A randomised controlled feasibility trial of a tailored digital behaviour change intervention with e-referral system to increase attendance at NHS Stop Smoking Services: The MyWay Project

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1. Project Lay Summary

Smoking is a leading cause of death and disease and costs the NHS billions each year. Most smokers want to quit and getting support from publicly funded stop smoking services (SSSs) means they are four times more likely to do so than when they attempt to stop alone. Although around one in every five people is a smoker, SSSs only ever reach around 5-10% of them and numbers attending SSS have been in decline in the last few years. We know that smokers experience lots of barriers to service access that are never addressed (e.g. feeling that they shouldn't need help to stop smoking). With continued pressure on public health funding, it is important to reach and support those most motivated to stop smoking to access available support, so that services can maximise success. It is also important to reach those most likely to experience poor health because of smoking. The 'StopApp', which was designed with help from a group of smokers and ex-smokers, aims to do this. StopApp is a brief, web-based support tool designed to be easily accessible and usable by smokers. It deals with people's barriers to SSS access and allows people to instantly book a SSS appointment, at a time and location to suit them, with text message and email confirmation and reminders. A future trial of this intervention could seek to find out if StopApp is successful at improving SSS bookings and attendance, but there is uncertainty about how easy it would be to recruit people and collect information from them, who would be willing to take part and the best locations to find them. A feasibility (small-scale test) trial is therefore proposed – the MyWay project.

MyWay project procedure: All smokers aged over 16 years will be identified from 4 GP practices, and invited to take part. We will also invite smokers encountered in a range of community settings (e.g. pharmacies, children's centres, libraries) and via online recruitment methods to access the study website. Participants will complete questions about age, gender, current smoking status, previous use of SSS, use of e-cigarettes, pregnancy status (if female) and motivation to stop. Smokers will be randomly allocated to one of two groups. The usual care (control) group will be asked to read an online leaflet about SSS. The intervention group will be asked to use the StopApp. Participants in both groups will be told they can book an appointment at a SSS, but that they are under no obligation to do so. At follow-up (2 months from the first invitation) questionnaires will be emailed to all participants to confirm smoking status, whether they booked and attended an appointment, set a quit date and reached a 4-week period of not smoking, confirmed by the individual SSSs. Other information to be collected includes: health and financial costs and benefits of the intervention; and participant ethnicity, socio-economic status, and number of cigarettes smoked. StopApp has been developed with input from smokers and ex-smokers, some of whom have used SSS, to ensure it is engaging and uses the right language. They have tested the app, provided input into the study design and recruitment; and will develop research materials, and contribute to reports of findings for organisations such as Public Health England, Action on Smoking and Health (ASH) and local authorities. We will also publish the study design and findings in an academic journal and at conferences.

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2. Trial Background information and Rationale

Smoking remains a leading cause of mortality and morbidity worldwide (ASH, 2015). It is the leading cause of preventable death and disease in the UK, accounting for 100 000 deaths per annum (ASH, 2014). In addition, the direct costs of smoking to the NHS have been estimated at between £2.7 billion and £5.2 billion, which is equivalent to around 5% of the total NHS budget each year (Ekpu and Brown, 2015). Stop smoking services (SSSs) provide free and tailored support to help people stop smoking, with the use of pharmacological and behavioural interventions. The services are available to smokers over 12 years of age, including those who are pregnant. The effectiveness of SSSs is judged by the number of smokers who set a quit date and are abstinent from smoking four weeks later, verified as standard by Carbon Monoxide (CO) testing (DH, 2011). Four-week quit rates have been shown to be a reliable predictor of long-term abstinence, with studies showing that collecting further follow-up data at 6 months provides only a modest increase in accuracy (NCSCT, 2014). Based on these measures, smokers who attend SSSs have been found to be four times more likely to quit smoking, than those who attempt to quit alone (West, 2012).

Although most smokers want to quit, and between 22 and 31% of them will make at least one attempt to quit each year (HSCIC, 2014), SSSs currently only reach 5-10% of the smoking population (Dobbie et al., 2015). In addition, despite the effectiveness of SSSs (HSCIC, 2014), relative to the number of smokers, uptake has declined in recent years (Kmietowicz, 2015). This may be explained in part by the recent proliferation of electronic cigarettes (EC) leading people to switch to these instead of quitting smoking or instead of accessing support to quit. However, 95% of SSS practitioners have encountered clients that use EC, suggesting that smokers do not view SSS use and EC as mutually exclusive (Beard et al., 2014). A third of smokers in England have used EC at least once (Brose et al., 2015), and whilst their use is associated with significant reductions in numbers of cigarettes smoked (Brose et al., 2015) this has not led to an overall rise in quit attempts (West and Brown, 2015). Therefore, SSSs are still needed to support quit attempts. Because some EC have recently become regulated, there is now an opportunity for SSSs to integrate this option into the range of nicotine replacement therapy (NRT) they offer. As with other types of NRT (Kotz et al., 2013), the effectiveness of EC in supporting quit attempts is likely to be enhanced with behavioural support from SSSs, and the proliferation of EC need not inhibit SSS access if smokers are aware that services will support their use.

