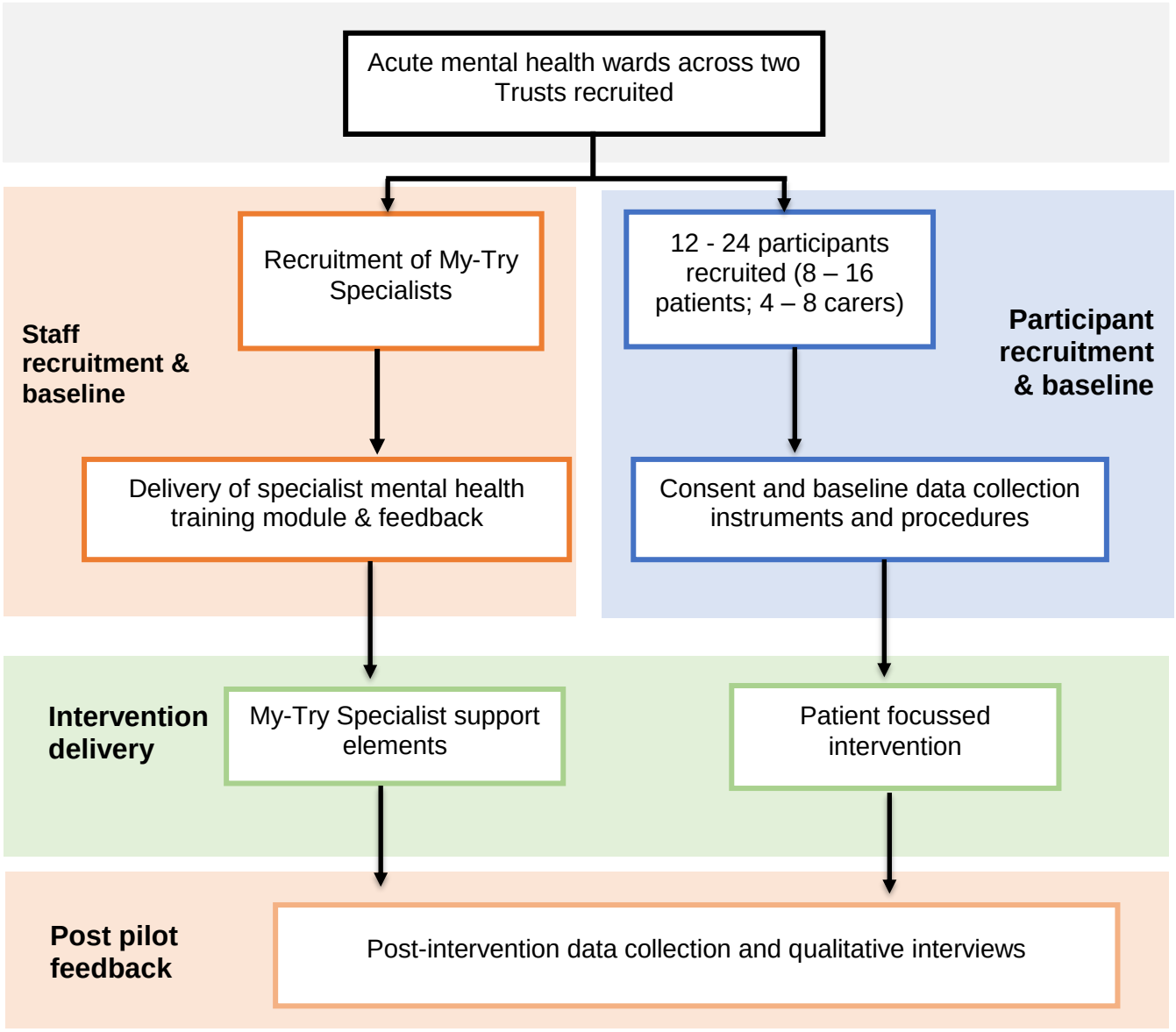
The PSC will meet annually and will include the Chief Investigator (Dr Ratschen), the Sponsor's representative, the funder's representative, an independent Chair, and independent statistician, an independent external member, and an independent PPI member. Members of the core and wider research team will attend the PSC as required. The PSC will act as an independent strategic oversight and will ensure transparency and that the work is reaching the relevant milestones. They will receive reports from the PMG.

Patient & Public Involvement (PPI)

The Study is supported by the SCEPTRE Co-applicants, Phil and Simon Hough. In addition, a SCEPTRE PPI group has been formed. The SCEPTRE PPI group comprises individuals who have severe mental illness, experience of admission to a smokefree mental health settings, and who are themselves former or current smokers, and convenes formally on a quarterly basis. In addition to formal meetings the SCEPTRE PPI group have contributed to the design of both the intervention components, participant study documents, intervention resources, and have provided input to the design of intervention delivery mechanisms and measures. PPI representatives will also be involved in the management of the research (attending PMC meetings), networking with existing PPI groups nationally, and dissemination activities with a focus on informing national policy in this area.

KEY WORDS: mental health; tobacco; smoking cessation; harm reduction; relapse prevention; smokefree settings; PH48

STUDY FLOW CHART



STUDY PROTOCOL

1 BACKGROUND

Tobacco smoking remains one of the leading preventable causes of death and disease in England and is responsible for an estimated 78,000 deaths annually (1). Although smoking prevalence of the UK general population has steadily declined over the last decades, no change has been observed among people with mental illness (2, 3). With average smoking prevalence figures of 40%, people with mental illness are more than twice as likely to be smokers as the UK general population (3), although smoking rates reach figures up to 70% in subgroups, such as hospitalised patients with severe mental illness (SMI) (3, 4). Combined with high levels of nicotine dependence (5), which results in generally high cigarette consumption, this results in substantially increased risks of premature smoking-related morbidity and mortality in this population (3), where up to 20 life years are lost largely to disease related to smoking, the biggest contributor to health inequalities (6).

Although people with SMI are similarly motivated (7) and able (8) to quit smoking to those without, main stream stop smoking services are not commonly accessed by this population (9, 10), and are decreasingly resourced to support the need of smokers with SMI for tailored support (11-13). With strong evidence that quitting smoking improves rather than exacerbates symptoms of mental illness (14), and that smoking may be causally linked to the development of mental illness (15) only emerging in recent years, smoking until very recently remained deeply embedded in the culture of UK mental health settings (16), where it was commonly accepted as a coping mechanism for patients (3, 17). The 2013 joint Royal College of Physicians/Royal College of Psychiatrists report and NICE guidance (PH48) draw attention to the need to address this ‘smoking culture’ The NICE guidance recommends that all mental health settings be entirely smokefree without exemption, with no facilitated smoking breaks, and evidence-based tobacco dependence treatment for smoking cessation, harm reduction and support for temporary abstinence available to all patients who smoke.

2 RATIONALE

For many mental health patients, a smokefree inpatient stay constitutes a rare if not the first experience of sustained abstinence, near-abstinence, or substantial reduction of consumption

of tobacco for a longer period of time in their adult lives (18). Evidence suggests individuals can successfully remain abstinent during their smokefree inpatient stay when behavioural and/or pharmacological support is offered (18, 19). However, where a smokefree stay resulted in temporary smoking abstinence or cessation, the risk of relapse post-discharge is high (20). Relapse to smoking post-discharge often occurs quickly, and the vast majority of smokers appear to return to smoking on the same day of discharge (21). A lack of support beyond discharge and the almost inevitably resulting relapse or return to heavy pre-hospital smoking patterns renders smoking-related resource input during the inpatient episode inefficient, as positive smoking behaviour change achieved during the inpatient stay may be lost. Therefore, it is vital to provide support post-discharge to prevent relapse.

3 THEORETICAL FRAMEWORK

The SCEPTRE intervention is a theory- and evidence-based intervention that aims to support smoking cessation and prevent relapse to tobacco following an inpatient stay in a smokefree mental health setting. The intervention has been developed from two systematic reviews and a Delphi-style consultation process with key stakeholders. The intervention development process was guided by the Behaviour Change Wheel model (22) and theoretically underpinned by the Theoretical Domains Framework (23) and the Behavioural Change Technique taxonomy (24). Learning from previous trials investigating interventions to assist smoking cessation in people with severe mental illness, such as the SCIMITAR and SCIMITAR+ studies (12, 25-27), has also been applied. To ensure fit within the context of mental health services, refinement of the draft intervention was undertaken in collaboration with clinicians and experts in the field of tobacco control. Measures to mitigate the impact of the current coronavirus pandemic and to ensure patient safety and preference in times of local uncertainty were designed through the conduct of several rapid scoping reviews of recently published literature and in consultation with Patient and Public Involvement (PPI) members.

