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

Protocol (Version 2.0_30.04.2024)

SCEPTRE Feasibility Study

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Co-Chief Investigators: Associate Professor Elena Ratschen & Professor Simon Gilbody

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This protocol has regard for the HRA guidance and order of content.

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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 trial in compliance with the approved protocol and will adhere to the principles outlined in the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), amended regulations (SI 2006/1928) and any subsequent amendments of the clinical trial regulations, GCP guidelines, the Sponsor's (and any other relevant) SOPs, and other regulatory requirements as amended.

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 clinical investigation without the prior written consent of the Sponsor.

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

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AMENDMENT HISTORY

Amendment Reference	Protocol Version Number	Date	Details of Changes
SA01	2.0	30.04.2024	**Page** — **Revision** 3 — Addition of Lesley Sinclair 4 — Addition of named statisticians Removal of John Hilley Addition of Gregor Russell Removal of Phil Hough Addition of Angie Davis 10 — Inclusion criteria: Clarified wording of 1st inclusion criterion to avoid any misunderstanding; Amended 2nd inclusion criterion to include receipt of unescorted leave and trust discretion for recruiting patients discharged out of area. Exclusion criteria: addition of discharge to a rehabilitation ward or other trust accommodation (to provide clarity for trusts). 11 — Follow-up duration: Revision to accommodate variable second follow-up period Outcome measures: Revision to accommodate variable second follow-up period 12 — Flow chart revised: Inclusion criteria added/amended and outcomes amended in line with p10 and 11 above. 15 — Outcomes were revised to reflect variable follow-up. 20 — Inclusion/exclusion criteria were revised in line with the amendment. 23 — Data collection: Revision of data collection time points to reflect the variable follow-up 24 — Follow-up assessments – core outcome measures: revision to reflect variable second follow-up period. 26-29 — Qualitative interviews – acceptability: Inclusion of intent to conduct qualitative interviews/focus groups with ward staff and trust-based researchers. 33 — Cost-effectiveness analysis: revised to reflect variable second follow-up period. 35 — Corrected – Sheffield is the Data Controller. Removal of 'joint' controller with University of York. 38 — PPI: Removed Phil Hough. Addition of Angie Davis

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1. LIST OF ABBREVIATIONS

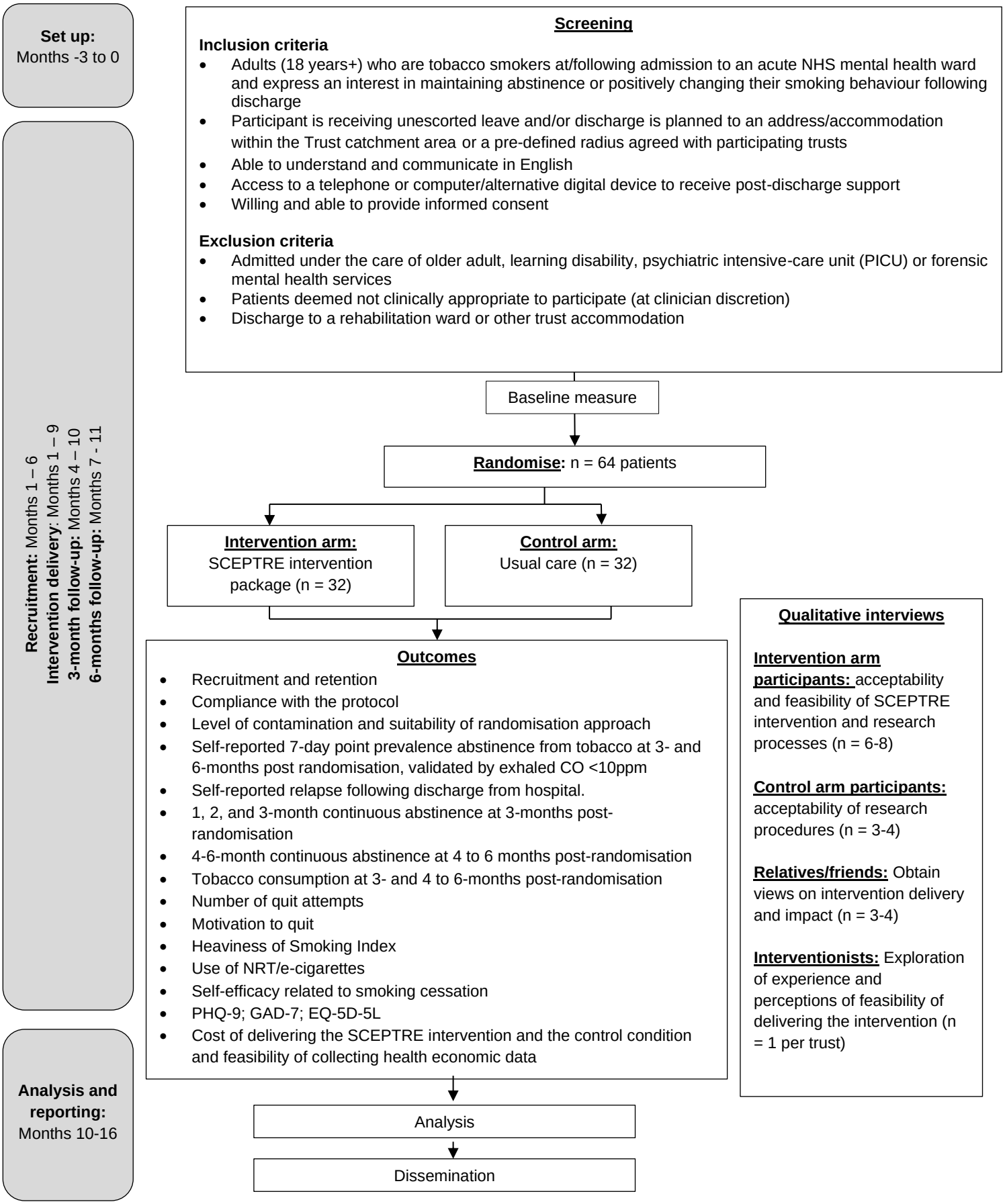
AE	Adverse Event
BMI	Body Mass Index
CI	Chief Investigator
CO	Carbon Monoxide
CRN	Clinical Research Network
GAD-7	Generalised Anxiety Disorder 7-item
GCP	Good Clinical Practice
GDPR	General Data Protection Regulations
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
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 and Care Research
NRT	Nicotine Replacement Therapy
PHQ-9	Patient Health Questionnaire-9
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
SAE	Serious Adverse Event
SHSC	Sheffield Health and Social Care NHS Foundation Trust
SMG	Study Management Group
SOP	Standard Operating Procedure
YTU	York Trials Unit

2. TRIAL SUMMARY

Trial Title	A randomised controlled feasibility study of the SCEPTRE intervention to support smoking cessation and prevent relapse to tobacco following a smokefree mental health inpatient stay
Short title	SCEPTRE feasibility study
Trial Design	Multi-centre parallel-group, individually randomised design - Randomised controlled feasibility study
Objectives	• Address uncertainties related to the delivery of the intervention and the conduct of the research process (including use of research measures), including: ▪ Feasibility and rate of recruitment and retention; ▪ Willingness of participants to be randomised; ▪ Barriers and facilitators to intervention delivery; ▪ Acceptability and compliance with the protocol; ▪ Feasibility to collect outcome measures; ▪ Level of contamination and suitability of the randomisation approach; ▪ Parameters for full RCT design: control group event rate • Obtain feedback from all stakeholders relating to the research participation process and the intervention (as a whole and in terms of single components) and gain an understanding of the importance of individual intervention components and their potential impact. • Estimate the cost of delivering the SCEPTRE intervention and the control condition and the feasibility of collecting health economic data • Based on the above, refine the intervention as indicated in readiness for further testing.
Trial Participants	Inclusion criteria: • Adults (18 years+) who are tobacco smokers at/following admission to an acute NHS mental health ward and express an interest in maintaining abstinence or positively changing their smoking behaviour following discharge • Participant is receiving unescorted leave and/or discharge is planned to an address/accommodation within the Trust catchment area or a pre-defined radius agreed with participating trusts • Able to understand and communicate in English • Access to a telephone or alternative digital device to receive post-discharge support • Willing and able to provide informed consent Exclusion criteria: • Admitted under the care of older adult, learning disability, psychiatric intensive-care unit or forensic mental health services • Patients deemed not clinically appropriate to participate (at clinician discretion) • Discharge to a rehabilitation ward or other trust accommodation
Intervention	SCEPTRE intervention package consisting of components aimed at promoting or maintaining smoking-related behaviour change among patients following discharge from a smoke-free mental health inpatient setting. The intervention will be delivered by trained mental health workers.