Between 1999 and 2010 in the UK, the Government funded a number of mass media tobacco control campaigns (focussing on the harms of smoking to promote quitting and uptake of SSSs). Suspension of these costly campaigns in 2010 provided an opportunity for a natural experiment to assess the impact they had on behaviour associated with quitting smoking (Langley et al., 2014). Whilst quit line calls, smoke-free web hits and requests for cessation support packs decreased dramatically, there was no effect on attendance at SSSs (Langley et al., 2014). It is therefore unlikely that reintroduction of such campaigns would be an effective intervention for addressing the decline in SSS uptake, and innovative cost-effective approaches to increase SSS uptake are instead required.

Internet based interventions have considerable potential for providing innovative and cost-effective health promotion solutions but concerns are often raised about their potential for disproportionately improving outcomes for those from higher socioeconomic status (SES) groups. Given that smoking contributes considerably to the issue of health inequality (Jha et al., 2006), such concerns require particular attention for online smoking interventions. Research suggests that smokers from lower SES groups *are* being reached by SSS (Kotz and West, 2009)

however variation exists across services (West et al., 2013a). Smokers from the lowest SES groups are half as likely to successfully quit as those from the highest SES grouping, even though they are at least as motivated to quit as those with high SES (Kotz and West, 2009). This significantly increases the chances of poor health outcomes caused by smoking for many of the most vulnerable groups in society (Jha et al., 2006). Interventions designed to address smoking-related behaviours need to ensure that the health inequalities, and where possible, social and environmental inequalities (e.g. access to support and services; presence of smoking in the environment) associated with this issue are addressed. Concerns about the health equity associated with web and app based interventions may not be fully warranted however. Recent research found that a web-based smoking cessation intervention that engaged lower SES groups in development was *only* effective at supporting smoking cessation in lower SES groups in a randomised controlled trial (Brown et al., 2014). Arguably, a well-designed and well targeted web-based intervention has the potential to contribute to reducing health inequalities associated with smoking, and this potential requires further investigation.

A range of studies conducted since the commissioning of SSSs began, suggest that smokers (in particular those from lower socio-economic status (SES) groups) are often unaware that SSSs exist, or what type of service they offer (Roddy et al., 2006, Benson et al., 2014, Copeland et al., 2010, Ussher et al., 2006, Vogt et al., 2010). Other barriers include negative beliefs about the service including that it lacks efficacy, will be impersonal, judgmental, and not tailored to individual needs (Roddy et al., 2006, Copeland et al., 2010, Benson et al., 2014). Our own research supports these findings and identified that smokers often also feel that needing support to quit smoking is a sign of 'weakness' (Fulton et al., 2016). These barriers to service uptake have not typically been the focus of interventions or health promotion campaigns targeted at smokers, possibly because until recent years access to SSSs had been robust and growing (see Langley et al., 2014). Research has shown however, that booklets explaining the efficacy of services to those who have registered with SSSs can increase attendance rates (Matcham et al., 2014) and that proactively recruiting smokers through GP practices can increase attendance at SSSs and four-week quit rates (Murray et al., 2008). A recent trial (Start2quit) assessing personalised risk information (in the form of a letter from patients' GPs including risk information tailored for any conditions they may have (e.g. heart disease)) and an offer of SSS taster sessions was both effective and cost-effective at increasing SSS uptake (Gilbert et al., 2012, 2016). Given that public health budgets are under increasing pressure, and evidence suggests smokers seeking help themselves are more successful at stopping than those referred by others (Borland et al., 2012), it will become increasingly important that SSSs are used by more of those making quit attempts each year to enhance their chances of success. Implementing inexpensive strategies to help this to happen will maximise effectiveness and cost-effectiveness of increasingly tight public health resources.

A handful of other intervention studies have addressed SSS access (Gilbert et al., 2016; 2017; Matcham et al., 2014; Murray et al., 2008), and all have used leaflets or letters from GPs to reach smokers. StopApp is a brief, novel web-based behaviour change intervention, developed with input from smokers from across the SES spectrum that targets the known barriers to service access to improve users' motivation and capability to access SSS. StopApp links to an existing on-line booking system (PharmOutcomes) to provide the opportunity to get a first appointment at SSSs at a time and location to suit the user and could be promoted and accessed across the public health system. Although leaflet and letter based methods are effective, StopApp is unique in that its systematic evidence based development (Fulton et al., 2016; see also detailed description in section 7 below), aimed to address all identified barriers to accessing SSSs whilst also taking account of (or will take account of during evaluation) affordability, practicability, effectiveness (and cost-

effectiveness), acceptability, side-effects (and safety), and equity (Michie, 2014). The StopApp intervention would likely be delivered at even lower ongoing cost than the cost-effective Start2quit letter and taster session (Gilbert et al 2016; 2017), and if well marketed could reach currently unreached smokers.

A future potential randomised controlled trial will enable us to establish whether and to what extent StopApp is effective and cost-effective at increasing SSS bookings and attendance in comparison to standard methods of recruitment. If effective and cost-effective, it is instantly scalable because PharmOutcomes is used extensively across the UK. Because of the novelty of this intervention, the potential for overlooking health inequalities associated with smoking when using digital interventions, and the limited extant research employing the required trial design across recruitment contexts that replicate real-world use of the intervention (including online and community settings), a feasibility trial is required to establish whether a future RCT can be done and achieved without extensively over-representing or under-representing certain demographic groups.