4 DESCRIPTION OF THE SCEPTRE INTERVENTION PACKAGE

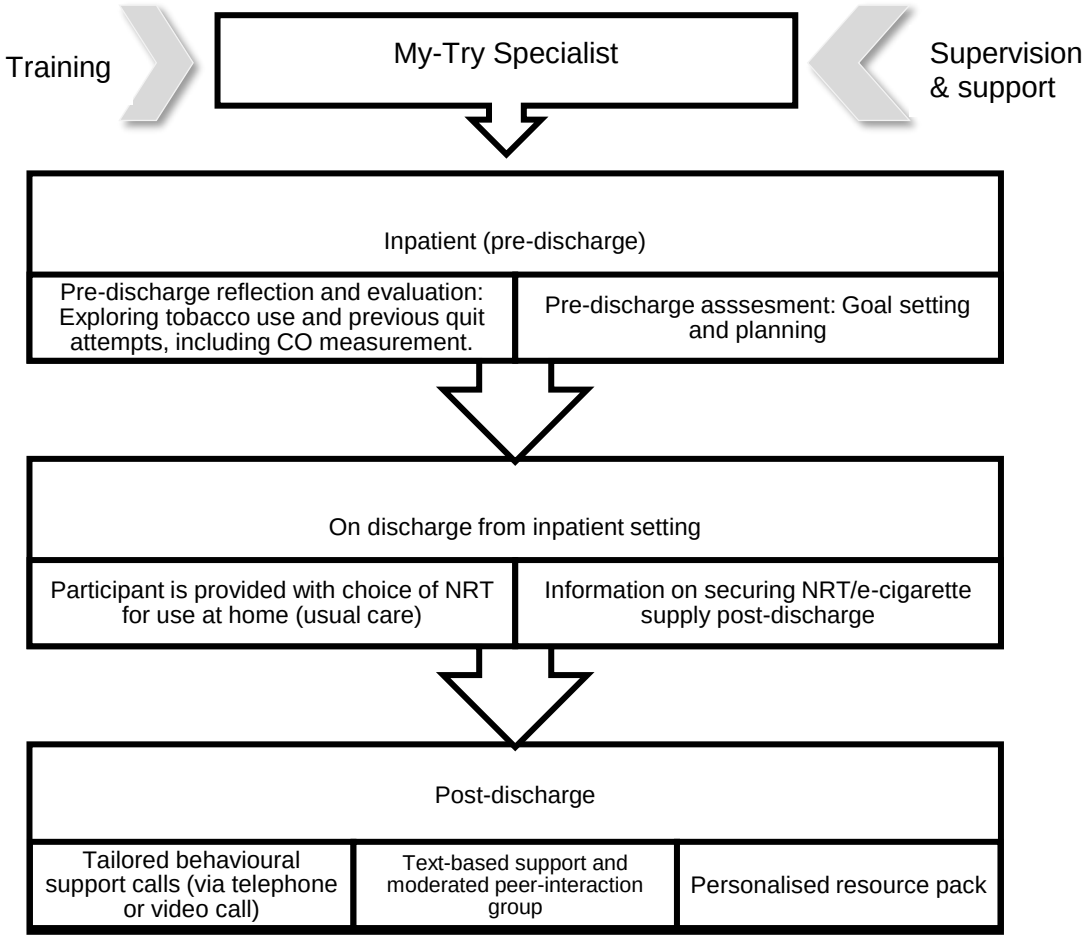
4.1 Summary of the Intervention

The intervention consists of components that aim to support smoking-related behavioural change among patients following discharge from a smokefree mental health setting (see Figure 1). The intervention will be delivered by a mental health worker – named the My-Try

Specialist (MTS) - who has received enhanced training and on-going support in supporting people with mental illness to remain smokefree following discharge or, where they have not been abstinent during admission, to achieve positive change to their smoking related behaviours post discharge. The terminology 'MTS' was decided by the PPI group, and links to the name of the personalised resource folder provided to participants as part of the SCEPTRE intervention (see section 4.2.2 *Personalised Resource Folder – 'My Try'*).

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 smokefree mental health ward. Intervention components include: (1) pre-discharge reflection and evaluation; (2) personalised resource folder (My-Try; (3) Nicotine Replacement Therapy (NRT) / e-cigarette selection and advice; (4) tailored in-person support (via telephone or video call); (5) text-based support, and (6) opportunity for peer interaction (moderated remotely).

Figure 1. SCEPTRE Intervention pathway



4.2 Core patient support elements

4.2.1 Pre-discharge reflection and evaluation

This component aims to provide personalised and tailored support by the MTS to assist participants in identifying and planning their smoking-related behaviour change goals. Evaluations will be participant-led and up to two 45-minute will be offered to participants. Participants will also be provided with a personalised resource folder named 'My-Try' (described in the following section).

The MTS will meet with the participant prior to discharge and initiate discussion of: (1) reflections on experience and impact of stay on the smokefree ward and exploration of intentions for maintaining and/or building on their progress so far; (2) plans and goal setting for preventing relapse, harm reduction or a quit attempt; (3) participant goals and monitoring milestones; (4) choice of pharmacotherapy, or obtaining and use of e-cigarettes); (5) individual motivations for the participant (i.e. physical and/or mental health, financial benefits), and (6) identification and involvement of a potential social support network. A range of NRT and e-cigarettes are provided to participants as part of usual care under NICE PH48. **The SCEPTRE intervention will not provide additional products, prescribe, or commence participants on new pharmacotherapies prior to or following discharge.**

The MTS will discuss participant preferences for NRT or e-cigarette support during the pre-discharge evaluation and subsequent support calls, as well as providing practical advice in relation to using the products and obtaining a longer-term supply in the future (for example, obtaining from GPs or local Stop Smoking Services, particularly if GPs are unwilling to prescribe once discharge supply has finished). Where participants are unhappy with their current e-cigarette device, the MTS will provide information and advice to enable the participant to make an informed choice in purchasing a new device. Discussions will also determine if participants would like to make use of the addition text-based and peer-interaction components. Finally, participants will receive a presentation and walk-through of the personalised resource folder (detailed in Section 4.2.2.).

4.2.2 Personalised resource folder – My-Try

A personalised resource folder was identified as beneficial for addressing participant needs in terms of both practical information and motivational content to continue smoking-related behavioural change following discharge from an inpatient setting. The name 'My-Try' was identified by the SCEPTRE research team and agreed with the PPI group members. PPI group members believed this name indicated flexibility would be permitted, and the support would not be too concrete or instructing to the participants.

In addition to core materials such as a copy of the participants behaviour change plan, journal pages for reflection, and information relevant to both the general and mental health experience of quitting or changing smoking behaviours, personalised information will also be included. Examples of personalised resources include information on creating smokefree homes, financial trackers of money saved, and distraction objects.

4.2.3 Tailored in-person support (via telephone or video call)

The literature indicates that telephone behavioural support increases the chances of stopping smoking, whether or not individuals are motivated to quit or are receiving other stop-smoking support (28). However, it is important to offer this behavioural support during the first day's post-discharge as the risk of relapse post-discharge is high (20, 21). Relapse to smoking post-discharge often occurs quickly, and the vast majority of smokers appear to return to smoking within a few days of discharge (21).

The tailored behavioural support aims to: (1) provide personalised and tailored support (both emotional and physical); (2) assist the participant in maintaining positive change achieved during their smokefree admission and achieving their behavioural change goals; (3) provide feedback and encouragement on the progress of the participant's individualised goals (set initially during the pre-discharge evaluation), and (4) to offer the opportunity for the participant to reflect on their own progress; have the chance to discuss this progress and whether they are meeting the goals initially set. If goals are not being met, the MTS will work with the participant to revise new, appropriate goals. Alternatively, if a participant who initially did not want to quit decides to make a quit attempt, the MTS's focus will shift from building motivation and confidence to assisting the participant in achieving their behavioural change goals. The sessions will aim to provide support and maintain participant motivation. Notes will be taken during each session and a copy of key points and changes will be posted or sent electronically

to the participant (dependent on individual preference) for inclusion in the personalised resource folder or storage on a personal device.

Once discharged, participants will receive up to 14 individual telephone or video-call behavioural support sessions, each lasting up to 30 minutes over a period of 12 weeks with the MTS. Telephone or video calls will be made daily on the first three days post-discharge, and then weekly thereafter. Participants will receive a reminder text prior to scheduled support sessions. Three attempts will be made at each timepoint to try and reach participants. When participants do not respond to any of these contacts at a given timepoint, the specialist will wait until the next scheduled contact to start this procedure again. Calls will be conducted between 09:00 – 17:00 on Monday to Friday. Where the participant is discharged on a day where one of the first three calls would fall on a weekend, the first call will be made on the following Monday.

During the initial assessment, the MTS will obtain the participant's contact preferences (e.g., preferred number, back up number and their preferred time slot for the call between 'normal' working hours). MTSs will contact participants via their chosen medium (voice or telephone call), decided upon during the initial assessment. Should participants choose, they are free to change from one medium to another as many times as needed throughout the intervention. will also be led by participants from the outcome of the pre-discharge evaluation. Participants will be free to amend their choice of delivery mode throughout their participation.

At the pre-discharge evaluation, the MTS should provide the participant with their work mobile number, so they have the details of the MTS who is contacting them. Participants can also contact this number to cancel/rearrange appointments as necessary. If participants select a telephone call (or video call via telephone, e.g., WhatsApp), the MTS will contact the participant via their work mobile. If participants select a video call via a virtual online meeting platform (e.g., Zoom/Skype), the MTS will ask the participant for either their email address or contact number (dependent on preference) so an electronic link can be provided to the web-hosted meeting space, accessible for free to participants.