Control	Usual care
Planned sample size	64
Treatment duration	12 weeks
Follow up duration	3-months and 4 to 6-months follow-up (post-randomisation)
Planned Study Period	14 months
Outcome measures	• Recruitment and retention • Compliance with the protocol • Level of contamination and suitability of randomisation approach • Self-reported 7-day point prevalence abstinence from tobacco at 3- and 6-months post randomisation, validated by exhaled CO <10ppm • Self-reported relapse following discharge from hospital • 1, 2, and 3-month continuous abstinence at 3-months post-randomisation • 4, 5, and 6-month continuous abstinence at 4 to 6-months post-randomisation • Tobacco consumption at 3- and 4 to 6-months post-randomisation • Number of quit attempts; Motivation to quit; Heaviness of Smoking Index; Use of NRT/e-cigarettes; Self-efficacy related to smoking cessation • PHQ-9; GAD-7; EQ-5D-5L • Cost of delivering the SCEPTRE intervention and the control condition and feasibility of collecting health economic data • Additional qualitative and quantitative measures of acceptability

3. STUDY FLOWCHART



4. BACKGROUND AND RATIONALE

Tobacco smoking remains one of the leading preventable causes of death and disease in England and is responsible for an estimated 74,600 deaths annually (1, 2). Although smoking prevalence of the UK population has steadily declined over the last few decades, prevalence remains at least 50% higher for people with mental health conditions (3). With average smoking prevalence figures of 40%, people with mental illness are more than twice as likely to smoke compared to the UK general population (4), with smoking rates of up to 70% in subgroups, such as hospitalised patients with mental health conditions (4, 5). Combined with high levels of nicotine dependence (6), which results in generally high cigarette consumption, this results in substantially increased risks of premature smoking-related morbidity and mortality in this population (4). Up to 20 life years are lost largely to diseases related to smoking, the biggest contributor to health inequalities (7).

Although people with mental health conditions are able (8) and more likely to be motivated (9) to quit smoking to those without, mainstream stop-smoking services are not commonly accessed by this population (10, 11), and are decreasingly resourced to support the needs of smokers with mental illness for tailored support (12-14). Recently emerging evidence suggests that quitting smoking improves rather than exacerbates symptoms of mental illness (15), and that smoking may be causally linked to the development of mental illness (16). Despite this, smoking until recently remained deeply embedded in the culture of many UK mental health settings (17), where it used to be commonly accepted as a coping mechanism for patients (4, 18). However, 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.

4.1 Rationale

For many mental health patients, a smokefree inpatient stay constitutes a rare or first experience as an adult of sustained abstinence, near-abstinence, or substantial reduction of tobacco consumption (19). Evidence suggests individuals can successfully remain abstinent during their smokefree inpatient stay when behavioural and/or pharmacological support is offered (19, 20). However, where a smokefree stay resulted in temporary smoking abstinence or cessation, the risk of relapse post-discharge is high (21). Relapse to smoking post-discharge often occurs quickly, and most smokers appear to return to smoking on the same day as discharge (22). A lack of support beyond discharge and the almost inevitably resulting relapse or return to heavy prehospital 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.

4.2 The SCEPTRE research programme

The SCEPTRE research programme was designed to develop and test the effectiveness and cost-effectiveness of a complex intervention aimed at promoting or maintaining smoking-related behaviour change among patients following discharge from a smoke-free mental health inpatient setting. The programme is based on the MRC framework for the development

and testing of complex interventions and on the principles of co-production. It includes (1) an intervention development phase, (2) a randomised controlled feasibility study, (3) a fully powered randomised controlled trial (RCT), and (4) a health economic cost-effectiveness analysis. Having co-produced a new evidence and theory-based intervention (20, 23, 24), this protocol outlines the randomised controlled feasibility stage.

5. OBJECTIVES

The overall aim of this study is to determine the feasibility and acceptability of delivering the multi-component SCEPTRE intervention in mental health services.

The primary objectives of this study are to:

1. Identify central parameters for the design of a randomised controlled trial, including:
    a. feasibility and rate of recruitment and retention;
    b. willingness of participants to be randomised;
    c. barriers and facilitators to intervention delivery;
    d. compliance with the protocol;
    e. feasibility to collect outcome measures (including burden on participants);
    f. level of contamination and suitability of the randomisation approach;
    g. control group event rate.
2. Obtain feedback from all stakeholders relating to the research participation process and the acceptability of the intervention (as a whole and in terms of single components) and gain an understanding of the importance and potential impact of individual intervention components.
3. Estimate the cost of delivering the SCEPTRE intervention and the control condition and the feasibility of collecting health economic data.
4. Based on the above, refine the intervention in readiness for further research.

6. TRIAL DESIGN

6.1 Summary of SCEPTRE feasibility trial design

SCEPTRE is a pragmatic, randomised controlled, feasibility trial with adult smokers recruited from NHS acute mental health inpatient settings.

6.2 Outcome measures/endpoints

6.2.1 Outcome measures

This being a feasibility study, a range of quantitative and qualitative data for all participants (intervention and control arm) determining the acceptability and feasibility of intervention delivery and research procedures will be collected, including:

1. Feasibility and rate of recruitment and retention
2. Willingness of participants to be randomised
3. Barriers and facilitators to intervention delivery

4. Compliance with the protocol
5. Feasibility to collect outcome measures (including carbon monoxide measurement and health economic data
6. Level of contamination and suitability of the randomisation approach
7. Self-reported 7-day point prevalence abstinence from tobacco at (3-months and 4 to 6-months) post randomisation, validated by exhaled CO <10ppm
8. Self-reported relapse following discharge from hospital
9. One-months continuous abstinence at 3-months post-randomisation
10. Two-months continuous abstinence at 3-months post-randomisation
11. Three-months continuous abstinence at 3-months post-randomisation
12. Four-months continuous abstinence at 4 to 6-months post-randomisation
13. Five-months continuous abstinence at 5 to 6-months post-randomisation
14. Six-months continuous abstinence at 6-months post-randomisation
15. Tobacco consumption at 3- and 4 to 6-months post-randomisation
16. Number of quit attempts at baseline, 3- and 4 to 6-months post-randomisation
17. Motivation to quit at baseline, 3- and 4 to 6-months post-randomisation
18. Heaviness of Smoking Index at baseline, 3- and 4 to 6-months post-randomisation
19. Use of NRT/e-cigarettes at baseline, 3- and 4 to 6-months post-randomisation
20. Self-efficacy related to smoking cessation at baseline, 3- and 4 to 6-months post-randomisation
21. PHQ-9; GAD-7; EQ-5D-5L at baseline, 3- and 4 to 6-months post-randomisation
22. Cost of delivering the SCEPTRE intervention and the control condition and feasibility of collecting health economic data

6.3 Progression criteria

A decision as to whether the programme should progress to full trial stage will be made based on the following criteria:

Progression criterion	**Target at end of internal pilot**	**Green** (Progression to full RCT without major modifications)	**Amber** (Progression to full RCT may be possible with modifications)	**Red** (Full RCT not feasible)
Participant recruitment	64 Participants recruited	100% (64)	60-99% (38-64)	<60% (<38)
Participant retention (Primary outcome data available at 6 months)	At least 80%	80-100% (51-64)	60-80% (38-51)	<60% (<38)
Trusts enrolled Each Trust expected to provide 1-2 sites/wards (can be more)	8	80-100% (6-8)	60-80% (5-6)	<60% (<5)

Feasibility of collecting carbon monoxide reading (biochemically validated primary outcome measure)	CO reading collected for at least 75% of all participants (intervention and control group) reporting to be abstinent	75-100% (absolute figures to be confirmed)	50-75%	<50

7. TRIAL SETTING

The study will be conducted within up to ten NHS mental health Trusts in the UK. To be eligible to participate, NHS mental health Trusts must have or be starting to implement a smokefree policy that covers inpatient settings (in line with national guidance).

8. TRIAL ARMS

8.1 Trial intervention arm

8.1.1 Intervention development: summary

The intervention development process was guided by the Behaviour Change Wheel model (25) and theoretically underpinned by the Theoretical Domains Framework (26) and the Behavioural Change Technique taxonomy (27). Intervention components were identified and further developed based on two systematic reviews and a Delphi-style consultation process with key stakeholders, including clinicians and patients (20, 23, 24). 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, and members of the SCEPTRE PPI panel.

The SCEPTRE intervention was piloted in a small-scale study to test the manualised procedures, research materials and processes for fitness of purpose, conceptual and logistic flaws, and preliminary acceptability to the target population. Based on the findings from the small-scale pilot study, the intervention has been revised prior to implementation in the current feasibility study. Most notably, the revision included the embedding of the digital Smoke Free Application (app) into the intervention. The main rationale was that the app, including its offer of 24/7 live smoking cessation advisor support, could help bridge gaps in support through the trained mental health workers who deliver the SCEPTRE intervention that may arise in the context of discharges close to/over the weekend and bank holidays (as those delivering the intervention are usually recruited from staff groups that work non-rota-ed 5-day weeks). It was also considered well-aligned with recent national developments, which have seen the roll-out of digitalised smoking cessation support for the general population within the NHS (28, 29).

8.1.2 Intervention delivery

The 12-week intervention consists of components aimed at promoting or maintaining smoking-related behaviour change among patients following discharge from a smoke-free mental health inpatient setting (see Figure 1). These components are summarised in section 8.1.3 and described in detail in Appendix 1.

The intervention will be delivered by trained mental health workers, named ‘My-Try Specialists’ (MTSs). The PPI group decided on the term ‘My-Try Specialist’ (MTS), as it links to the name of the personalised resource folder provided to participants as part of the SCEPTRE intervention, the ‘My-Try Kit’. The MTS role aims to provide patients with tailored behavioural and social support and information to enable the continued change in smoking behaviours following discharge from a smoke-free mental health ward.