3. Aims and Objectives

3.1 Aim:

The aim of the proposed research is to establish the feasibility and potential health equity of a future randomised controlled trial of the StopApp intervention.

3.2 Primary Objective

To conduct a feasibility trial of StopApp to estimate recruitment and attrition rates of participants across three settings: GP surgeries, community settings and on-line; at baseline, intervention access, and two-month follow-up.

3.3 Secondary Objectives

Secondary objectives of the feasibility trial are to estimate the:

- **3.3.1** acceptability of randomisation and the StopApp intervention for participants
- **3.3.2** acceptability of primary and secondary outcome measures and measures required for cost-effectiveness and cost utility analyses in a future trial
- **3.3.3** key costs which would be incurred in delivering the intervention and usual care, including a comparison of non-attendance at SSS (Did-not-attend or DNA rates) between each arm of the trial.
- **3.3.4** feasibility of accessing SSS and GP data (if recruited via GP) on attendance, quit dates set and four-week quits for trial participants
- **3.3.5** any differential recruitment and attrition rates across socio-economic groups and age and gender
- **3.3.6** rate of SSS attendance in the treatment and control groups to estimate the event rate of the primary outcome measure for a future trial and support future trial sample size calculations

4. Methodology

4.1 Study design

The proposed study is a two-arm parallel group individual participant randomised feasibility RCT of StopApp (intervention) compared with standard promotion of and referral to SSSs (control). The study will also have a nested qualitative process evaluation.

4.2 Setting and Participants

Smokers who are aged 16 years and over will be recruited from 3 settings across Warwickshire including 4 GP surgeries, a range of community settings (e.g. pharmacies, children's centres, libraries) and online. All current smokers aged over 16 years registered with participating GP practices in Warwickshire, or accessing participating community services or viewing advertising for the study online, will be invited to take part in the feasibility trial.

4.3 Recruitment

Recruitment to this feasibility trial is via three settings: GP practices, community settings and online.

4.3.1 GP surgery recruitment

The study is eligible for adoption to the NIHR portfolio and the process of application has begun. We will apply for joint primary care and public health portfolio status. The Clinical Research Network (CRN) are supporting recruitment via GP surgeries. GP practices in Warwickshire have been invited to participate and of those who are interested, we will select four for the feasibility trial (stratified by indices of Deprivation, to ensure we are reaching diverse groups). Patients listed as smokers on the practice records will be checked by practice staff to ensure they meet the inclusion criteria (see 4.4 below) of being aged 16 years or older and a smoker. To remove the chances of contamination, we will contact one smoker per household only. Where two or more smokers cohabit, the resident whose first name is alphabetically first will be selected for invitation to the study and the other resident(s) will receive the control intervention (a web-based pdf with stop smoking service information) after the study has ended. Note: the reason for non-selection will not be provided to the co-habiting smoker to avoid disclosing that the selected resident is a smoker or participating in the study.

Smokers (one smoker per household) will be sent an email and/or text or letter (dependent on GP and patient communications set up) from their GP inviting them to take part in the 'MyWay' study. This will inform them that the study will investigate the best ways of using the internet to help people to stop smoking. Where a GP practice's preferred method of contact with patients is via postal letter, Docmail services will be used to distribute letters as recommended by the CRN. For ethical reasons we will not attempt to recruit people aged less than 16 years as they would typically require parental consent to participate in research and parents may not be aware of their child's smoking status. The email/text/letter (see appendix M & N) will include brief information and a web link/QR code to the study website where further

information and the secure electronic consent process can be accessed (see section 4.9 Procedure below for further information).

4.3.2 Recruitment from other community settings

Contact has been made with the county council leads for libraries, wellbeing hubs, all pharmacies and all children's centres in Warwickshire, and with the family information service and the registrar's office in order to provide information about the proposed study and gain in principle agreement to support recruitment. We have so far gained in principle support from four pharmacies, over 30 children's centres, all seven wellbeing hubs, the family information service and the registrar's office and will be acting on further suggestions from our PPI group for community recruitment locations (e.g. dentists). Following suggestions from our PPI group, we will also be including bus stop and bus based advertising to aid recruitment.

We will supply each participating community setting with posters to display in prominent locations advertising the 'MyWay' study with contact details of the research team and a community-setting specific QR code to gain immediate access to the study website for participants. We will train all staff in participating locations about the study to enable them to answer any basic queries and to promote it confidently. We will also combine staff promotion of the study via leaflets and a very brief verbal introduction with ad hoc research assistant presence for active promotion and recruitment on site. Where staff provide a leaflet, access to the study will be either through QR code/web link to project website or via contact with the research team. Where a research assistant recruits on site, physical copies of the participant information sheet will be available and immediate access provided to the study via tablet computers. People will have the option to gain access to the study but consider participation and return later to the website to provide informed consent.

4.3.3 Online recruitment

The marketing and communications team at Warwickshire County Council (WCC) will be supporting all online recruitment activities. Specifically, they will provide support for online promotion of the study via social media, targeted email marketing, Google advertising and all WCC internal and external channels such as press releases and electronic newsletters. Social media will include Facebook ads as well as via their standard social media channels including twitter feed, Facebook pages and web pages. These ads will appear to anyone in the Warwickshire area searching for health-related products or services. We will run a three-month long campaign to advertise the study. In addition, participating community settings including children's centres, pharmacies and wellbeing hubs will also promote the study online via their communication channels including social media such as Facebook and twitter. Anyone hearing about the study via this method will be able to link directly to the study website.