4.3 Additional patient support elements

4.3.1 Text-based support

Text messaging is an established cessation modality (29) and has been shown to promote smoking cessation in the short-term (30) and long-term (31). Moreover, electronic communication technology can be a viable, time- and cost-saving alternative to interpersonal counselling (32) and text messages can provide an opportunity for semi-tailored information delivery that may be accessed easily, independent of time and place. A text messaging component was selected over a smartphone app for several reasons: (1) the majority of mobile phone owners across most demographic groups use text messaging (33); (2) 80% of mobile users send/receive text messages compared to only 43% who download apps (33), and (3) app installation may feel intrusive, as 57% of app users decline to install apps due to privacy concerns (33).

The text message support will provide motivational and practical information to participants via text message. The aims of the text-based support are to: (1) provide additional support to participants by texting tips to address tobacco norms and challenges encountered; (2) provide additional motivation to participants by increasing self-efficacy and sending reminders about potential financial rewards, and (3) provide a continuation of contact between the participant and the MTS. Text message content will be adapted from a previous intervention (34). This text message content was adapted from Naughton's matrices, which tailors messages to tobacco users' progress in quitting (29). Content for each user group will be tailored according to participant goals. Text message content will be standardised on templates, with options for personalised greetings.

The text messaging schedule and content for those planning to quit or remain abstinent is presented in Appendix 2, and the text messaging schedule and content for those not ready to quit is presented in Appendix 3. If during the behavioural support calls, the participant indicates that they wish to change their goals (e.g., a participant who was initially not ready to quit now wants to plan to quit), the text messaging schedule will begin again starting with the correct text messaging schedule and content for their goals.

Those participants who are planning to remain abstinent or quit will receive text messages which: (1) provide information on personal risk of tobacco use/cessation challenges; (2) provide information on the benefits of remaining smokefree or from quitting; (3) provide

information about second-hand smoke; (4) increase patient's self-efficacy; (5) provide information about relapse prevention and self-efficacy; (6) motivate to use social support for smoking cessation; (7) provide tips for smoking cessation; (8) provide information on rewards for quitting, and (9) provide information about withdrawal symptoms. Those who have not expressed an interest to quit will receive text messages addressing: (1) risk of tobacco use; (2) benefits of quitting; (3) risk of second-hand smoke; (4) possibility of financial reward; (5) tips to replace tobacco use, and (6) patient's self-efficacy.

If during the behavioural support calls the participant indicates that they wish to change their goals (e.g., a participant who was initially not ready to quit now wants to plan to quit), the text messaging schedule will begin again starting with the correct text messaging schedule and content for their goals. Each participant will receive up to 30 text messages for 8-15 days after discharge. The frequency and content of the messages will vary depending on the participants' motivation to quit. Participants remaining abstinent or preparing to quit in the following 30 days post-discharge will receive two messages a day over the course of 15 days. Those not ready to quit will receive two messages a day over the course of 8 days. The decision to send two daily texts was based on a meta-analysis that reported fixed-scheduled messages performed better than decreasing or variable schedules (35).

Messages will be sent by the MTS using a template to construct messages. MTSs will receive brief training in the composition and timing of text messaging according to the schedule. A smart phone will be used to type the message and will register the time the message was delivered. Each MTS will send texts to participants in their designated caseload. Each text message will take approximately three minutes to type and send.

Opting in and out of the optional text-messaging component

Participants will automatically be enrolled into the text-messaging support component unless they express a negative preference during the pre-discharge evaluation. The message protocol used in this study will be unidirectional, but the inbox on each of the MTS's phones will be monitored in case participants do attempt to send a response or wish to opt-out of the interventional component. Participants can opt-out of the texting component at any time without giving a reason by replying 'STOP' to any of the messages or by contacting their assigned MTS.

Participants can opt-out and opt back in at a later date if they wish to do so by contacting their MTS. If participants disclose any information via text that may be a cause for concern or relate to the safety of the participant or any other individual, the MTS will contact a designated relevant healthcare professional.

4.3.2 Moderated peer interaction group

There is strong evidence to suggest that social networks play an important role in an individual's quit attempt (36-40), and our recent systematic review identified all BCTs referring to social support (emotional, practical and unspecified) as 'promising' both in terms of likely effectiveness and feasibility (19). Furthermore, the domain 'social influences' was identified as likely to be a key mediator of the delivery of smoking cessation or temporary abstinence interventions in mental health settings (undergoing peer-review). Therefore, an additional opportunity for peer interaction was selected as an interventional component to provide participants with a forum to reflect on their experiences, share stories with each other, and derive social support from both the MTS and their peers. Participant interest in attending these peer interaction groups will be obtained during the pre-discharge evaluation. However, participants who do not initially express interest can ask to join at a later date (via the tailored support calls), and those who do express interest are not obliged to attend every available session. Participants are able to join as frequently as they wish to do so, without this affecting the delivery of the other interventional components.

The groups will be held at the same time on a four-weekly basis via an online platform (i.e., Zoom or Skype). The meetings will last for a maximum of 60 minutes. The purpose of the group will be to initiate the discussion of reflection of individual experiences, progress and achievement of goals; challenges encountered and solutions to overcome these challenges; individual motivations, and support strategies or services that have worked for each individual. While the group will be primarily participant-led, two MTS's will be present in these groups to support participants, facilitate an open and honest dialogue, and answer any questions or queries that may be raised by participants.

MTSs will receive brief practical training in the facilitation of small groups. It is anticipated that during the pilot, one group in each of the participating Trusts will be formed. Should two or less participants from one or both trusts express and interest in participating in the group, a single joint-trust group will be formed. This hybrid group will be moderated by one MTS from each Trust.

5 RESEARCH AIM AND OUTCOMES

5.1 Aim

This study aims to test the SCEPTRE intervention, manuals, and research materials and processes for fitness of purpose, conceptual and logistic flaws and acceptability to the target population.

5.2 Objectives

The primary objectives of this study are to:

a) Assess the usability of the manual and research measures (relating to smoking status before and during admission, and post discharge, and general mental and physical health).

b) Assess participant and staff acceptability (including interest in participation, consent, and engagement).

c) Obtain feedback from all stakeholders relating to the research participation process and the intervention (as a whole and in terms of single components).

5.3 Outcomes

The primary focus of this study will be 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).

6 STUDY DESIGN

A non-randomised pilot study with measures pre- and post-intervention will be conducted with patients recruited from acute mental health inpatient settings. The design has been chosen in line with MRC guidelines on the development and evaluation of complex interventions. The study will implement the SCEPTRE package (the intervention to be tested). All participants recruited will receive the intervention in addition to usual care.

7 STUDY SETTING

The study will be set within two NHS mental health Trusts in the North of England [Tees, Esk, and Wear Valleys NHS Foundation Trust (TEWV) and Leeds and York Partnership Foundation

Trust (LYPFT)]. To be eligible to participate, NHS mental health Trusts must currently implement a smokefree policy.

There is no restriction on how many wards will be identified for inclusion within each Trust. Due to the high turnover of patients reported by the participating Trusts, this is not anticipated to have an effect on the planned feasibility stage.

8 PARTICIPANTS

8.1. Patients

All patients who report smoking cigarettes or tobacco at least weekly on admission to the included mental health inpatient wards who meet the study inclusion criteria will be eligible to participate. A purposive sampling approach will be used, and we will aim to recruit between eight and 16 participants across two NHS mental health Trusts. Between four to eight patients will be recruited from each Trust.

8.1.1 Inclusion criteria for patients

- Adults aged 18 years and older (no maximum age)
- Present admission to an acute inpatient mental health setting
- Planned discharge to own residence or step-down setting
- 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)
- Patients living in the catchment area of the Trust where they are admitted
- Able to understand and communicate in English
- Able to provide informed consent

8.1.2 Exclusion criteria for patients

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

8.2 Carers

All carers who currently have a relative or friend admitted to the included mental health inpatient wards who meet the study inclusion criteria will be eligible to participate. A purposive sampling approach will be used, and we will aim to recruit between four and eight participants across two NHS mental health Trusts. Between two to four carers will be recruited from each Trust.

8.2.1 Inclusion criteria for carers

- Adults aged 18 years and older (no maximum age)
- Carers, family members or friends of patients who are currently admitted to an acute inpatient mental health setting
- 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)
- Carers, family members or friends of patients who have consented to receiving the SCEPTRE intervention
- 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
- Able to understand and communicate in English
- Able to provide informed consent

8.2.2 Exclusion criteria for carers

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

9 STUDY PROCEDURES

The study procedures are outlined in detail below. A table summarising the schedule of study procedures is provided in Appendix 4.

9.1 Recruitment

9.1.1 Patient Identification

Each included ward will be visited regularly by a Clinical Studies Officer (CSO) to identify potentially eligible patients. The CSO will work closely with the clinical teams and other health care professionals on the wards to anonymously screen admitted patients for potential participants who meet the eligibility criteria. The CSO will approach eligible patients to ascertain their interest in the study and to seek their permission to provide further information on the research.

Ward staff will be encouraged to actively promote the study, for example, in ward community meeting and in interactions with patients. Where ward staff identify potentially eligible participants, staff will contact the CSO for a visit to be arranged. Patients who are identified by the CSO as potential participants, but who are considered to be too unwell for participation at the time identification will be frequently reviewed, so as to allow participation in the study should their mental health allow.