Knowledge of evidence-based smoking cessation methods is required, and participants will be expected to have completed the National Centre for Smoking Cessation Training (NCSCT) level 2 module or be willing to undertake the course prior to commencement of the trial. In addition, MTSs will be required to complete the NCSCT mental health online module covering the evidence base for and the delivery of smoking cessation support for people with mental illness, and a bespoke training session covering e-cigarette use and interactions between tobacco smoke and certain antipsychotic medications (e.g., clozapine) in line with Royal College of Psychiatrists guidance (30, 31). MTSs will be provided with training to deliver the manualised SCEPTRE intervention and receive both clinical and procedural supervision on a fortnightly basis throughout the interventional period of the study.

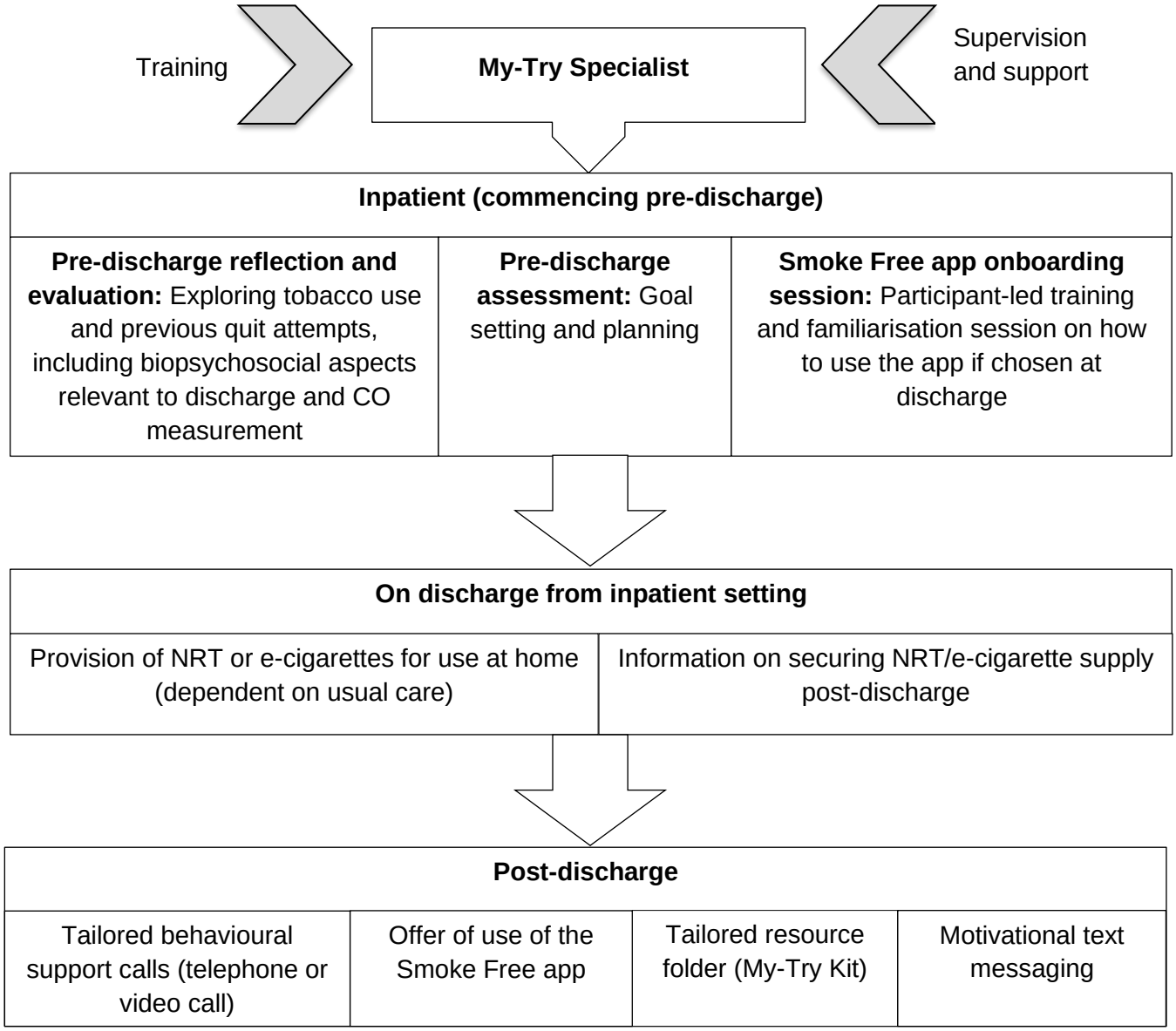


Figure 1. SCEPTRE intervention pathway

8.1.3 Intervention components

A manualised SCEPTRE intervention toolkit/folder will be provided which will contain details of all intervention components. Table 1 provides a summary, and a detailed description of all intervention components is provided in Appendix 1.

Table 1. Summary of individual SCEPTRE intervention components

Intervention component	Core/ additional	Aim	Frequency	Delivery
Pre-discharge reflection, evaluation and goal setting sessions	Core	Provide personalised and tailored support to assist participants in identifying and planning their smoking-related behaviour change goals. Discussions will also determine if participants want to use additional intervention components.	Participant-led; may include up to two sessions lasting up to 45 minutes each	MTS to deliver

Provision of a bespoke and personalised resource folder: My-Try kit	Core	Kit including practical information and motivational content to support participants following discharge.	One kit provided pre-discharge	MTS to provide kit
Nicotine Replacement Therapy (NRT)/e-cigarette selection and advice	Core	To discuss preferences for NRT or e-cigarette support as well as practical advice in relation to using the products and obtaining a longer-term supply.	Discussed during pre-discharge reflection and evaluation session, and MTS will continue to provide advice in behavioural support calls	MTS to deliver
Tailored behavioural support calls (via telephone or video call)	Core	Provide personalised and tailored support, assist the participant in maintaining positive change achieved during their smokefree admission and achieving their behaviour change goals, and provide feedback and encouragement on participant's progress.	Calls lasting 10-30 minutes each for 12-weeks. On the first five days post-discharge, calls will be made daily, and weekly thereafter for the remaining eleven weeks	MTS to deliver
Smoke Free app	Additional	Provide additional support to participants, including its offer of 24/7 live smoking cessation advisor support.	As required	MTS to deliver 'onboarding' session; smoking cessation advisors to provide advice via app
Text-based support	Additional	Personalised text messages to provide practical and motivational information to participants based on their individual goals (Appendix 2 shows example text messages)	15-30 text messages for 8-15 days dependent on goals	MTS to deliver

8.2 Usual care arm

Participants randomised to the control arm will receive usual care. The local offer of smoking cessation support is variable across NHS mental health Trusts. Usual care in some Trusts may be comprehensive and include behavioural and pharmacological support during admission, whereas others may provide limited support (e.g., access to nicotine replacement therapy). Detailed information on what usual care entails on each inpatient ward will be collected. All participants will be provided with information of how to access Stop Smoking Services post-discharge.

9. PARTICIPANTS

9.1 Inclusion criteria

- Adults (18 years+) who are tobacco smokers at/following admission to an acute NHS mental health ward and express an interest in maintaining abstinence or positively changing their smoking behaviour following discharge.
- Participant is receiving unescorted leave and/or discharge is planned to an address/accommodation within the Trust catchment area or a pre-defined radius agreed with participating trusts
- Able to understand and communicate in English
- Access to a telephone or computer/alternative digital device to receive post-discharge support
- Willing and able to provide informed consent

9.2 Exclusion criteria

- Admitted under the care of an older adult, learning disability, psychiatric intensive-care unit (PICU) or forensic mental health services.
- Patients deemed not clinically appropriate to participate in study (at clinician discretion).
- Discharged to a rehabilitation or any other trust accommodation

10. TRIAL PROCEDURES

10.1 Patient identification and screening for eligibility

Participating NHS Trusts will identify all admitted adult smokers from their electronic patient records. A member of the Trust research team will work with the clinical teams and other healthcare professionals on the wards to screen admitted smokers for potential participation who meet the inclusion criteria. A member of the Trust research team will approach eligible patients to ascertain their interest in the study and seek their permission to provide further information about the research. In addition to using electronic records, each included ward will be visited regularly by a member of the Trust research team to ensure potentially eligible patients have not been missed from the initial screening. Approaches of and reasons for not approaching potential participants, will be entered onto a screening log, along with outcomes from eligibility screening.

Ward staff will be encouraged to actively promote the study, for example, in ward community meetings and during interactions with patients (e.g., during pre-discharge assessments and discharge planning). Where ward staff identify potentially eligible participants, staff will contact a member of the Trust research team for a visit to be arranged. Patients who are identified as potential participants but who are considered to be too unwell for participation will be frequently reviewed to allow participation in the study when their mental health allows.

The study will also be promoted on social media platforms (e.g., Twitter accounts belonging to participating Trusts). Where patients self-identify through responding to promotional adverts on Twitter, a member of the Trust research team will visit the ward to screen potential participants for eligibility.