4.4 Inclusion Criteria

All smokers over the age of 16 years and either 1) registered with a participating GP practice in Warwickshire or 2) who self identifies as eligible for study participation and responds to study promotion via community settings or online, will be eligible to participate. We will not ask those under 16 years of age. It does not matter whether participants have previously attended a SSS or not. Participants need to have access to the internet via a computer or smartphone to create a participant account in the study software, complete study measures and view the StopApp or control content,

and a mobile phone and/or email address for the receipt of SMS reminders to attend an appointment.

4.5 Exclusion Criteria

Via self-assessment, smokers who do not understand written English or are under 16 years of age, will be excluded from taking part.

4.6 Randomisation

Randomisation will be carried out through the study website during months 10-14 of the study. For this purpose, a digital bespoke randomisation tool (embedded within the study website) will be developed in collaboration with our statistician Prof Sparks and with oversight by the Clinical Trials Unit (CTU) at the University of Warwick. This will auto-randomise at the individual level (1:1) using minimisation to ensure balance. Via the study website (hosted by eNgage – see below), the research team will have access to a table that presents live data on condition assignment; NB. the research team will be blind to condition assignment – just condition A and B will be presented. Please see procedure below (section 4.9) for further detail on how and when randomisation occurs.

4.7 Intervention

The StopApp is a web-based self-administered interactive intervention designed to address the barriers that smokers typically face in accessing SSSs. In brief, the intervention comprises 1) an introduction to StopApp, 2) collection of information about age, gender, previous attempts to quit and previous use of SSSs in order to tailor content accordingly. Age and gender are used to provide messaging from similar others to enhance perceptions that 'people like me use SSS'. Information about previous quit attempts and use of SSSs is used to tailor the way in which the subsequent content is framed, 3) StopApp then provides users with information about what SSSs are like, to address negative perceptions many smokers have about what the service offers and how they will be treated. Infographics and messages from real SSS users are used to try to keep textual information minimal and enhance positive norms about who uses SSS. 4) Throughout engagement, the option to go straight to booking an appointment is provided in case people are already motivated to do this. 5) Users are then provided with a list of other potential barriers to SSS access that they may have and can select as many as apply. This then determines which further content is supplied which addresses 6) practical barriers 7) fears about trying and failing and 8) beliefs that needing support to stop smoking is a 'weakness'. At the end of the process users have the option to either 9) book an appointment or 10) get a reminder to re-access the intervention one month later, if they feel they are not yet ready. We have appended an example route through the StopApp (see Appendix F) to illustrate the content. It is linked to the on-line outcomes reporting systems (PharmOutcomes and Outcomes4Health) used by SSSs in Warwickshire (and many other local authority areas across the UK). PharmOutcomes is used by pharmacists and others offering stop smoking services. Outcomes4Health is used by GP practices offering SSS appointments. These secure systems support service providers in recording information about what they have provided to a service user and the outcomes associated with this, including whether or not a quit date was set and whether or not a CO verified 4 week quit rate was achieved by a service user.

The StopApp is a website, so requires internet access for use (i.e. it is not downloaded to the user's device), but is optimised for use on smartphone and tablet devices. It therefore has the feel of an 'app' with content and features that look

appealing on a small screen device. We developed the intervention in collaboration with the Tobacco Control lead at Pubic Health Warwickshire.

As well as applying co-production and usability methods (further detailed below) the content of the StopApp intervention was systematically developed using the Behaviour Change Wheel approach (Michie et al., 2014), which is underpinned by a model of the determinants of behaviour; the COM-B model (Michie et al., 2011) and maps onto to the theoretical domains framework (Cane et al., 2012). In applying the COM-B, StopApp aims to increase the **capability** and **motivation** (**C** and **M** from **C**O**M**-B) of smokers to access support to stop smoking and then provides the **opportunity** (**O** from C**O**M-B) to **book an appointment** instantly at a convenient time and location for the user (our target **B** - **behaviour**), and with text message or email confirmation and reminders to **attend the appointment** (a further target behaviour). Applying the COM-B allowed us to map identified barriers to service access with intervention functions and behaviour change techniques (BCTs) most likely to address those barriers. Specific content within the app delivers 19 BCTs identified as most useful for supporting SSS access behaviour (Fulton et al., 2016). For example, the BCT 'Provide information about social/environmental consequences' was identified as one of several that can improve 'Psychological Capability' to access SSSs. Application of this BCT occurs more than once, but an example relating to psychological capability and the theoretical domain of 'knowledge' includes providing information about the benefits of SSS, about what they do, how they have helped others, and what they offer including that you can have more than just one appointment.

The control group will receive access to a web-based pdf 'leaflet', hosted online which is part of Warwickshire's standard stop smoking service provision and containing much of the same information about services: see 'Quit4Good' Service Leaflet (Appendix G). The leaflet does not link to an on-line booking system and does not provide tailored routing according to the types of barriers a smoker may have to SSS access. It has not been systematically designed to address barriers to service access and is not underpinned by a theory of behaviour change or identified BCTs.