The study will also be promoted on social media platforms (e.g., Twitter accounts belonging to SCEPTRE and participating Trusts). Where patients self-identify through responding to promotional adverts on Twitter, staff will contact the CSO, and a visit will be arranged. The text used for Twitter accounts is presented in Appendix 4.

All patients identified as potentially suitable for the SCEPTRE study will be given a copy of the Participant Information Sheet (PIS), encouraged to discuss their participation with others, and given the opportunity to ask questions to the CSO. Contact details of a member of the SCEPTRE research team are also provided on the PIS, so patients can contact a member of the research team directly if they have further questions. Those indicating interest in participation will be visited by the CSO to screen for eligibility.

9.1.2 Carer Identification

Carers will be identified utilising two methods. Firstly, during visiting times to the ward when the person they are visiting is a participant in the SCEPTRE intervention (ward-based identification) or secondly via the SCEPTRE intervention participant during the post-discharge phase of the intervention (participant-based identification)

9.1.2.1 Ward-based carer identification

Each included ward will be visited regularly by a CSO to identify potentially eligible carers. The CSO will work closely with the clinical teams and other health care professionals on the wards to identify potential participants who meet the eligibility criteria. The CSO will approach eligible carers to ascertain their interest in the study and to seek their permission to provide further information on the research.

Ward staff will be encouraged to actively promote the study, for example, when interactions with carers, relatives, or friends of patients. Where ward staff identify potentially eligible carers, staff will contact the CSO, and a visit or telephone call/video call will be arranged, dependent on individual preference.

The study will also be promoted on social media platforms (e.g., Twitter accounts belonging to SCEPTRE and participating Trusts). Where carers self-identify through responding to promotional adverts on Twitter, staff will contact the CSO, and a visit or telephone/video call will be arranged, dependent on individual preference. The text used for Twitter accounts is presented in Appendix 4.

All carers identified as potentially suitable for the SCEPTRE study will be given a copy of the Carer Information Sheet, encouraged to discuss their participation with others, and given the opportunity to ask questions to the CSO. Those indicating interest in participation will be contacted by the CSO (either via visit to the ward or via phone/video call, dependent on individual preference) to screen for eligibility.

9.1.2.2 Participant-based carer identification

During the post-discharge phase of the intervention, a participant receiving support may indicate they have a carer, family member or friend who is potentially eligible to take part in the study. The MTS will inform a member of the research team, who will seek the participant's permission to contact their carer, family member or friend to provide further information, and ascertain their interest in participation.

Carers identified as potentially suitable for the SCEPTRE study will be given a copy of the Carer Information Sheet (either via post or email, dependent on individual preference), encouraged to discuss their participation with others, and given the opportunity to contact the

researcher to ask any questions. Those indicating interest in participation will be contacted by a member of the research team via phone/video call to screen for eligibility.

9.1.3 Eligibility screening for patients

A CSO will ask potential participants if they smoked at time of admission. The CSO will then make inquiries to establish if participants are a) if they are not smoking at the moment, have they decided or would they consider remaining smokefree once discharged, or b) if they are currently smoking, are they or would they consider cutting down (or continuing to cut down) or quit all together following discharge from the ward. Potential participants will also be asked about concurrent drug or alcohol use, and in the case of female potential participants, questions about pregnancy or breastfeeding.

9.1.4 Treatment of ineligible or non-consenting participants

All ineligible and non-consenting participants will continue to receive usual care.

9.2 Consent

9.2.1 Patient consent

All participants will receive a PIS and prior to obtaining consent. The CSO will go through the PIS with the patient. A full verbal explanation will be given, covering all the elements specified in the PIS. It will be emphasised that the person may withdraw their consent to participate at any time without loss of benefit to which they otherwise would be entitled. These discussions will assure the researcher that the patient is able to provide consent, and to ensure that any risks, benefits, burdens, and rights of participation are understood, and removing the risk of coercion.

For patients who decide to participate, informed consent will be obtained by the CSO, or the clinic staff authorised to do so by the Chief Investigator (CI), as detailed on the study Delegation of Authority and Signature Log for the study site. The patient must personally sign and date the latest approved version of the informed consent form before any study specific, baseline procedures are performed. The consent form will also contain statements in relation to consent to interview for the qualitative aspect of the study.

Participants will provide written informed consent. A form, completed in triplicate, will be completed to indicate consent, and will be signed and dated by both the participant and a

member of the research team. The original copy will be stored at the University of York in the Study Master File, a copy will be included in the participant's clinical notes, and a copy will be provided to the participant.

9.2.2 Carer consent

All participants will receive a Carer Information Sheet and prior to obtaining consent, the CSO or member of the research team will go through the Carer Information Sheet with the carer (dependent on carer identification strategy, outlined in section 9.1.2). A full verbal explanation will be given, covering all the elements specified in the Carer Information Sheet. It will be emphasised that the person may withdraw their consent to participate at any time without loss of benefit to their relative/friend, and this will not affect the delivery of the SCEPTRE intervention to their relative/friend. These discussions will assure the researcher that the carer is able to provide consent, and to ensure that any risks, benefits, burdens, and rights of participation are understood, and removing the risk of coercion.

For carers who decide to participate, informed consent will be obtained by a member of the research team, or the CSO (dependent on carer identification strategy, as outlined in section 9.1.2). In relation to ward-based carer recruitment, consent will be obtained while the carer's relative/friend is still on the ward (at the beginning of the intervention). Therefore, there will be a gap of 12 weeks while their relative/friend receives the intervention before a member of the research team contacts the participant to conduct an interview. The carer must personally sign and date the latest approved version of the informed consent form at the beginning of the intervention. A form, completed in duplicate, will be completed to indicate consent, and will be signed and dated by both the participant and a member of the research team. The original copy will be stored at the University of York in the Study Master File, and a copy provided to the participant.

In relation to the participant-based recruitment method, consent can be obtained by: (1) completing a hard copy of the consent form and returning via post; (2) providing an electronic signature on the consent form and returning via email, or (3) using the telephone consent procedure, whereby potential participants give verbal consent to participate in the post-intervention questionnaires via telephone/video call.

9.3 Withdrawal of participants

A study participant may be withdrawn from the pilot study by the specialist, SCEPTRE researcher or they may choose to do so themselves. If the withdrawal is due to an adverse event, procedures will follow the Standard Operating Procedures (SOPs) for Adverse Events (AEs). Reasons for withdrawal may include pregnancy, admission to hospital for reasons unrelated to the study, attendance at bespoke clinics available as part of their Trust's usual care, or inability to attend pre-discharge evaluation sessions. Relapse to resuming smoking is not seen as reason to withdraw since participants can resume treatment and make several attempts to quit smoking. Where participants lose capacity to consent during their time in the study, they will be withdrawn from further follow up; however, data collected until this point will be retained for use. No further data would be collected, or any other research procedures conducted in relation to the participant. Data will be collected as to the nature of the withdrawal. Withdrawal from the study does not affect the patients' treatment or access to NHS services. Any data collected from the participant prior to withdrawal will still be included in the final analysis of the data.

9.4 Adverse Events and Serious Adverse Events

An adverse event is any unexpected effect or untoward clinical event affecting the participant. It can be directly related, possibly related or completely unrelated to the intervention. It can also be classed according to severity, such that non-serious Adverse Event (AE) includes discomfort or slight worsening of symptoms, or Serious Adverse Event (SAE), which may be particularly harmful, dangerous or require hospitalisation.

9.4.1 Detecting and recording AEs and SAEs

Any adverse events will be recorded at each visit by the MTS or the researcher following the end of study questionnaire/interview visit. All events related and unrelated to the smoking cessation intervention will be recorded on adverse events forms. Any SAEs will be reported to the Programme Manager within 24 hours who will inform the Sponsor and the Research Ethics Committee. Further information may be requested for follow up of these events. Detailed records will be kept of all adverse events.

9.4.2 Evaluation of AEs and SAEs

All adverse events will be evaluated for seriousness, causality, severity and expectedness by the investigator and reviewed by an independent clinician/mental health specialist. All AEs/SAEs judged as having a reasonable suspected causal relationship (e.g. possibly,

probably, definitely) to the study intervention will be considered as an adverse reaction or serious adverse reaction (SAR).

10 TREATMENT OF STUDY PARTICIPANTS

10.1 Baseline data collection

Following consent procedures, patient participants will be asked to complete a suite of baseline data collection documents (see section 11.2). This process will take approximately 30-40 minutes. If required, consent procedures and collection of baseline data can be separated into two visits dependent on participant preference. The participant will then be informed that the MTS will visit them on the ward to introduce themselves and explain the intervention in more detail. This can be arranged on the same day or the next working day, dependent on participant preference and MTS availability.

10.2 Pre-discharge evaluation of smoking behaviour and goal setting

When the MTS visits the participant on the ward, they will undertake the first part of the pre-discharge evaluation. This will enable discussion of the participants smoking behaviour and any previous quit attempts. A measurement of exhaled carbon monoxide (CO) will be taken (see section 11.3). This will fulfil two purposes. Firstly, it will prompt conversations about the harms of smoking and the benefits of smoking behaviour change. Secondly, it will allow for the examination of the acceptability to participants of using exhaled CO monitoring in the context of the coronavirus pandemic.