All patients identified as potentially suitable for the 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 the member of the Trust research team questions. 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.

10.2 Informed consent

Consent will be obtained in person or via remote (telephone/video) call. All participants will have received a copy of the PIS at least 24 hours prior to obtaining consent. A member of the Trust research team 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 the standard or type of their usual care being affected in any way. 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. The consent form will also contain optional statements in relation to consent to interview for the qualitative aspect of the study.

Following REC/HRA approval of the recruitment materials, patients who are unable to read will be provided with an audio-recording of the patient information sheet to help facilitate recruitment into the trial. A one-page pictorial decision aid will be created to help patients with literacy problems. For patients who are visually impaired we will also inform them of freely available apps on the Royal National Institute of Blind People website (https://www.rnib.org.uk/) that can help with the reading of materials. Also, if the patient is visually impaired the recruitment materials could be read out aloud by a member of staff or next of kin who would sign the witness box.

There will be a number of options for consent into the SCEPTRE feasibility study.

Option 1: REDCap

Consent will be recorded via paper consent forms, which will be uploaded onto the secure web-based data collection interface 'REDCap' once complete, or via participant e-consent directly within the REDCap system. Informed consent will be obtained by a member of the Trust research team, or clinic staff who has been authorised to do so by the Principal Investigator, as detailed on the study Delegation of Authority and Signature Log for the study site.

Paper consent forms uploaded to REDCap will be accepted as valid if participants place a tick/cross (instead of their initials) in the consent statement boxes, provided that they have printed their name, and signed and dated the form.

The original signed form will be retained at the study site within the Investigator Site File (ISF). A copy of the signed Informed Consent will be given to participants, retained in the participant electronic medical record, and provided to York Trials Unit. Record of e-consent will be emailed to the participant and site for filing (where no participant email address is provided, a copy will be printed and provided to participants).

Option 2: Verbal consent:

Interested patients who are found to be eligible to participate but who have not completed a written or online consent form, will be asked to provide their verbal consent to participate in the study. The process of verbal consent will involve participants confirming to the Trust researcher that they have received the study information, have had the opportunity to ask questions, that they agree to each of the consent statements on the consent form (included in the study information pack they will have received) and that they agree to participate in the study. Study researchers will clearly document this verbal consent to participate in the study to include name and researcher signature and date of participant verbal consent to participate. A copy of this verbal consent will be provided to recruited participants.

10.3 Baseline Assessment

Once participant eligibility has been confirmed and consent has been obtained (as per Section 10.2) a baseline visit will be completed to collect all baseline data (see Section 11.3).

10.4 Randomisation

Following a baseline assessment, randomisation will be undertaken by a member of the Trusts research team using REDCap at the baseline visit. The system will perform independent randomisation 1:1 (Intervention: Control), stratified by recruiting site and use randomly permuted blocks of randomly varying sizes.

10.4.1 Blinding

The allocation schedule will be generated by a statistician at YTU not involved in the recruitment of participants. Due to the nature of the SCEPTRE intervention, the researchers and participants will not be blinded to allocation. The trial statistician conducting the analyses will not be blinded.

Following allocation to a study arm, the researcher will receive an email with the participant's allocation attached. The outcome of the allocation will be communicated to the participant where possible in person but may also be communicated by text or telephone call. In the case of those participants randomised to the intervention arm, information will be provided when the MTS contacts them.

Participants allocated to the control group, who have expressed an interest in changing their smoking behaviour, will be flagged to ward staff to allow for the delivery of usual care.

All participants' GPs will be informed of their allocation by letter. A copy of the GP letter will also be held in the Trust electronic notes, so Community Mental Health Teams (CMHTs) are aware of who is involved in the study.

11. DATA COLLECTION

11.1. General information

Data will be collected either using bespoke case report forms (CRFs) completed electronically via the secure web-based outcome data collection interface 'REDCap', over the telephone with a SCEPTRE researcher, or collected on paper CRFs returned via free post envelopes to York Trials Unit. All reporting of data collection will be undertaken in line with the Consolidated Standards of Reporting Trials (CONSORT) statement (32).

All participants (intervention and control arm) will be followed up for the purposes of the study via self-completed questionnaires at 3 months post-randomisation and, depending on when during the recruitment phase they are randomised, a second follow-up questionnaire will be completed at 4-, 5-, or 6-months post-randomisation. We will ask participants for full contact details at baseline (including mobile phone number, email, and address) and any contact preferences.

At three months and at the second follow-up, a link to complete the relevant electronic questionnaire on REDCap will be sent to participants via email. Participants have the option to be sent a paper copy for postal completion or complete it with a researcher over the phone instead, as preferred. If no response is received within one week, an automated reminder will be sent to the participant. If participants do not respond following the automated reminder, a member of the research team will contact the participant via their preferred contact preference to prompt completion.

11.2. Screening for eligibility assessment

Screening for eligibility will be undertaken by a member of the Trust research team within participating Trusts. All patients screened will be recorded in the eligibility screening log, with reasons for ineligibility and, approach outcomes. Prior to approaching potentially eligible participants, a member of the Trust research team will review patient's electronic or ward-based records to assess for initial eligibility. Patients meeting the eligibility screen will be approached to confirm eligibility for participation in the trial. Patients not meeting the eligibility screen will be added to the screening log with reasons for ineligibility noted.

11.3. Baseline assessment

Following consent procedures, but prior to randomisation, participants will be asked to complete a baseline questionnaire. This process will take approximately 45 minutes. If required, consent procedures and collection of baseline data can be separated into two visits dependent on participant preference.

The following measures will be collected at baseline:

1. Demographic measures (gender, age, marital status, ethnicity, primary mental health diagnosis, smoking status, housing/accommodation status)
2. Mental and physical health measures: The nine-item Patient Health Questionnaire depression scale (PHQ-9) (33), the Generalised Anxiety Disorder 7-item scale (GAD-7) (34), and the quality-of-life scale (EQ-5D-5L) (35), will be included. The presence of co-morbid long-term conditions will be explored. The frequency of use

of health services during the inpatient stay and in the last six months (before hospital admission and during inpatient stay) will also be collected.

3. Smoking history and behaviour: Smoking history and behaviour prior to admission (including number of cigarettes smoked per day, number of past quit attempts, use of e-cigarettes and NRT); smoking history and behaviour during inpatient stay (including number of cigarettes smoked per day, greatest length of time abstinent during stay, nicotine dependence as assessed by the Heaviness of Smoking Index (HSI) (36), Strength of urges to smoke (37) level of motivation to quit as assessed by the Motivation to Quit Questionnaire (38) to assess how motivation changes over time and affects cessation outcomes, and use of e-cigarettes and NRT. Participants will also be asked about their smoking status intention post-discharge.

Participants who self-report they have not smoked will be asked to provide a carbon monoxide (CO) reading. Taking a measurement of exhaled CO 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.

Ventilation, and hygiene measures will be strictly observed, and the researcher and participants briefed in advance of the procedure. Use of CO monitors on wards may be restricted due to local infection prevention and control procedures. Taking CO readings will, therefore, be determined against local Trust policy. However, the small-scale pilot indicated that the use of CO monitors was acceptable to both members of the Trusts research team and participants. Should participants object to the procedure, this will be noted on the CRF and the reason for non-conduct recorded.

Additionally, detailed information on what usual care entails on each inpatient ward will be collected from the Trust PI.

11.4. Follow-up assessments: core outcome measures

All participants will be asked to complete follow-up questionnaires with a member of the research team at 3-months and at 4, 5, or 6-months post-randomisation. Participants will be contacted by a member of the research team and a convenient time and date agreed upon. The questionnaire may be completed electronically, in person or via telephone or video-call with the participant, dependent on self-reported smoking status. This process will take approximately 30 minutes. Where questionnaires are completed in person, the researcher will arrange to conduct these in a suitable location in the community and adhere to local lone working policies.

The following core outcome measures will be collected:

1) Smoking-related measures: Smoking status; 7-day point prevalence abstinence, continuous abstinence, nicotine dependence as assessed by the Heaviness of Smoking Index (HSI) (36), strength of urges to smoke (37), level of motivation to quit as assessed by the Motivation to Stop Smoking Questionnaire (39) to assess how motivation changes over time and affects cessation outcomes, and use of e-cigarettes and NRT since discharge.

2) Mental and physical health measures: The nine-item Patient Health Questionnaire depression scale (PHQ-9)(33), the Generalised Anxiety Disorder 7-item scale (GAD-7)(34), the quality-of-life scale (EQ-5D)(35), will be included. Frequency of use of health services (health economic data) since discharge will also be collected.

During completion of the follow-up questionnaires, participants who self-report that they have not smoked in the previous seven days will be invited to undertake a CO measurement to validate their abstinence from tobacco. Participants who choose not to accept the invitation will be asked to provide a reason for declining and this will be recorded on the questionnaire.

Participants who agree to undertake this procedure will be provided with a range of dates and times by the researcher and asked to confirm a date/time which is convenient for the researcher to visit and collect the reading. Visits may be undertaken at the participant's home, place of work, or another suitable location.