4.8 Intervention access

Following randomisation, both groups will be sent an email with near identical content, asking participants to either follow a web-link to read an information leaflet about SSS (control group) or follow a web-link to the StopApp (intervention group). A reminder email will be sent to all participants two weeks later. Please see procedure below for further information on when access to these materials is provided. Participants in both conditions will be told that if they wish to book an appointment at the SSS, then they are free to do so, but in taking part are under no obligation to do so. Acceptability of randomisation and the intervention will be assessed by follow-up qualitative interviews with a sub-sample of participants (see nested qualitative process evaluation below for further information on these interviews).

4.9 Procedure

The feasibility study involves two elements: A) a feasibility trial and B) a nested qualitative study. Selected participants in the feasibility trial will be invited to participate in the qualitative study at the end of baseline data collection (see below). Additionally, members of staff within recruitment settings will also be invited to participate in the qualitative study.

A – Randomised feasibility RCT

4.9.1 Procedure for participants

Please refer to Figure 1 for flow diagram illustrating participants' route through the project. Eligible smokers will be recruited from one of three settings (described above in section 4.3) and provided with a link and/or QR code to the study webpage. The study webpage is delivered via secure bespoke study management software known as 'eNgage' which is hosted on Coventry University servers (see below for information on eNgage) [https://engage.coventry.ac.uk].

Participants will be required to endorse mandatory consent statements (time/date stamped and version of participant information sheet recorded) before being able to participate. Informed consent will be obtained online in accordance with the updated General Data Protection Regulation (GDPR) guidelines.

Following consent, participants will be guided through the process of completing questionnaires and accessing the intervention/control materials (see procedure for data management below for further detail on how this will happen). They will be asked to complete a baseline questionnaire (appendix E) which will take approximately 20 minutes to complete. They will then be randomised to either the intervention group, and then directed to the StopApp, or the control group, and then directed to the online pdf leaflet. Participants in both groups will have continued access to the content of either the intervention or the control materials (although they have been designed to be used as a one off). Two months later all participants will be asked via email to complete an online follow-up questionnaire (appendix E). Participants will also be asked if they are interested in taking part in telephone interviews to investigate the acceptability of MyWay (by endorsing a box at end of the baseline questionnaire). Consenting participants will complete one telephone interview after follow-up. Staff from recruitment settings (community and GP) will also be invited to participate in telephone interviews about their involvement in the study. See procedure for nested qualitative process evaluation below for further details (Part B; page 21).