The second session of the pre-discharge assessment may take place immediately after the first session or on another day depending on the preference of the participant. The second session will explore the participants motivation for changing their smoking behaviour, set goals, and plan with the support of the MTS how to achieve their own behaviour change. The support offered by the SCEPTRE intervention package will be discussed and participants will be able to choose from the optional components offered.

During the pre-discharge evaluation, participants will receive a personalised resource folder (My Try), containing both practical information and motivational content to continue smoking-related behavioural change following discharge (see section 4.2.2 for more detail).

10.3 Post-discharge intervention delivery

To minimise face-to-face contact and reduce the risk of transmission of COVID-19, all participant contact following discharge will take place remotely, either by video call or telephone.

The participant intervention components will be delivered over 12 weeks by the MTS. The MTS will support the participant in addressing their smoking behaviour. Support provided by the SCEPTRE intervention will be in line with best practice guidance relevant to the provision of all NHS Stop Smoking interventions (including for those with mental illness) (3). All participants will remain under the care of their mental health team and GP and will continue to receive their usual NHS treatment.

10.4 Post-intervention data collection

Patient participants will be asked to complete a post-intervention questionnaire with a member of the research team in the week following their final contact with the MTS. The questionnaire will take no longer than 30 minutes to complete. Participants will also be invited to take part in a short semi-structured interview to discuss their experience of participating in the study and receiving the SCEPTRE intervention. Carer participants will be asked to participate in interviews to gain a more in-depth understanding of the acceptability of the study procedures and intervention delivery, as well as the impact of the intervention on their relative/friend. Post-intervention data collection will be conducted remotely, either by video call or telephone, dependent on participant preference.

11 DATA COLLECTION

Data will be collected to assess outcomes related to recruitment, retention/withdrawal, acceptability of study procedures and the intervention (as a whole and as individual components), intervention delivery and fidelity, and feasibility. Data will be collected to reflect both the participant and MTS experience.

11.1 Recruitment

Researchers in each Trust will be asked to keep a record of the frequency of potentially eligible patients approached if they express an interest or their reasons for declining participation.

11.2 Baseline questionnaire

A baseline questionnaire will be administered to participants by the CSO or member of the clinic team (as authorised by the CI). The baseline questionnaire will be separated into three sections: (1) sociodemographic information; (2) mental and physical health status, and (3) smoking-related characteristics pre-admission and during inpatient stay. The questionnaire will take approximately 45 minutes to complete and will also include the measurement of carbon monoxide (CO). The following information will be collected:

- Sociodemographic information: Ethnicity, highest educational qualification, employment status, marital status and accommodation type.

- Mental and physical health:
    - Mental health status: most recent mental health diagnosis, number of mental health admissions in the last 12 months, self-reported mental health state, Recovering Quality of Life (ReQoL-10) (41), Patient Health Questionnaire-8 (PHQ-8) (42), and Generalised Anxiety Disorder 2-item (GAD-2) (43).
    - Physical health status: self-reported physical health state, EQ-5D-5L (44), and body mass index (BMI). BMI will be calculated using measured or self-reported body weight and height.
    - Health service use: frequency of use of health services during participants inpatient stay, and frequency of contact with community-based professionals in the last six months (before hospital admission and during inpatient stay).

- Smoking history and behaviour:
    - Smoking history and behaviour prior to admission: number of cigarettes smoked per day, number of past quit attempts, use of e-cigarettes and NRT.
    - Smoking history and behaviour during inpatient stay: number of cigarettes smoked per day, greatest length of time abstinent during stay, nicotine dependence as assessed by the Fagerstrom Test of Nicotine Dependence (45), level of motivation to quit as assessed by the Motivation to Quit Questionnaire (46) and use of e-cigarettes and NRT.

- Smoking status intention post-discharge: if not currently smoking, plans to remain smokefree post-discharge, or if currently smoking, plans to cut down or quit.

11.3 Exhaled carbon monoxide measurement

Taking carbon monoxide readings is a safe clinical standard procedure, in the process of which participants exhale into a small hand-held measuring device, closing their lips tightly around the mouthpiece. Social distancing, ventilation, and hygiene measures will be strictly observed, and the researcher and participants briefed in advance of the procedure. Individual mouth pieces for the CO monitors will be discarded immediately after use in clinical waste bins and the monitor core piece disinfected with Clinell disinfecting and cleaning wipes. The researcher and participant will be provided with PPE – surgical face masks and plastic gloves. Use of CO monitors on wards may be restricted due to the Covid-19 pandemic. Taking CO readings will, therefore, be determined against local Trust policy. Should participants object to the procedure, this will be noted on the CRF and the reason for non-conducted recorded. Participation in CO monitoring is optional.

11.4 Fidelity of intervention delivery

The MTS will complete a log which will record all contacts with participants (face-to face meetings, phone calls, video-meetings, or text-based conversations), and the research team will judge the degree to which the intervention as designed is actually delivered in practice.

11.5 Withdrawal and being withdrawn, drops out

MTS's will document those participants who withdraw and those who drop-out/are uncontactable.

11.6 Post-intervention data collection

11.6.1 Post-intervention questionnaire

Participants will be asked to complete a questionnaire in the week following their last contact with the MTS. Participants will be contacted by a SCEPTRE Research Officer (based in each of the participating Trusts) and a convenient time and date agreed upon. The questionnaire may be conducted via telephone or video-call with the participant. The post-intervention questionnaire will be separated into two sections: (1) mental and physical health status, and

(2) smoking-related characteristics since discharge. The questionnaire will take approximately 30 minutes to complete. CO monitoring will not be carried out. Each section will include:

- Mental and physical health:
    - Mental health status: self-reported mental health state, Recovering Quality of Life (ReQoL-10) (41), Patient Health Questionnaire-8 (PHQ-8) (42), and Generalised Anxiety Disorder 2-item (GAD-2) (43).
    - Physical health status: self-reported physical health state, EQ-5D-5L (44), and BMI. BMI will be calculated using measured or self-reported body weight and height.
    - Health service use: frequency of use of health services since discharge and contact with community-based professionals in the last six months (since inpatient stay).
- Smoking history and behaviour since discharge: number of cigarettes smoked per day, greatest length of time abstinent since stay, nicotine dependence as assessed by the Fagerstrom Test of Nicotine Dependence (45), level of motivation to quit as assessed by the Motivation to Quit Questionnaire (46) and use of e-cigarettes and NRT).

11.6.2 Qualitative interviews

All participants will be offered the opportunity to take part in a semi-structured interview to explore their experience of taking part in the study and their perceptions of the intervention. Semi-structured interviews will also be conducted with the MTSs to explore their experience and perceptions of delivering the intervention. Participant and MTS interviews will be transcribed verbatim by a member of the research team. During transcription, any personally identifiable data will be anonymised or removed. Audio files will be securely transferred in an encrypted format, and all data will be securely stored on a password protected computer server at the University of York. Audio files will be deleted upon completion of transcription.

Interviews, guided by a schedule of topics developed from the APEASE criteria will examine the process, facilitators, barriers and impacts of the intervention, in order to identify the processes and factors associated with whether the intervention implementation was acceptable. This will allow for future refinement and improvement of the intervention and research processes involved.

12 DATA ANALYSIS

12.1 Quantitative data analysis

Continuous variables will be summarised descriptively using the mean, standard deviation, median, minimum, and maximum. Categorical data will be summarised as counts and percentages. As this is a pilot study, statistical hypothesis testing for effectiveness will not be carried out. No interim analyses will be conducted.

The number of patients screened, eligible, consenting and drop-out/withdrawn, and reasons for ineligibility and non-consent given where possible. All participant and close contact data, along with questionnaire completion rates and adverse event data, will be summarised overall and by Trust, as appropriate.

12.2 Qualitative data analysis

Qualitative feedback will be explored using qualitative content analysis, with a focus on core themes such as acceptability and feasibility of individual intervention components, duration and structure of the overall intervention, and barriers and facilitators to participation and implementation.

13 ETHICAL AND REGULATORY CONSIDERATIONS

13.1 Ethical considerations

We 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 (see Risk Protocol and SOP).

However, we do not anticipate any material ethical issues since we 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. Issues concerning the assessment and management of risk are addressed in the following sections.

Individual participants may benefit from this study directly. Risks and burdens to participants have been considered and mitigated throughout the design phase of the research. Burdens will include questionnaire completion at baseline and post-intervention. In addition, participants will be invited to attend a remote-based interview lasting approximately 30-45 minutes.

Finally, it will cost participants time to complete study procedures although this is believed not to be substantial. Participants will be given as much time as they need to decide whether or not they would like to take part. These risks are explained in the participant in the PIS.

13.2 Assessment and management of risk

13.2.1 Risk assessment

A risk assessment will be carried out by members of the Programme Management Group prior to the start of the study. During the pilot study, ongoing assessments of all aspects of the study will be made by the core research team, and PMG and PSC committees. All participants will receive usual GP and/or mental health specialist care, and no treatment will be withheld/prohibited by participating in this study.

13.2.2 Prescribing and interaction of smoking cessation and certain anti-psychotic medication

Clear guidance on the prescription of stop smoking medications in the presence of SMI (including safety considerations) have been published and will be made available to all participating Trusts if requested. The medication profile of the individual participants will be reviewed by their care team or mental health specialist to assess any potential safety issues (in line with the latest practice guidance on the provision of smoking cessation interventions in the NHS). It is an important aspect of the design of this study that the SCEPTRE team or the MTS will have no direct influence over prescribing decisions by members of the participants mental health team since this not a drug trial or an investigation of a medicinal product.