Hygiene measures will be adhered to when collecting the sample of breath and the monitor will be cleaned prior to and after use with each participant. Researchers will be provided with sealable bags to dispose of the mouth pieces and D-pieces, which will then be disposed of. Participants will be contacted by the researcher the day before (or the nearest working day) to confirm the date, time, and location of the visit.

Participants will be offered incentives of up to £30 in shopping vouchers to complete the follow-up measures. The first payment of £15 will be paid on completion of the 3-month data collection period. The second payment of £15 will be paid following completion of the second follow-up questionnaire.

We will review the suitability and definitions of the two-core smoking-related outcome measures, as per current debate in the field (40), as follows:

1. For 7-day point prevalence abstinence, we will review and potentially adjust downward the CO threshold of <10 ppm for biochemical validation, depending on suitability of this approach for our patient population;
2. For the multiple continuous abstinence outcome measures (1 – 6 months), we will review availability and congruency of data and define one consistent secondary outcome measure accordingly.

11.5. Additional qualitative and quantitative measures of feasibility and acceptability

11.5.1. Recruitment and retention

All participants screened will be recorded in the eligibility screening log, with reasons for ineligibility and approach outcomes (outlined in section 11.2). Retention rates will be monitored throughout the duration of the study and the flow of participants will be detailed in a CONSORT diagram.

11.5.2. Compliance with the protocol

In addition to the interviews with MTSs (see section 11.5.4), compliance to the protocol and fidelity of intervention delivery will be optimised through monthly supervision sessions and monitored using self-assessment checklists and logs for MTSs delivering the intervention. The log will allow MTSs to record all contacts with participants, and the research team will judge the degree to which the intervention as designed has been delivered in practice. Any deviations from the protocol will be reported to the York Trials Unit using a protocol deviation log (outlined in detail in section 14.3).

11.5.3. Level of contamination and suitability of randomisation approach

The suitability of the individual randomisation approach will be assessed by using qualitative and quantitative data of control group participants who quit or reduced smoking at 3- and 4, 5, or 6-months post-randomisation. Quantitative investigation will take place in the context of follow-up, to identify and specify smoking behaviour change. Qualitative data will be obtained via interviews (outlined in Section 11.5.4) to investigate reasons for smoking behaviour change and identify potential (unintentional) links with the SCEPTRE intervention. Qualitative exploration, structured by COM-B, will be undertaken with up to ten of control group patients to investigate in depth reasons for smoking behaviour change and identifying potential (unintentional) links with our intervention. Based on our findings, we will estimate the presence/extent of contamination in the control group, and the need to change the unit of randomisation to clusters. If more than 30% of control participants appear to have changed aspects of their smoking behaviour due to factors directly related to our intervention, we will consider strategies to reduce contamination in the full RCT, including the possibility of designing the full RCT as a cluster trial, with wards as the unit of randomisation.

11.5.4. Qualitative interviews exploring additional markers of acceptability and feasibility of research processes and intervention content/delivery

11.5.4.1. Objectives

A variety of additional qualitative (and some complementary quantitative) data will be collected in semi-structured face-to-face interviews or via focus group discussions (FGDs) to:

1) Explore control and intervention group participants' experience of the research process (including burden of completing outcome measures and willingness to be randomised), and perceived barriers and facilitators to processes;
2) For participants in the intervention arm, explore their experience of the SCEPTRE intervention, including uptake of different components and perceived barriers and facilitators;
3) Explore MTSs experiences of delivering the intervention, including the feasibility of and barriers and facilitators to delivery
4) Explore compliance with the protocol and assess barriers and facilitators that may impact fidelity and quality of intervention implementation (in addition to self-assessment checklists outlined in section 11.5.2)
5) Explore the experiences and perceptions of trust-based stakeholders of supporting the conduct of the research.

11.5.4.2. Participants

The study will include patients allocated to the intervention and control arms, carers, and MTSs, and stakeholders.

11.5.4.3. Sampling approach

Sampling to the qualitative study will be purposive (41), with selection based on participant characteristics, including gender, age group, diagnostic category and associated Trust. For participants in the intervention arm, successful and unsuccessful attempts to change smoking behaviours will also contribute to the sampling. Adoption of this selection criteria will enable the identification of a varied sample of participants with a view to developing an in-depth explanation of experiences of intervention delivery and research processes.

Selection to the friends/family interviews will be based on characteristics which promote a variation in sample, for example, the individual's relationship with the participants, age, and smoking status.

Selection to MTS interviews will be based on the personal, professional, and employing trust characteristics, and participant success in achieving sustained smoking-related behaviour change. This will enable an in-depth understanding of the factors influencing delivery of the SCEPTRE intervention and inform how to optimise implementation of the intervention.

Selection to the stakeholder focus groups will be based on professional role and the success of the employing trust in participant recruitment. We will seek to recruit stakeholders from the highest and lowest recruiting trusts, in the first instance to obtain an in-depth understanding of the facilitators and challenges to study delivery and participant recruitment.

11.5.4.4. Data collection

Semi-structured interviews will be conducted by the SCEPTRE research team, using topic guides designed to focus on perceptions and experiences of each interviewee group. The guide will be applied in a flexible manner, allowing the interviewer to follow-up on other cues that may arise during interviews, which will help to capture nuances and reflections expressed in participants' own words and framed in the context of their own experience.

Qualitative interviews with patient participants:

All participants (control and intervention arms) will be invited to take part in a short semi-structured interview (up to 30 minutes in duration) following completion of the SCEPTRE intervention to gain a more in-depth understanding of the acceptability and feasibility of the study procedures. Participants allocated to the intervention arm will be asked to provide feedback on their experience of receiving the intervention. We will aim to interview between nine and 12 participants in total (6-8 participants from intervention arm; 3-4 participants from control arm).

Qualitative interviews with relatives/friends:

Individuals providing informal care and support to participants in the intervention arm will be invited to take part in short semi-structured interviews (up to 30 minutes in duration) at 3-month follow-up to obtain the views of relatives, informal carers or friends on the acceptability and feasibility of the delivery methods of the SCEPTRE intervention. We will aim to interview a total of 3-4 relatives, informal carers, or friends.

The inclusion criteria for relative/friends include:

- Adults aged 18 years and older (no maximum age)
- Relatives or friends who are in regular contact with the participant and therefore able to provide feedback about the SCEPTRE intervention
- Willing and able to understand and communicate in English
- Willing and able to provide informed consent

Qualitative interviews with MTSs:

Semi-structured interviews will also be conducted with one MTS from each of the Trusts in the week following the completion of the final participant in the intervention. Interviews will explore the MTSs experience and perceptions of delivering the intervention, and also assess the fidelity of delivery. Interviews will last approximately 20-30 minutes.

Focus groups/interviews with trust stakeholders

We will aim to recruit between four and six stakeholders to participate in the online focus groups. Each focus group will last between 45 and 60 minutes. Participants will receive a £20 electronic Love to Shop voucher.

11.5.4.5. Data analysis

Interviews and focus groups, guided by a schedule of topics developed from the APEASE criteria will examine the intervention delivery process, facilitators, and barriers of delivering the intervention, as well as the obtaining feedback from intervention arm participants. This will allow for future refinement and improvement of the intervention and research processes involved.

All interviews and focus groups will be digitally audio-recorded (with consent), anonymised and transcribed. The transcripts forming the data for analysis. 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.

Analysis will be undertaken by group, e.g., participants, MTSs, friends/family, Trust stakeholders. Data will be analysed using NVivo software (QSR International Pty Ltd, Melbourne, Australia). First, an inductive approach using thematic analysis will be used to

identify nodes and sub-themes in the data (42). Following this, a deductive approach will be used to chart sub-themes to the APEASE criteria (40).

Transcripts will be coded line by line by two researchers, with preliminary code names assigned to the data items and iteratively developed. Preliminary codes will be checked and discussed with a third researcher, experienced in qualitative research and the behaviour change wheel, and assigned deductively to the APEASE criteria. The data will be presented and discussed in a wider research team meeting to refine and confirm the final interpretation.

11.5.4.6. Rating of intervention components

Participants will also be asked to rate each intervention component. Ratings will be based on participant's satisfaction with each individual component, the perceived value of the component in supporting smoking-related behaviour change, and feasibility of delivery. Ratings will be assigned to each component (1 = low satisfaction; value; feasibility – 5 = high satisfaction; value; feasibility). Information from MTSs self-assessment checklists (outlined in section 11.5.2) will also be considered when calculating a mean rating for feasibility of delivery.

11.5.5. Parameters of acceptability and feasibility of offering the Smoke Free app as an adjunct to the SCEPTRE intervention

In collaboration with the Smokefree App IT team, the following anonymised, patient-unidentifiable data will be reviewed to gain an understanding of app use in the study population.

11.5.5.1 Data collection

Data will be collected on the date of first use of the app by participants, the number of advisor-sessions accessed by participants and the length of each session, and the number of times participants used a particular feature (advisors, quit coach, missions etc.).

11.5.5.2 Data analysis

Data will be summarised descriptively, with no formal analysis being undertaken. Feature engagement and length of time of each advisor-session will be summarised using descriptive statistics (n, mean, standard deviation, median, minimum, maximum).