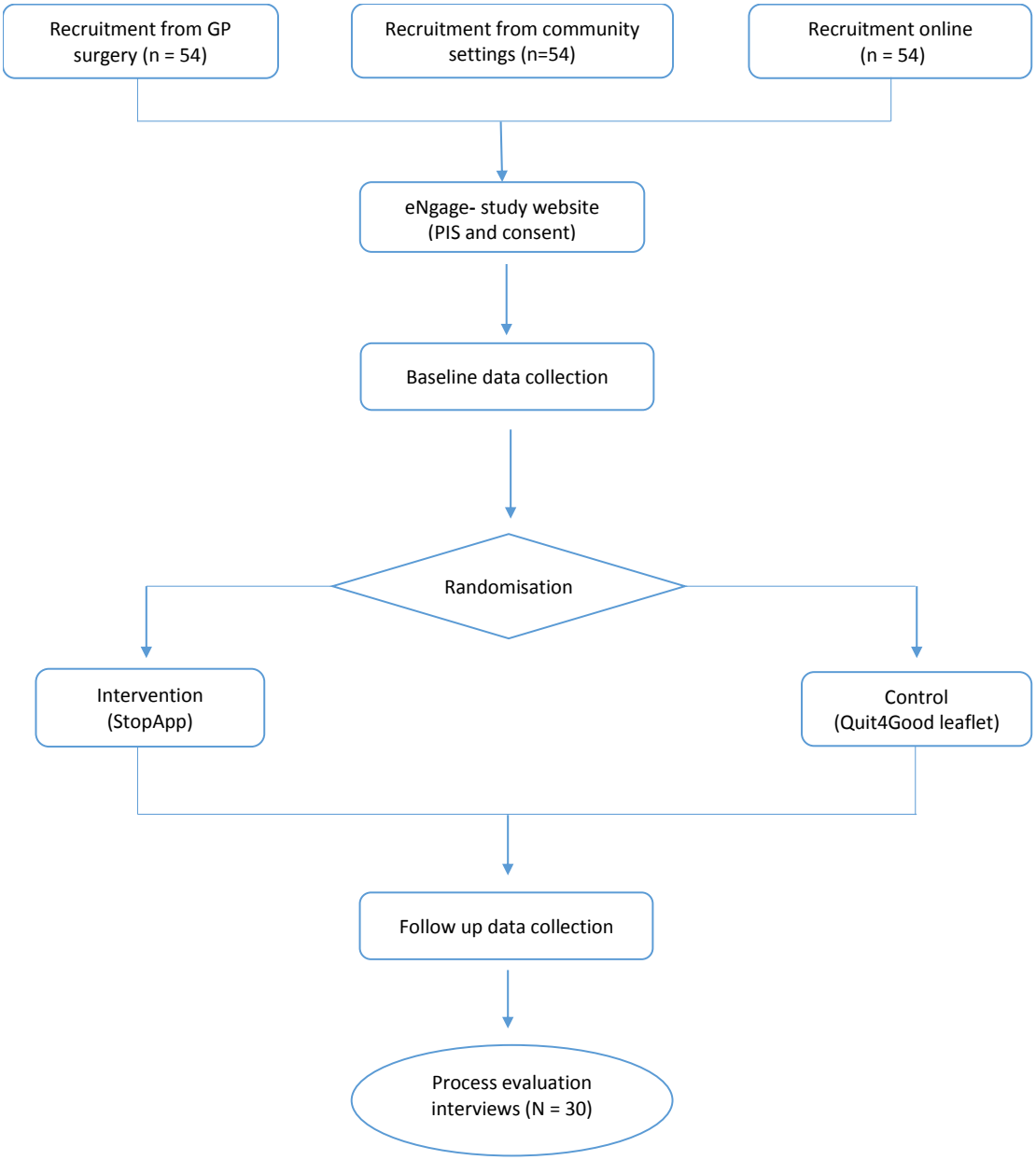

Figure 1: Flow diagram illustrating participant's route through project.

4.9.2 Procedure for data management

Please refer to Figure 2 for a data management flow diagram. Up until the point at which all data is downloaded for analysis (see 'downloaded data' below), it will be stored online across four secure web applications as follows:

eNgage – is an online research platform owned by Coventry University (CU). It is hosted on CU's secure server and has been assessed by CU's Information Protection Unit (IPU) as meeting GDPR data protection requirements. eNgage has been developed to work seamlessly with other web applications; namely Qualtrics and Matomo (see below); these applications have been integrated using APIs (application programming interfaces) that enable data to be transferred from one application to the other.

eNgage hosts details of current and previous CU research projects. These are presented as separate webpages which contain a 1) project name and summary, 2) inclusion criteria, 3) participant information details (i.e. information about the project for participants; downloadable as pdf), 4) consent statements, 5) research team names and contact details. Some consent statements are mandatory i.e. those regarding ethics issues/implications that users must indicate that they understand in order to participate. All mandatory consent statements must be endorsed by the user before a 'join project' button becomes active.

If a participant has already registered with eNgage (for participation in a previous project) then they will be asked at this point to sign-in. If they are a new user, they will be prompted to register. Registration requires users to provide their name (first name and last name) and their email address. eNgage stores for each participant that joins a project (downloadable by the lead researcher): their full name, their email address, a unique participant ID created by eNgage, the date and time at which they 'join project' (i.e. provide consent), and the version of the participant information details they consented to.

On 'joining' a project, eNgage directs participants to Qualtrics to complete baseline measures. The participant's email address is transmitted by eNgage to Qualtrics to enable auto-scheduled email invitations and reminders to be sent throughout the project at relevant time points (i.e. completion of questionnaire and access to intervention). Each participant's unique ID is also transmitted to enable all data collected within eNgage and Qualtrics to be linked (e.g. provision of consent and questionnaire responses).

The randomisation of participants to experimental conditions occurs within eNgage. After each participant has completed their baseline questionnaire within Qualtrics, eNgage will assign condition. Whilst assignment is random, the algorithm applied uses minimisation to ensure balance by factors that are likely to affect SSS access (gender, self-report socio-economic status). Data with respect to these factors is collected for each participant within the baseline questionnaire. On study set-up within eNgage, the research team specify what these factors are and their location within the baseline questionnaire (e.g. Qs1-4). eNgage retrieves this data from Qualtrics and uses it to nominate assignment. eNgage uses the participant's unique ID (sent to Qualtrics previously) to identify the individual. Each participant's response to these questions and condition assignment is additionally stored within eNgage to enable auditing of this process.

Following assignment, participants are directed to the respective intervention or control materials (both stored on the CU server). Analytics data on their use of these materials is collected by Matomo (see below). Following this, participants are directed to complete the follow-up questionnaire within Qualtrics, at 2-months after baseline.

NB. for the My Way study, there will be a number of identical eNgage project pages, one for each of the different recruitment settings. The purpose of this is to enable the unique ID created for each participant to be associated with the type of setting they were recruited from. This is necessary to assess the success of our recruitment strategy across the different settings. The URL for each page will be the only thing that is different for each project page and this will be provided accordingly for those recruited within each of the settings.

Qualtrics – is an application for creating and hosting online questionnaires. It has been assessed by CU's IPU and approval has been given for use. As specified above, Qualtrics has been integrated with eNgage to enable the collection of participant data for university research projects. All project data (baseline and follow-up) is held within Qualtrics until downloaded by the research team. Using the unique ID (created within eNgage and sent to Qualtrics), these two data sets can be linked together. On download, this survey data will be stored entirely separately to the eNgage data (as described above) although the unique participant ID can be used to verify that each entry (response by an individual participant to baseline and follow-up questionnaire) relates to a specific participant who provided consent. In this sense the survey data is pseudo-anonymised i.e. the eNgage data acts as a linking file which enables a data subject to be re-identified. This linking file will be retained for 6 years after the study is complete to act as a record of participant consent (see 'downloaded data' below).