13.2.3 Suicide and risk of harm

Protocols and SOPs have been developed to identify and manage risks of suicide and harm to participants.

13.3 Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study, a favourable opinion will be sought from an NHS REC for the study protocol, informed consent forms and other relevant documents. Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.

All correspondence with the REC will be retained and the CI will notify the REC of the end of the study. If the study is ended prematurely, the CI will notify the REC, including the reasons for the premature termination. Within one year after the end of the study, the CI will submit a final report with the results, including any publications/abstracts, to the REC.

13.4 Regulatory Review & Compliance

Before any site can enrol patients into the study, the CI or designee will ensure that appropriate approvals from participating organisations are in place.

The Investigator(s) must ensure that source documents and other documentation for this study are made available to study monitors, the REC or regulatory authority inspectors. Authorised representatives of the Sponsor and University of York (UoY) may visit the participating sites to conduct audits/inspections as indicated in the Sponsor's risk assessment of the study. Monitoring of the study will be conducted by the UoY on behalf of the Sponsor according to the study monitoring plan. The extent and nature of monitoring will be determined by the study objectives, purpose, design, complexity, number of patients and sites, and endpoints.

The Sponsor may suspend or prematurely terminate either the entire study, or the study at an individual site, for significant reasons that must be documented (e.g. an unacceptable risk to participants or serious repeated deviations from the protocol/regulations). If this occurs, the Sponsor shall justify its decision in writing and will promptly inform any relevant parties (i.e. participants, investigators, participating sites, REC, regulatory bodies).

A study specific monitoring plan will be developed to outline any monitoring or audit considerations.

For any amendment to the study, the CI or designee, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The CI or designee will work with sites (R&D departments at NHS sites as well as the study

delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

13.5 Amendments

Any changes in research activity, except those necessary to remove an apparent, immediate hazard to the participant, will be reviewed and approved by the CI. Amendments to the protocol will be submitted in writing to the REC and local R&D for approval. Only once approval has been granted will the amended protocol be implemented.

13.6 Protocol compliance

The Investigator should not implement any deviation from the protocol without agreement from the CI and REC and Trust R&D approval, except where necessary to eliminate an immediate hazard to trial participants. In the event that an Investigator needs to deviate from the protocol, the nature of and reasons for the deviation will be recorded in the CRF. If this necessitates a subsequent protocol amendment, this will be submitted to the REC and local R&D for review and approval if appropriate.

13.7 Data protection and patient confidentiality

The research teams at UoY and participating NHS Trusts will comply will all aspects the General Data Protection Regulations (May 2018). All documents will be stored safely in confidential conditions. Any paper forms containing participant identifiable information (e.g. consent to contact form and consent form) will be held in a location separate to the questionnaire data. Identifiable information held by UoY will be stored securely in a locked filing cabinet, in an office only accessible via registered swipe card access held by the UoY research team.

On all study-specific documents, other than the signed consent and consent to contact form, the participant will be referred to by the study participant number/code, not by name. Personal data held electronically, will be stored on the study specific participant management system which will record identifiable information and participant activity to enable study coordination (including personal addresses, postcodes, and other contact details of consenting participants for the purposes of assisting in follow-ups during the study). The study specific participant management system will be developed by the SCEPTRE research team for the purposes of this study. The system will be housed on UoY servers, which are secure and is subject to rigorous testing and continued backup.

Data from qualitative interviews will be transferred onto a secure server at the UoY as soon as possible and data removed from the portable recording device (e.g., audio recorder, laptop) as soon as possible. Transcribers will have a signed confidentiality agreement with the University including a section which acknowledges that any recordings downloaded, or transcript files will be deleted after being sent to the researcher.

13.8 Data security

The research teams at UoY and participating NHS Trusts will comply will all aspects of the General Data Protection Regulations (May 2018). All documents will be stored safely in confidential conditions. Any paper forms containing participant identifiable information (e.g., consent to contact form and consent form) will be held in a location separate to the questionnaire data. Identifiable information held by UoY will be stored securely in a locked filing cabinet, in an office only accessible via registered swipe card access held by the UoY research team. On all study-specific documents, other than the signed consent and consent to contact form, the participant will be referred to by the study participant number/code, not by name. Personal data held electronically, will be stored on the study specific participant management system which will record identifiable information and participant activity to enable study coordination (including personal addresses, postcodes, and other contact details of consenting participants for the purposes of assisting in follow-ups during the study). The study specific participant management system will be developed by the UoY research team for the purposes of this study. The system will be housed on UoY servers, which are secure and is subject to rigorous testing and continued backup.

Data from qualitative interviews will be transferred onto a secure server at the UoY as soon as possible and data removed from the portable recording device (e.g., audio recorder, laptop) as soon as possible. Transcribers will have a signed confidentiality agreement with the University including a section which acknowledges that any recordings downloaded, or transcript files will be deleted after being sent to the researcher.

Data will be archived by the UoY for a minimum period of 10 years following the end of the study. Personal data will be processed under Article 6 (1) (e) (Processing necessary for the performance of a task carried out in the public interest) and Special Category data under Article 9 (2) (j) (Processing necessary for ... scientific ... research purposes) of the General Data Protection Regulation (May 2018).

13.9 Confidentiality of personal data

All information collected during the course of the study will be kept strictly confidential. Personal addresses, postcodes and other contact details of consenting participants will be stored on a secure password protected server located at the UoY, for the purpose of assisting with follow-ups during the study. All personally identifiable participant data will be coded, pseudonymised by unique participant number, in all manual and electronic files.

Access to participant personal data will be required by the research team at the University of York and the MTSs within the participating Trusts during the study. Arrangements for physical storage and confidentiality at the UoY have been previously described. The storage and use of data by MTS's will be on secure, encrypted NHS laptops, backed up on to secure NHS servers. Personal address data will be used to contact the participant for the purposes of delivering the intervention. The PIS and consent form will inform participants of who may hold such data and seek consent for its use.

13.10 Source data

The original copy of the consent form and questionnaire booklet filled out and returned by participants will be treated as source data. Forms and questionnaires will be stored separately in locked filing cabinets in offices at the UoY or participating Trusts, as appropriate. Questionnaire data will be entered on to a study-specific database.

Information provided by MTS's will be in the form of electronic spreadsheets or paper records. Emails from MTS's may also contain source data. Electronic records and emails will be stored on secure drives at the UoY. Paper records will be stored in locked filing cabinets in offices at the UoY.

Source data will be recordings/transcripts and notes from participant or MTS interviews. Electronic records will be stored on secure drives at the UoY, as required. Paper records will be stored in locked filing cabinets in offices at the UoY, as appropriate.

Trackers and logs completed by the MTSs will be source data. Email correspondence and the final pro-forma generated as a result of the patient support sessions will also be source data. Electronic records will be stored on secure drives at the UoY or participating NHS Trusts, as appropriate. Paper records will be stored in locked filing cabinets in offices at the UoY or participating NHS Trusts. Direct access will be granted to authorised representatives from the

Sponsor, host institution, and the regulatory authorities to permit trial-related monitoring, audits and inspections.

13.11 Data storage

After a suitable period, once necessary regular access to the essential documents for queries, etc. passes, the essential documents will be transferred to an approved off-site archive provider. Records will be retained for a period of 10 years, although this may be extended if required by regulatory authorities, funder, or sponsor.

Electronic records will be archived on UoY secure servers with restricted access. Identifiable data and non-identifiable data will be stored separately. Identifiable data, including participant details, will only be accessible by the CI and Programme Manager. Timing of destruction of data will be agreed with the sponsor, and the sponsor must provide written authorisation of destruction in conjunction with approval from CI.

13.12 Indemnity

The Sponsor is Sheffield Health and Social Care Trust. Participants in this study are NHS patients. For indemnity to meet the potential legal liability of the Sponsor/investigators for the harm to participants arising from the management or conduct of the research, NHS indemnity schemes apply.

For insurance and/or indemnity to meet the potential legal liability of the employer for harm to participants arising from the design of the research, University of York indemnity applies.

13.13 End of study

The Investigators and/or the trial steering committee have the right at any time to terminate the study for clinical or administrative reasons. The end of the study will be reported to the REC within 90 days, or 15 days if the study is terminated prematurely. The Investigators will inform participants and ensure that the appropriate follow up is arranged for all involved.

13.14 Access to the final study dataset

Access to the final data set will be restricted to the University of York research team and members of the SCEPTRE Programme Management committee to inform any required revisions before proceeding to a randomised feasibility trial.

14 DISSEMINATION POLICY

14.1 Dissemination policy

The findings of the research will be presented at conferences and will be submitted for publication in relevant peer-reviewed journals and/or relevant conference fora. All activity and findings will be submitted and available via open access in the final report to the NIHR at the end of the study. We will produce a short newsletter summary of the results that can be distributed to all study participants, participating wards and mental health Trusts, as well as the SCEPTRE PPI group.