11.6. Managing participant change of status

Patients will be able to change status and/or withdraw completely from the study at any time without implication. If a patient requests this, the local research team will clarify what aspect of the trial the patient is withdrawing from: for example, withdrawal from SCEPTRE intervention; withdrawal from ongoing data participation/data collection; withdrawal from the

trial in full. However, patients will be encouraged to provide primary outcome data even if they have withdrawn from other aspects of the trial, unless they specifically request to withdraw from primary outcome data collection. Patients who request to change status will be invited to complete a withdrawal form, which will otherwise be completed by the local trial team and sent to the YTU. All participants will be provided with contact details of local and central research teams for queries, etc.

If participants lose capacity after trial enrolment, identifiable data already collected with consent would be retained and used in the study. No further data would be collected, or any other research procedures carried out on or in relation to the participant. We would withdraw the participant from completion of patient questionnaires.

Patients who are readmitted to hospital for their mental health condition during the course of the study will not be automatically withdrawn but offered a discussion with their MTS of their preferences relating to continuing study participation. If choosing to stay enrolled (continuing to receive phone calls and text messages from their MTS), they will be followed up as per protocol and invited to take part in an interview at the end of the study, during which details of the duration of the stay, the smoking-related support received during the stay and the role of the SCEPTRE intervention will be qualitatively explored. Insights from these explorations will inform procedures related to managing re-admissions for a fully powered RCT.

11.7. End of Trial

The end of the trial will be defined as last patient, last visit (LPLV), the date that the last patient reaches the last follow up time point.

12. SAFETY REPORTING

12.1 Risks and anticipated benefits

12.1.1 Adverse Events (AEs)

For the purposes of the SCEPTRE feasibility trial, AEs are defined as any untoward medical occurrence (i.e., any unfavourable and unintended sign, symptom or disease), experienced by a clinical trial participant and which is temporally associated with study treatment (interventions or control) and/or is related to the study intervention or control treatments.

Sites should report adverse events when there is concern and consider this in relation to section 12.2.2 below, and the study team will help to determine relevance.

12.1.2 Serious Adverse Events (SAEs)

A serious adverse event is any untoward medical occurrence that:

- Results in death
- Is life-threatening*

- Requires inpatient hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability/incapacity
- Consists of a congenital anomaly or birth defect

Other ‘important medical events’ may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences.

*NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

All SAEs must be reported immediately (and within 24 hours of knowledge of the event) by the PI at the participating site to the YTU.

12.2 Reporting procedures for (S)AEs

All AEs occurring during the study observed by the investigator or reported by the MTS or participant, will be recorded on the SCEPTRE Adverse Event Form for return to York Trials Unit.

The following information will be recorded: description, date of onset and end date, assessment of relatedness to study intervention and/or procedures, outcome, expectedness, and action taken. Follow-up information should be provided as necessary.

Where repeated adverse events of similar type are observed, these will be discussed with the Data Monitoring and Ethics Committee (DMEC) and will be onward reported should concerns be raised in relation to the type of event and/or frequency observed.

All SAEs will be entered onto the SAE reporting form and sent via REDCap or encrypted email to YTU within 24 hours of the investigator becoming aware of the event. Once received, causality and expectedness will be confirmed by the Chief Investigator (CI) or a medical co-applicant or Programme Steering Committee (PSC) member not acting as a site Principal Investigator (PI). Any change of condition or other follow-up information should be sent as soon as it is available or at least within 24 hours of the information becoming available. Events will be followed up until the event has resolved or a final outcome has been reached.

SAEs that are deemed to be unexpected and related to the trial will be notified to the REC and sponsor within 15 days by York Trials Unit. All such events will be reported to the PSC and DMEC at their next meetings.

12.3 Reporting urgent safety measures

An “urgent safety measure” is a procedure which is not defined by the protocol that can be put in place with immediate effect without needing to gain prior authorisation by the REC, in order to protect clinical trial participants from any immediate hazard to their health and safety.

If any urgent safety measures are taken by an investigator, these must be reported to YTU within 24 hours. YTU will take responsibility for reporting of urgent safety measures to the Sponsor within 1 working day (if not already aware) and the relevant REC if required.

12.4 Suicide and self-harm

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

13. STATISTICS AND DATA ANALYSIS

13.1 Statistical analysis plan

Analyses will be described in detail in a Statistical Analysis Plan (SAP), which will be finalised prior to the end of data collection and reviewed and approved by the independent data monitoring committee. Analyses will be carried under the principles of intention-to-treat. All analyses will be conducted taking into consideration the reporting requirements of the Consolidated Standards of Reporting Trials (CONSORT) (32).

13.2 Sample size calculation

The feasibility study will be conducted across a sample of approximately 12 acute adult mental health inpatient wards of the participating eight Trusts. Based on combined monthly discharge figures of ~200 patients, of which we estimate conservatively that ~140 will be eligible to participate, a smoking prevalence of ~60%, and a conservative estimate of willingness of smokers to take part of 20%, we will aim to recruit a minimum of 64 patients over a minimum period of 4 months, who will be individually randomised, at a 1:1 ratio, to the SCEPTRE or the control intervention. A trial of this size (43) will also allow a participation rate of 15% and completion rate of 80% to be estimated within a 95% confidence interval of ±3% and ±10% respectively (44).

13.3 Statistical analysis methods

A statistical analysis plan (SAP) giving details of the planned analyses will be drafted before data collection has been completed and reviewed by the Trial Management Group and Trial Steering Committee. A brief description of the planned analyses is given below.

The statistical analysis will be carried out by a statistician at York Trials Unit, using Stata v17 or later. The reporting of this trial will follow CONSORT guidelines for pilot and feasibility trials (32). A flow diagram will be produced, depicting the flow of patients through the trial. The number of patients screened, eligible, consenting, and randomised will be summarised, with reasons for ineligibility and non-consent given where available.

Baseline data will be summarised descriptively by randomised group, with no formal statistical comparisons being undertaken (45). Continuous variables will be summarised using descriptive statistics (n, mean, standard deviation, median, minimum, maximum), while categorical variables will be summarised using counts and percentages. Participant outcomes will be summarised descriptively by randomised group and timepoint, including the amount of missing data.

Relevant measures of recruitment and retention will be calculated and compared against the pilot progression criteria. The recruitment rate will be estimated and presented alongside a corresponding 95% confidence interval.

Measures of contamination will be summarised descriptively. For participants randomised to the intervention group, engagement with the multiple components of the intervention will be summarised descriptively.

13.4 Cost-effectiveness analysis

Health economics analysis will be conducted as a preparatory step towards a comprehensive economic evaluation in the subsequent definitive RCT.

We will estimate the costs associated with the delivery of the SCEPTRE intervention and usual care. All resources used in the provision of the intervention, such as the training for the MTSs, the staff time spent on delivering the intervention, and the NRT and e-cigarettes dispensed, will be recorded alongside the trial. We will collect data on the resources used in usual care through self-completed questionnaires at 3- and 4 to 6-months post-randomisation. A micro-costing approach, collecting detailed information about health service use, will be applied to generate estimated intervention costs for both arms by multiplying the quantity of each identified resource by its corresponding unit cost.

We will pilot the data collection tools used to gather health economics data. We will test the feasibility and acceptability of the health service use questionnaire and the outcome measure instrument (i.e., the EQ-5D-5L questionnaire). We will examine the completion rates, identify any challenges or barriers to completion, and make necessary modifications to the questionnaires for use in the full trial. The methods and findings will be summarised in a report that can be used to inform the design and conduct of the economic evaluation in the full trial stage.

14. DATA MANAGEMENT

14.1 Data entry and reconciliation

A member of the research team at University of York and/or local sites will enter data onto the secure web-based REDCap interface. Data will be held securely on a cloud-hosted REDCap server. Access to the study interface will be restricted to named authorised individuals granted user rights by a REDCap administrator at YTU.

The staff involved in the trial (at the sites, MHARG, and YTU) will receive training on data protection. The staff will be monitored to ensure compliance with privacy standards. A detailed Data Protection Impact Assessment (DPIA) for the trial will be developed for approval by the relevant parties.

Data will be checked according to procedures detailed in the trial specific Data Management Plan.

14.2 Data storage and archiving

Each site will hold data according to the General Data Protection Regulations (GDPR) and the Data Protection Act 2018. Data will be collated electronically via the secure online data collection software “REDCap” or paper CRFs and questionnaires in some cases (e.g., where a participant requests completion of a questionnaire in paper form). CRFs will be identified by a unique identification number (i.e., the Trial number) only. A Trial Enrolment Log at the sites will list the ID numbers. YTU will maintain a list of trial numbers for all trial patients at each site.

All YTU data recorded electronically will be held in a secure environment with permissions for access as detailed in the delegation log. The University of York has a backup procedure as part of the University’s Disaster Recovery process for central IT systems, allowing data to be restored in the event of a catastrophic failure. Backups are made on central filestores, and the backup service takes periodic copies of data on the filestores, meaning they can be restored to that point in time if needed. All study files will be stored in accordance with Good Clinical Practice guidelines. Study documents (paper and electronic) held at YTU will be retained in a secure (kept locked when not in use) location for the duration of the trial. Once sites have completed a close out report and this is approved by the Sponsor, they will be instructed to archive their site file and trial data according to their local SOPs.