Matomo – is CU hosted web analytics software that enables data on individuals' use of websites/applications to be collected (e.g. frequency and duration of visits). This will be used to collect data on each participant's use of eNgage, and either StopApp or the control website. This data is useful to identify points in the participant journey where significant drop-out occurs e.g. at the point of consent and also to examine intervention dose. This data collection will occur in the background (within eNgage and the intervention/control websites) during the project with each participant's consent. Matomo has been integrated with eNgage. Each participant's unique ID will be pushed through to this application. When analytics data is downloaded from Matomo it will be linked to the outcome data (collected via Qualtrics) for each participant using the unique ID.

PharmOutcomes/Outcomes4Health – this application is not owned by CU, not hosted on the CU server and not integrated with any of the above applications. It is owned by Pinnacle Health and commonly used for recording data by public health and primary care service providers. CU have carried out due diligence checks and confirmed that its processes are GDPR compliant. PharmOutcomes/Outcomes for Health is used by Stop Smoking Services in Warwickshire to record data on patient attendance at stop smoking appointments, quit dates and 4-week quit rates (stop smoking data). When an intervention participant using the stopapp decides that they would like to book a stop smoking service appointment and clicks on 'book now' they reach a map/service search page that asks for a postcode or town name, after the stopapp user enters the information and clicks search, the API that connects stopapp to PharmOutcomes/Outcomes4Health draws live information about which services are currently offering appointments near that location and presents the sites for the user to select from. When a site is selected, the API connecting stopapp and PharmOutcomes/Outcomes4Health pushes information from the calendar function in PharmOutcomes/Outcomes4Health about which appointments are available. The stopapp user can select a preferred time and date and an alert is sent to the relevant service provider within PharmOutcomes/Outcomes4Health about the appointment request for them to respond to. Service providers then use the PharmOutcomes or Outcomes4Health system to record all further information about the users' engagement with the service as they would for any other service client.

We will receive data for each of our participants who consented from PharmOutcomes and Outcomes4Health on whether or not they booked an appointment, whether or not they attended an appointment, whether or not they set a quit date and whether or not they achieved a 4 week quit including whether or not this was CO verified. The stop smoking service data will be sent to a secure NHS.net email address held by one member of the research team, in report format,

and will include only trial participants who consented to the research team being sent information about their SSS use. This data will be recorded by hand by a researcher directly into a spreadsheet alongside each participant's unique ID generated by eNgage. Each participant's name will be used to link the data (unique ID and stop smoking data) but will not be recorded within the database. Coventry University is currently developing a data sharing agreement with Warwickshire Public Health and Pinnacle Health for this purpose. Recruitment will not begin until this (as well as all other ethics and governance approvals) is in place.

A drop-down box within the Pharmoutcomes/Outcomes4Health appointment data input form used by SSS staff, will include a compulsory prompt to staff to ask whether their client is taking part in the MyWay research project/study (with details of the trial to help recall). If the client answers yes, they will be asked if they agree (consent) to the researcher's contacting the service to collect information about their use of the service, with a 'YES/NO' drop-down box. This acts as a proof of participant consent for Pinnacle health, in order to generate a report of trial participants who provide consent only.

Downloaded data - on completion of data collection, the following will occur:

1) The eNgage data (to include for each participant: full name, email address, unique participant ID, the date and time consent given, the version of the participant information details they consented to, responses to optional consent questions, responses to randomisation questions and experimental condition assignment) will be retained within eNgage for six years after the end of the study to act as a record of participant consent. This data will be retained in this full form for six years after the end of the study (in case a participant wishes to make a claim against the university in which case both proof of consent plus associated data can be provided). The name and email addresses of those who provided consent (optional) to be contacted about future eNgage studies will be copied into a new datafile (marketing opt-in datafile).This data will be shared with the eNgage lead administrator who will store this on their private password protected OneDrive folder (located on CU server).
2) The survey data (baseline and follow-up questionnaire responses collected in Qualtrics) will be downloaded, postcode data removed (to anonymise), and then stored on the team's shared password protected project folder (SharePoint – access rights outlined below; located on CU server)
3) Postcode data (taken from baseline survey) and associated unique ID to be downloaded and stored on the research lead's private password protected OneDrive folder (located on CU server). Postcode data to be converted to IMD score. IMD score to be added to downloaded baseline survey data (linked to participant ID). Postcode data will be retained until the end of data processing (data analysed and findings reported) and then deleted.
4) The analytics data (from Matomo) will be downloaded and stored on the team's shared password protected project folder (SharePoint – access rights outlined below; located on CU server); NB this data is anonymised IP address masked by default.
5) The project stop smoking data will be stored on the team's shared password protected project folder (SharePoint – access rights outlined below; located on CU server)
6) In preparation for analysis, data from 2, 3, 4 and 5 will be linked using each participant's unique ID to create the complete datafile in preparation for analysis; initially this will be within Excel format but will likely also be exported

to SPSS (all data will however remain within the shared password protected project folder)

7) Research team to agree that all required data (in required format) present/complete and then all research data will be permanently deleted from Qualtrics and Matomo
8) The complete datafile (anonymised data created in step 6 above) will be retained for six years after the study has ended (the source files 2, 3, 4 and5) will be deleted

Data access rights:
Sharepoint project folder – accessible to the research team (CU: Prof Katherine Brown, Dr Emmie Fulton, Dr Katie Newby, Dr Kajal Gokal, Lauren Schumacher, Kayleigh Kwah, Tim Sparks; external: Dr Felix Naughton, Dr Louise Jackson, Prof Tim Coleman)

eNgage – accessible only to CU members of research team with eNgage administrative rights (Prof Katherine Brown, Dr Emmie Fulton, Dr Katie Newby, Dr Kajal Gokal, Lauren Schumacher, Kayleigh Kwah); permissions (editing rights) vary however.