14.2 Authorship eligibility guidelines and any intended use of professional writers

The SCEPTRE Authorship and Outputs Policy is informed by ICMJE Authorship Guidelines has been developed and approved by all co-applicants and collaborators.

APPENDIX 1: REQUIRED DOCUMENTATION

All local documentation required prior to initiating a participating site (see attached documentation).

Recruitment	
1	Patient Participant Recruitment Poster
2	Carer Participant Recruitment Poster
Consent	
1	Patient Participant Information Sheets
2	Carer Participant Information Sheets
3	Patient Participant Consent Form
4	Carer Participant Consent Form
Intervention Delivery	
5	Intervention Manual
Data Collection	
6	Case Report Form (CRF)
7	Baseline Questionnaire
8	Post-Intervention Questionnaire
9	Patient Participant Interview Topic Guide
10	Carer Participant Interview Topic Guide
11	My Try Specialist Interview Topic Guide
12	My Try Specialist Intervention Log
13	My Try Specialist Recruitment Tracker

APPENDIX 2: TEXT MESSAGE CONTENT – QUIT ATTEMPT

Time	Objective	Message content	
		Text 1	Text 2
Day 1	Introduction	*Hi (name), deciding to quit is a huge step. You should be proud of yourself.*	*We are going to send you a daily text message over the next 15 days to help you to make changes related to your use of cigarettes. To stop these messages, please reply 'STOP' to this text message.*
Day 2	Reminder about the goal	*Hi (name), we are happy to hear you are interested in quitting.*	*Don't forget your goal!*
Day 3	Provide information on risk of tobacco use/cessation challenges	*Hi (name), congratulations for being concerned about your health and trying to quit smoking!*	*Smoking is damaging to your physical health. Keep this in mind to help you quit*
Day 4	Provide information on benefits from quitting	*Hi (name), do you know that people who quit smoking reduce their risk of death from heart attack in half after a year?*	*Improvements in physical activities as well as money savings are other advantages of quitting.*
Day 5	Provide information on second-hand smoking	*Hi (name), people that do not smoke but share spaces at home or at work with smokers are 30% more likely to have lung cancer and 25% more likely to have a heart attack.*	*Congratulations on your decision to change your smoking behaviour, you are also helping people close to you to preserve their health.*
Day 6	Increase self-efficacy (past quit attempts)	*Hi (name), you were able to go [insert number here: obtained from pre-discharge evaluation] days during your hospitalisation without smoking and [insert number here: obtained from pre-discharge evaluation] days in a previous quit attempt.*	*This is a great achievement! Remember what helped you to stay smokefree during that time. This can help you overcome any current difficulties.*
Day 7	Feedback about confidence – increase self-efficacy	*Hi (name), it is great to know you're confident in your ability to stay smokefree.*	*Avoid being around other smokers while they smoke. If that is not possible, practice saying 'no, thank you'. Talk to former smokers and learn how they quit*

Day 8	Relapse prevention and self-efficacy	*Hi (name), it may be hard not to smoke when you are anxious or are at home watching TV.*	*Other activities like reading or gardening can help. Try out those activities, especially during the first few days*
Day 9	Relapse prevention and self-efficacy	*Hi (name), it may help to be smokefree inside the home. Keep in mind that this strategy may help a lot.*	*Changes during the first days are really helpful!*
Day 10	Provide information about social support	*Hi (name), telling close friends or relatives that you are quitting can be very helpful.*	*Try to spend more time with people that support your decisions and who can help distract you from cravings*
Day 11	Provide information about environment changes	*Hi (name), environmental changes are important to help you quit smoking.*	*Make a smokefree space, throw away cigarettes and ashtrays.*
Day 12	Reminder about reward for quitting	*Hi (name), what about saving the money that you spend on cigarettes to buy something for yourself?*	*You can use this money to buy something you want, or buy something for someone special, or even keep it in your savings account*
Day 13	Provide information on withdrawal symptoms	*Hi (name), do not worry if you are craving a cigarette – this is normal.*	*Think about the most difficult moments and make a list of things that could help you keep your hands and mind busy.*
Day 14	Provide information on withdrawal symptoms	*Hi (name), do you still crave a cigarette? Do not worry. Keep your hands and mind busy.*	*We are confident you can make it!*
Day 15	Conclusion	*Hi (name), congratulations on getting this far!*	*This is the last text we will send now, but remember you will still receive your weekly calls. Congratulations again!*

APPENDIX 3: TEXT MESSAGE CONTENT – NOT YET READY TO QUIT

Time	Objective	Message content	
		Text 1	**Text 2**
Day 1	Introduction	*Hi (name), do not worry that you are not ready to quit just yet.* .	*We are going to send you a daily text message over the next 8 days to help you to make changes related to your use of cigarettes. To stop these messages, please reply 'STOP' to this text message*
Day 2	Orientation about risk of tobacco use	*Hi (name), congratulations for being concerned about your health and trying to change your smoking-related behaviours.*	*Smoking is damaging to your physical health. Keep this in mind to help you cut down*
Day 3	Orientation about benefits from quitting	*Hi (name), do you know that people who quit smoking reduce their risk of death from heart attack in half after a year? .*	*Improvements in physical activities as well as money savings are other advantages of quitting*
Day 4	Orientation about second hand smoking	*Hi (name), people that don't smoke but share spaces at home or at work with smokers are 30% more likely to have lung cancer and 25% more likely to have a heart attack.*	*If you decide to change your smoking behaviour, you are also helping people close to you to preserve their health*
Day 5	Orientation about financial reward	*Hi (name), what about saving the money that you spend on cigarettes to buy something for yourself?*	*You can use this money to buy something you want, or buy something for someone special, or even keep it in your savings account*
Day 6	Reminder about tips to replace tobacco use	*Hi (name), it may be hard to plan to quit when you are feeling anxious.*	*Other activities like reading or gardening can help. Try out these activities, they may help to keep your mind and hands busy.*

Day 7	Increase self-efficacy (past quit attempts)	*Hi (name), you were able to go [insert number here: obtained from pre-discharge evaluation] days during your hospitalization without smoking and [insert number here: obtained from pre-discharge evaluation] days in a previous quit attempt.*	*This is a great achievement! You could do this again!*
Day 8	Conclusion	*Hi (name), we hope these texts have helped to build your confidence in changing your smoking-related behaviours.*	*This is the last text we will send now, but remember you will still receive your weekly calls.*

APPENDIX 4: TWITTER CONTENT FOR PROMOTING THE SCEPTRE INTERVENTION

Promotional tweets for patient participants

SCEPTRE account:

We are working with @TEWVresearch and @LypftResearch to recruit people staying in a smokefree mental health hospital interested in staying smokefree, quitting smoking, or cutting down. @SCEPTREresearch aims to provide support to maintain your goals long-term! Please DM for more info!

Participating Trust accounts:

Are you staying at [insert Trust name/ward here]? Are you interested in staying smokefree, quitting smoking, or cutting down? Then, @SCEPTREresearch might be for you! @SCEPTREresearch aims to provide support to help maintain your goals in the long-term. Please DM us for more info!

Promotional tweets for carer participants

SCEPTRE account:

Tweet 1: We are working with @TEWVresearch and @LypftResearch to recruit relatives/friends of those staying in a smokefree mental health hospital interested in staying smokefree, quitting smoking, or cutting down. @SCEPTREresearch aims to provide support to maintain smoking goals long-term!

Tweet 2: If your relative/friend decides to participate in @SCEPTREresearch, we would love to hear from you too. Please DM us for more info!

Participating Trust accounts:

Tweet 1: Is a relative/friend staying at [insert Trust name/ward here]? Are they interested in staying smokefree, quitting smoking, or cutting down? Then, they may be interested in @SCEPTREresearch! @SCEPTREresearch aims to provide support to help maintain your goals in the long-term.

Tweet 2: If your relative/friend decides to participate in @SCEPTREresearch, we would love to hear from you too. Please DM us for more info!

APPENDIX 5: SCHEDULE OF PROCEDURES

Procedure	Screening	Baseline	Pre-discharge	Intervention week												Follow-up
				1	2	3	4	5	6	7	8	9	10	11	12	
Participant identification	■															
Eligibility screening	■															
Informed consent	■															
Demographic data collection		■														
Baseline questionnaire		■														
CO measurement			■													
Intervention delivery			■	■	■	■	■	■	■	■	■	■	■	■	■	
Pre-discharge evaluation			■													
Behavioural support				■	■	■	■	■	■	■	■	■	■	■	■	
Peer interaction group				■	■	■	■	■	■	■	■	■	■	■	■	
Text-message support				■	■											
Log of intervention fidelity			■	■	■	■	■	■	■	■	■	■	■	■	■	
Post-intervention questionnaire																■
Focus groups																■
Interviews																■

APPENDIX 5: AMENDMENT HISTORY

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC.