All essential study documents, including source documents, will be retained for a minimum period of ten years after study completion, in line with the Sponsors’ policy. The separate archival of electronic data will be performed at the end of the trial, to safeguard the data for the period(s) established by relevant regulatory requirements. No archived documents/data will be destroyed without authorisation from the Sponsor.

The electronic data will be stored for a minimum of 10 years in electronic format in accordance with guidelines on Good Research Practice. All electronic records will be stored on a password protected server. All paper records will be stored in a secure storage facility or off-site by York Trials Unit.

Essential documents will initially be stored in the YTU archive room. Once regular access is no longer required, they will be relocated to the YTU approved off-site archive provider, DeepStore Ltd. Permission from the lead statistician will be needed to request access. Electronic records will be stored on an electronic archive drive only accessible by named people.

All work will be conducted following the University of York's data protection policy which is publicly available (Data Protection - Records Management and Information Governance, University of York).

14.3 Participant confidentiality and data protection

The researchers and clinical care teams must assure that patients' anonymity will be maintained and that their identities are protected from unauthorised parties. Patients will be assigned a Unique Trial Number, and this will be used on CRFs; patients will not be identified by their name in order to maintain confidentiality.

Data will be processed in accordance with the General Data Protection Regulations (GDPR) and the Data Protection Act 2018. All records will be kept in secure locked locations. All consent forms will be securely stored on password protected, authorised access only, servers and/or in a secure locked cabinet. Clinical information will only be accessed by responsible individuals from the study team, the Sponsor, the NHS Trust, or from regulatory authorities; where it is relevant to the patient taking part in this research as he/she would have agreed to at the time of consent.

Sheffield Health and Social Care NHS Foundation Trust will be the data controller. Documents/data will be stored for a minimum of 10 years after trial completion.

14.3 Reporting Protocol Deviations and Breaches

Any deviations from the protocol will be reported to York Trials Unit using a protocol deviation log. Details of corrective and preventative actions will be recorded to mitigate the deviation and prevent recurrence.

Any deviation from the protocol which is like to effect to a significant degree either:

i. the safety or physical or mental integrity of the participants of the trial; or
ii. the scientific value of the trial

will be considered a serious breach and will be reported to YTU within 24 hours of being made aware of the breach. YTU will take responsibility for reporting of serious breaches to the Sponsor within 1 working day (if not already aware) and the relevant REC if required.

15. QUALITY CONTROL AND ASSURANCE

15.1 Programme Management Group

A Programme Management Group (PMG) has been established to oversee the day-to-day management (e.g., protocol and ethics approvals, set-up, recruitment, data collection, data management) of the study, and is chaired by the CI. Membership will include the co-CIs, co-investigators, research staff on the project and PPI representation. The role of the PMG is to monitor all aspects of the conduct and progress of the trial, ensure that the protocol is adhered to and take appropriate action to safeguard participants and the quality of the trial itself. Throughout the project there will be regular videoconference contact supplemented by face-to-face meetings where required. Frequency of meetings will vary depending on the stage of the trial but at least monthly during the early stages and pilot.

15.2 Data Monitoring and Ethics Committee

The study will be regularly reviewed by the independent Data Monitoring and Ethics Committee (DMEC) composed of independent clinicians and health service researchers with appropriate expertise. The DMEC will meet at least twice per year.

The DMEC will provide project oversight to the trial. This will include monitoring safety and efficacy data as well as quality and compliance data and ensuring that the protocol is accurately followed, and the study is GCP compliant. The committee will recommend whether there are any ethical or safety reasons why the trial should not continue. The reporting relationship between the DMEC, PSC, and PMG is shown in Figure 2. The independent members of the DMEC committee will be allowed to see unblinded data.

The DMEC will meet at least bi-annually or more frequently if the committee requests. The minutes/records of these meetings will be stored at YTU and will be shared with the sponsor on a routine basis.

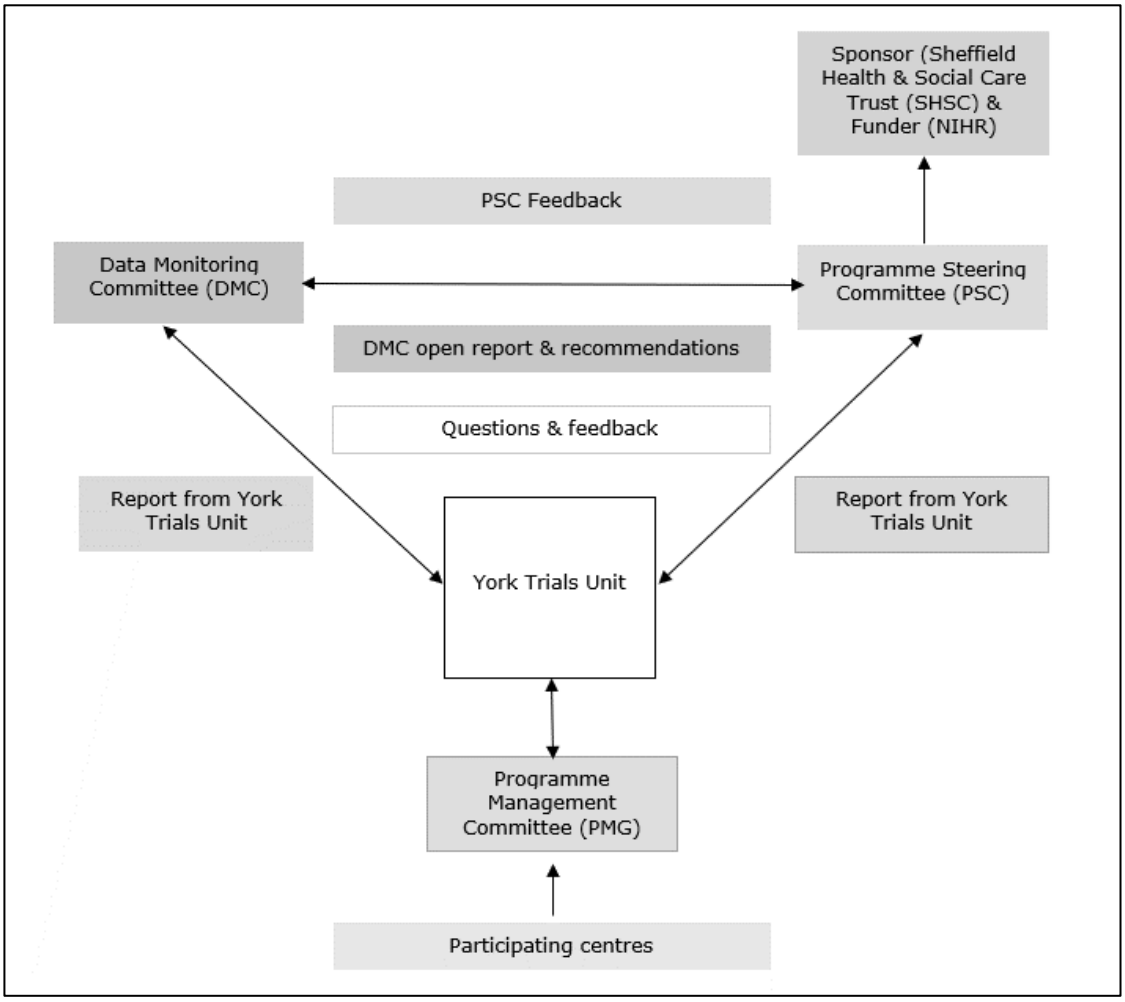


Figure 2. Reporting relationship between committees, the Sponsor, York Trials Unit, and participating sites

15.3 Programme Steering Committee (PSC)

An independent PSC has been established to provide overall independent oversight for SCEPTRE on behalf of the Sponsor and Project Funder and to ensure that the project is conducted to the rigorous standards set out in the Department of Health's Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice. The PSC will meet routinely during the trial and will monitor the progress of the trial and provide independent advice. Amongst its members are an independent chair, statistician, and lay member with lived experience of mental illness. A Sponsor representative will also be invited to attend the PSC meeting.

16. MONITORING, AUDIT & INSPECTION

YTU will develop a Trial Monitoring Plan which will be agreed by the Sponsor, PMG, PSC and CIs based on the trial risk assessment. No routine on-site monitoring will take place, however regular central monitoring will be performed according to GCP and the SCEPTRE Monitoring Plan. Data will be evaluated for compliance with the protocol and GCP and the applicable regulatory requirements.

17. ETHICAL AND REGULATORY CONSIDERATIONS

17.1 Ethics and approvals

We will adhere to the UK Framework for Health and Social Care Research (32, 45). The PIS for the study will be developed with the involvement of service users and our PPI/PAG groups and will give a balanced account of the possible benefits and known risks of the interventions. It will state explicitly that quality of care will not be compromised if the participant decides to a) not enter the trial or b) withdraw their consent. We will make it clear that there is no obligation to participate. Written informed consent will be obtained from all participants after they have had sufficient time to read the study materials and ask questions. An application for ethical approval will be made in set-up, which will include all participant documentation. We do not anticipate major ethical concerns with this study.