REFERENCES

1. NHS. Statistics on Smoking, England - 2016 2016 [Available from: https://digital.nhs.uk/data-and-information/publications/statistical/statistics-on-smoking/statistics-on-smoking-england-2016.
2. Richardson S, McNeill A, Brose LS. Smoking and quitting behaviours by mental health conditions in Great Britain (1993-2014). Addict Behav. 2019;90:14-9.
3. Psychiatrists RCo. Smoking and mental health London, UK Royal College of Physicians 2013 [
4. Meltzer H, Gill B, Hinds K, Petticrew M. The prevalence of psychiatric morbidity among adults living in institutions. Int Rev Psychiatry. 2003;15(1-2):129-33.
5. Williams JM, Ziedonis D. Addressing tobacco among individuals with a mental illness or an addiction. Addict Behav. 2004;29(6):1067-83.
6. Cheeseman H, Harker H. The stolen years: The mental health and smoking action report London, UK 2016 [
7. Siru R, Hulse GK, Tait RJ. Assessing motivation to quit smoking in people with mental illness: a review. Addiction. 2009;104(5):719-33.
8. Peckham E, Brabyn S, Cook L, Tew G, Gilbody S. Smoking cessation in severe mental ill health: what works? an updated systematic review and meta-analysis. BMC Psychiatry. 2017;17(1):252.
9. McNally L, Ratschen E. The Delivery of Stop Smoking Support to People with Mental Health Conditions: A Survey of NHS Stop Smoking Services. BMC Health Services Research. 2010;10(1):179.
10. McNally L, Todd C, Ratschen E. The prevalence of mental health problems among users of NHS stop smoking services: effects of implementing a routine screening procedure. BMC Health Services Research. 2011;11(1):190.
11. Knowles S, Planner C, Bradshaw T, Peckham E, Man M-S, Gilbody S. Making the journey with me: a qualitative study of experiences of a bespoke mental health smoking cessation intervention for service users with serious mental illness. BMC Psychiatry. 2016;16(1):193.
12. Peckham E, Man MS, Mitchell N, Li J, Becque T, Knowles S, et al. Smoking Cessation Intervention for severe Mental Ill Health Trial (SCIMITAR): a pilot randomised control trial of the clinical effectiveness and cost-effectiveness of a bespoke smoking cessation service. Health Technol Assess. 2015;19(25):1-148, v-vi.
13. Parker C, McNeill A, Ratschen E. Tailored tobacco dependence support for mental health patients: a model for inpatient and community services. Addiction. 2012;107 Suppl 2:18-25.
14. Taylor G, McNeill A, Girling A, Farley A, Lindson-Hawley N, Aveyard P. Change in mental health after smoking cessation: systematic review and meta-analysis. Bmj. 2014;348:g1151.
15. Wootton RE, Richmond RC, Stuijfzand BG, Lawn RB, Sallis HM, Taylor GMJ, et al. Evidence for causal effects of lifetime smoking on risk for depression and schizophrenia: a Mendelian randomisation study. Psychol Med. 2020;50(14):2435-43.
16. Ratschen E, Britton J, McNeill A. The smoking culture in psychiatry: Time for change. The British journal of psychiatry : the journal of mental science. 2011;198:6-7.
17. Lawn SJ. Systemic Barriers to Quitting Smoking among Institutionalised Public Mental Health Service Populations: A Comparison of Two Australian Sites. International Journal of Social Psychiatry. 2004;50(3):204-15.
18. Brose LS, Simonavicius E, McNeill A. Maintaining abstinence from smoking after a period of enforced abstinence - systematic review, meta-analysis and analysis of behaviour

change techniques with a focus on mental health. Psychological medicine. 2018;48(4):669-78.
19. Shoesmith E, Huddlestone L, Lorencatto F, Shahab L, Gilbody S, Ratschen E. Supporting smoking cessation and preventing relapse following a stay in a smoke-free setting: a meta-analysis and investigation of effective behaviour change techniques. Addiction. 2021;n/a(n/a).
20. Prochaska JJ, Fletcher L, Hall SE, Hall SM. Return to smoking following a smoke-free psychiatric hospitalization. Am J Addict. 2006;15(1):15-22.
21. Mussulman LM, Scheuermann TS, Faseru B, Nazir N, Richter KP. Rapid relapse to smoking following hospital discharge. Prev Med Rep. 2019;15:100891.
22. Michie S, Atkins L, West R. The Behaviour Change Wheel: A Guide to Designing Interventions. UK: Silverback Publishing; 2014.
23. Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. Implementation Science. 2012;7(1):37.
24. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. Ann Behav Med. 2013;46(1):81-95.
25. Gilbody S, Peckham E, Bailey D, Arundel C, Heron P, Crosland S, et al. Smoking cessation for people with severe mental illness (SCIMITAR+): a pragmatic randomised controlled trial. Lancet Psychiatry. 2019;6(5):379-90.
26. Peckham E, Arundel C, Bailey D, Brownings S, Fairhurst C, Heron P, et al. Smoking Cessation Intervention for Severe Mental Ill Health Trial (SCIMITAR+): study protocol for a randomised controlled trial. Trials. 2017;18(1):44.
27. Heron P, McCloud T, Arundel C, Bailey D, Ker S, Li J, et al. Standard smoking cessation services in sites participating in the SCIMITAR+ trial for people with severe mental ill health. BJPsych Bulletin. 2020;44(1):6-11.
28. Hartmann- Boyce J, Hong B, Livingstone- Banks J, Wheat H, Fanshawe TR. Additional behavioural support as an adjunct to pharmacotherapy for smoking cessation. Cochrane Database of Systematic Reviews. 2019(6).
29. Graham AL, Jacobs MA, Cohn AM, Cha S, Abroms LC, Papandonatos GD, et al. Optimising text messaging to improve adherence to web-based smoking cessation treatment: a randomised control trial protocol. BMJ Open. 2016;6(3):e010687.
30. Abroms LC, Ahuja M, Kodl Y, Thaweethai L, Sims J, Winickoff JP, et al. Text2Quit: Results From a Pilot Test of a Personalized, Interactive Mobile Health Smoking Cessation Program. Journal of Health Communication. 2012;17(sup1):44-53.
31. Whittaker R, McRobbie H, Bullen C, Borland R, Rodgers A, Gu Y. Mobile phone-based interventions for smoking cessation. Cochrane Database of Systematic Reviews. 2012(11).
32. Noar SM, Benac CN, Harris MS. Does tailoring matter? Meta-analytic review of tailored print health behavior change interventions. Psychol Bull. 2007;133(4):673-93.

33. Boyles JL, Smith A, Madden M. Privacy and Data Management on Mobile Devices2012. Available from: https://www.pewresearch.org/internet/Reports/2012/Mobile-Privacy.aspx.
34. Cruvinel E, Richter KP, Colugnati F, Ronzani TM. An Experimental Feasibility Study of a Hybrid Telephone Counseling/Text Messaging Intervention for Post-Discharge Cessation Support Among Hospitalized Smokers in Brazil. Nicotine Tob Res. 2019;21(12):1700-5.
35. Spohr SA, Nandy R, Gandhiraj D, Vemulapalli A, Anne S, Walters ST. Efficacy of SMS Text Message Interventions for Smoking Cessation: A Meta-Analysis. J Subst Abuse Treat. 2015;56:1-10.

36. Taylor AE, Howe LD, Heron JE, Ware JJ, Hickman M, Munafò MR. Maternal smoking during pregnancy and offspring smoking initiation: assessing the role of intrauterine exposure. Addiction. 2014;109(6):1013-21.
37. Monden CW, de Graaf ND, Kraaykamp G. How important are parents and partners for smoking cessation in adulthood? An event history analysis. Prev Med. 2003;36(2):197-203.
38. Pisinger C, Vestbo J, Borch-Johnsen K, Jørgensen T. It is possible to help smokers in early motivational stages to quit. The Inter99 study. Prev Med. 2005;40(3):278-84.
39. Kerr S, Woods C, Knussen C, Watson H, Hunter R. Breaking the habit: a qualitative exploration of barriers and facilitators to smoking cessation in people with enduring mental health problems. BMC Public Health. 2013;13(1):221.
40. Johnston V, Thomas DP. Smoking behaviours in a remote Australian Indigenous community: the influence of family and other factors. Soc Sci Med. 2008;67(11):1708-16.
41. Keetharuth AD, Brazier J, Connell J, Bjorner JB, Carlton J, Taylor Buck, E et al. Recovering Quality of Life (ReQoL): A new generic self-reported outcome measure for use with people experiencing mental health difficulties. Br J Psychiatry. 2018;212(1):42-49.
42. Wu Y, Levis B, Riehm, KE, Saadat N, Levis AW, Azar M, Rice DB, Boruff, J, Cujipers P, Gilbody S. Equivalency of the diagnostic accuracy of the PHQ-8 and PHQ-9: a systematic review and individual participant data meta-analysis. Psychological Medicine. 2019; 50:8.
43. Kroenke K, Spitzer RL, Williams KB, Monahan PO, Lowe B. Anxiety disorders in primary care: prevalence, impairment, comorbidity, and detection. Ann Intern Med. 2007;146: 317 - 25.
44. Herdman M, Gudex C, Lloyd A, Janssen MF, Kind P, Parkin D, Bonsel G, Badia, X. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Qual Life Res. 2011;20: 1727 - 1736.
45. Fagerstrom KO, Schneider NG. Measuring nicotine dependence: a review of the Fagerstrom Tolerance Questionnaire. J Behav Med. 1989;12(2):159-82.
46. Crittenden KS, Manfredi C, Lacey L, Warnecke R, Parsons J. Measuring readiness and motivation to quit smoking among women in public health clinics. Addict Behav. 1994;19:497 - 507.