We will seek national Health Research Authority (HRA) & Research Ethics Committee (REC) approval via the Integrated Research Ethics Application System (IRAS) system for the study. The local R&D departments of participating hospitals will approve their involvement in the trial. The trial will be subject to DMEC oversight. The trial manager/CI will submit and obtain approval from the above for all substantial amendments to the original approved documents.

17.2 Amendments

Once the PMG has agreed that an amendment is necessary, the amendment will be made to the required documentation and the HRA amendment tool completed. This tool will confirm the category of the amendment. Once Sponsor authorisation has been confirmed, YTU will submit and, where necessary, obtain approval from the Research Ethics Committee (REC), Health Regulatory Authority (HRA) and host institution(s) for approval of all substantial amendments to the original approved documents. Once approvals are received, the new documents/versions will be shared with sites and the study version control log will be updated for sites to check they are using only the most recent versions of trial documents.

17.3 GCP/Declaration of Helsinki

The Investigators will ensure that this study is conducted in full conformity with current regulations, the current revision of the Declaration of Helsinki, and with the principles of Good Clinical Practice.

18. PATIENT AND PUBLIC INVOLVEMENT (PPI)

The Study is supported by the SCEPTRE co-applicants Simon Hough and Angie Davis. In addition, a SCEPTRE PPI group has been formed. The SCEPTRE PPI group comprises individuals who have experience of admission to a smokefree mental health setting, and who are themselves former or current smokers, or relatives/friends of smokers or ex-smokers who have had experience of admission to a smokefree mental health setting. The PPI group 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.

19. FINANCING AND INSURANCE

19.1 Finance

The SCEPTRE Feasibility Trial is funded by Programme Grants for Applied Research (NIHR200607). The financial arrangements for the study will be as contractually agreed between the funder, the University of York and the Sponsor (Sheffield Health and Social Care NHS Foundation Trust).

19.2 Indemnity

Normal NHS Indemnity procedures will apply. The University of York will also provide relevant cover.

20. DISSEMINATION AND PROJECTED OUTPUTS

20.1 Authorship eligibility guidelines

Authors for any publications deriving from this protocol will be required to meet the International Committee of Medical Journal Editors (IJCMJE) defined authorship criteria for manuscripts submitted for publication. All key protocol contributors will be provided the opportunity to fulfil IJCMJE author criteria.

Details of planned publications and requirements for authorship are detailed in a publication plan.

21. ACCESS TO DATA

A statement of permission to access source data by study staff and for regulatory and audit purposes will be included within the patient consent form with explicit explanation as part of the consent process and Participant Information Sheet.

In principle, once YTU has completed the analysis and completed all intended outputs, anonymised data will be made available upon reasonable request. Requests for access to data will be reviewed by the Chief Investigator, TMG and study Sponsor.

The Investigator(s)/Institutions will permit monitoring, audits, and REC review (as applicable) and provide direct access to source data and documents.

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23. APPENDIX

Appendix 1. Detailed overview of SCEPTRE intervention components

(1) Pre-discharge reflection and evaluation sessions

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. The initial goal setting sessions will be participant-led and may include up to two 45-minute sessions.

The MTS will meet with the participant prior to discharge and initiate a discussion concerning (1) reflections on their experience and impact the smokefree ward has had on their previous smoking behaviour and exploration of intentions for maintaining and/or building on their progress so far; (2) plans and goal setting for preventing relapse, cigarette reduction or a quit attempt with special consideration of psychosocial factors that may be relevant after discharge (e.g., home environment); (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) for maintaining smoking behaviour change, 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 in line with NICE guidance NG209 (46). Information on interactions between hydrocarbon agents in tobacco smoke and drug metabolism will also be provided, in line with NICE guidance NG209 and Trusts' usual care approach.

Discussions will also determine if participants want to use other intervention components, specifically the 'My-Try' kit, the Smoke Free app, text-based support, and the moderated group session (outlined in more detail in the following sections). It will be highlighted that these additional components can be used at any point during the 12-week intervention, even if participants decline at this time point. Participants can opt-in (or opt out) by informing their MTS.

(2) Provision of a bespoke and personalised resource folder: My-Try Kit

A personalised resource kit was developed to address participants' needs regarding both practical information and motivational content to continue smoking-related behaviour change following discharge from an inpatient setting.

Core materials in the My-Try kit include: (1) a copy of the participant's behaviour change plan; (2) information relevant to both the general and mental health experience of quitting or changing smoking behaviours, and (3) journal pages for reflection. Additional materials can also be included, such as: (1) information on creating smokefree homes; (2) financial trackers of money saved, and (3) an activity planner to schedule activities during the week. If participants opt to receive the 'My-Try' kit, they will receive a presentation and 'walk-through' of the kit during the pre-discharge sessions.

(3) Nicotine Replacement Therapy (NRT)/e-cigarette selection and advice

During the pre-discharge reflection and evaluation sessions, the MTS will discuss participant preferences for NRT or e-cigarette support as well as provide practical advice in relation to using the products and obtaining a longer-term supply in the future. The MTS will continue to provide advice in subsequent behavioural support calls.

(4) Tailored behavioural support (via telephone or video call)

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 unmet, the MTS will collaborate 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 My-Try Kit (if the participant opted to receive this), or storage on a personal device.

Once discharged, participants will be offered individual telephone or video-call behavioural support sessions, lasting between 10 and 30 minutes approximately for the duration of the 12-week intervention, delivered by MTS. On the first five days post-discharge, calls will be made daily, and weekly thereafter for the remaining eleven weeks. Participants will receive a reminder text prior to scheduled calls. Three attempts will be made at each timepoint to reach participants. Should participants not respond to these contacts, the specialist will wait until the next scheduled contact point to start this procedure again. Calls will be conducted between 08:00 – 18:00 on Monday to Friday. When a participant is discharged on a weekend, participants will be made aware that they are able to contact a smoking cessation advisor via the Smoke Free app, should they wish to obtain support when the MTS is unavailable. The MTS will contact participants on the first working day following their discharge from the hospital. Where participants are unable /unwilling to use the app, the first call will be made by the MTS on the next working day.

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

The MTS will 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.

(5) Smoke Free app

The Smoke Free app is an evidence and theory-based smartphone app which includes Behaviour Change Techniques that research suggests are likely to improve the chances of quitting (outlined in detail in section 8.1.1). If participants opt to use the app, they will be offered a Smoke Free app training and familiarisation session prior to discharge.

Smoke Free app training and familiarisation session

This component, delivered by the MTS, aims to support patients in downloading and navigating the Smoke Free app. It will also include the delivery of guidance around app use and 24/7 live advisory support. The onboarding session will be participant-led and last up to 60 minutes, dependent on participant needs. Prior to taking part in this session, participants will be asked to ensure their smartphones are charged.

The MTS will provide information on the rationale for including the app within the SCEPTRE intervention and the potential benefits of using the app. The MTS will support the participant to download the app by providing a link or QR code, dependent on participant preference. The MTS will then outline a user-friendly terms and conditions document that covers the key points in relation to data protection. Where required, the MTS will assist the participant to create an account based on the information provided during the pre-discharge reflection and evaluation session. For example, goals and motivations to change smoking behaviour should be transferred to the app. The MTS will demonstrate key features of the app, personalisation, and general navigation guidance. Participants will be given a practice task to familiarise themselves with the app and its functions before discharge. Upon completion of the session, participants will be provided with an information resource pack and informational videos will be emailed to the participant for further support in-app use and navigation to refer to in their own time. The videos will include a series of short 1–2-minute clips developed by the app team to assist with various app elements. For example, how to input a quit date, personalise the dashboard, navigate to favourite features, and use the 24-hour smoking cessation advisor function. Throughout the onboarding session, the MTS will adopt a guided approach to promote autonomy, rather than a step-by-step instructional demonstration. Participants will have the opportunity to ask any questions throughout the onboarding session.

(6) Text-based support

Text messages sent by MTSs will provide motivational and practical information to participants. 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. The text message content will be adapted from a previous intervention (34). This text message content was adapted from Naughton's matrices, which tailor messages to tobacco users' progress in quitting (47). Content for each user group will be tailored according to participant goals (those planning to quit or remain abstinent, those not ready to quit).
The text message content will be standardised on templates, with options for personalised greetings and information obtained from the pre-discharge reflection and evaluation session. If, during the behavioural support calls, participants indicate 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.

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

Appendix 2. Example text-messages

Participants aiming to cut down to quit

Day 2

Text 1: Hi [name], congratulations for being concerned about your health and trying to change your smoking behaviour.

Text 2: Smoking is damaging to your health. Keep this in mind to help you cut down.

Day 5

Text 1: Hi [name], what about saving the money that you spend on cigarettes?

Text 2: You can use this money to buy something for yourself, or even keep it in a savings account.

Participants aiming to remain abstinent

Day 6

Text 1: Hi [name], you were able to go [insert number of days obtained from pre-discharge assessment] days while in hospital without smoking and [insert number of days/weeks obtained from pre-discharge assessment] in a previous quit attempt.

Text 2: This is a great achievement! Remember what helped you to stay smokefree during that time. This can help you overcome any current difficulties.

Day 14

Text 1: Hi [name], do you still crave a cigarette? Do not worry. Keep you hands and mind busy.

Text 2: We are confident that you can make it!