Matomo – accessible only to CU members of research team (Prof Katherine Brown, Dr Emmie Fulton, Dr Katie Newby, Dr Kajal Gokal, Lauren Schumacher, Kayleigh Kwah)

Qualtrics – accessible only to CU members of research team (Prof Katherine Brown, Dr Emmie Fulton, Dr Katie Newby, Dr Kajal Gokal, Lauren Schumacher, Kayleigh Kwah)

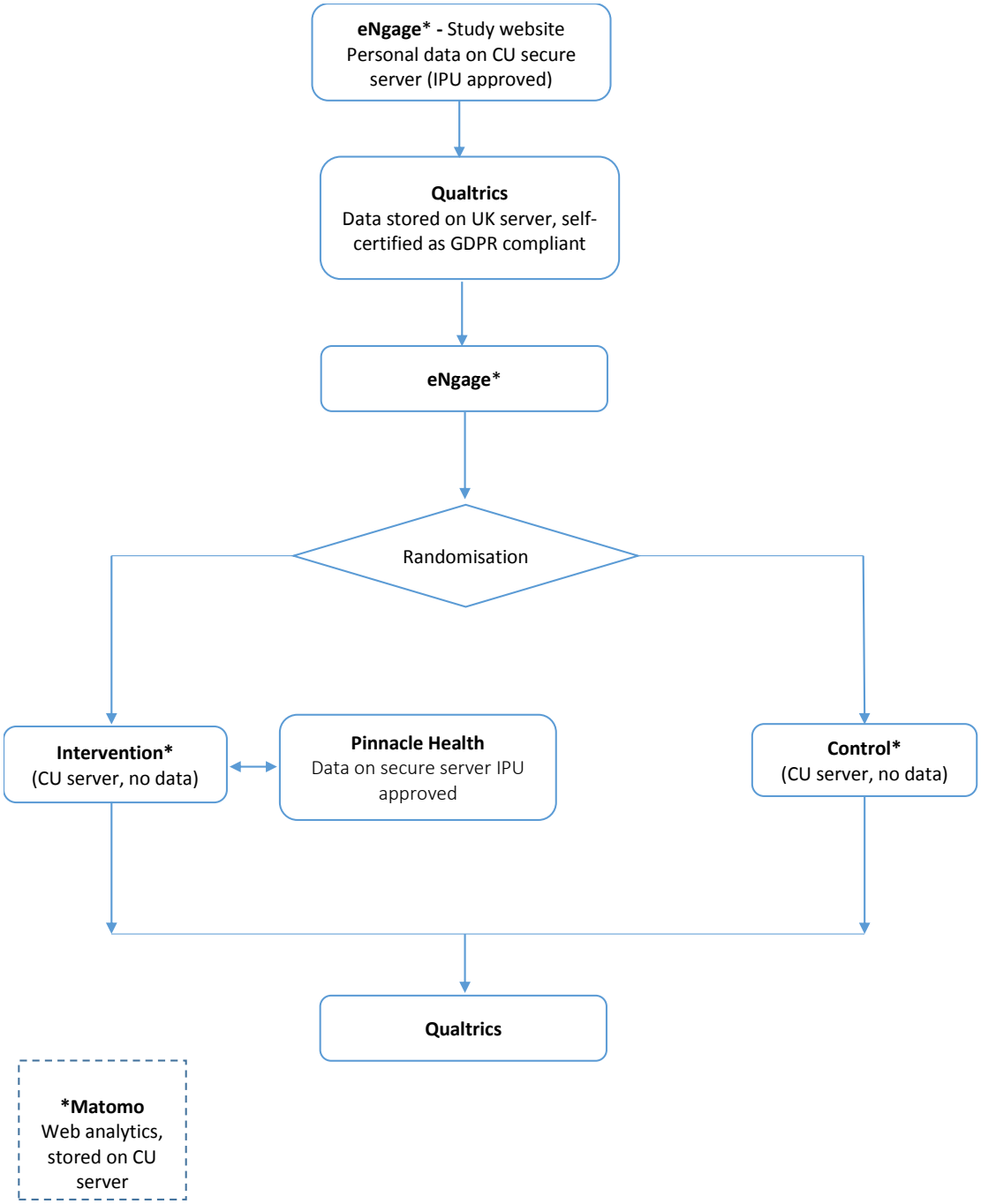

Figure 2: Flow diagram of data management (* web analytics data collected by Matomo)

4.9.3 Withdrawal of data

All participants will be informed that they have the right to withdraw their data from the study up to the point at which it is downloaded for analysis and used to create the study linked database (30th June 2019; step 5 above). Participants will be informed that should they wish to withdraw from the study they should contact the research team using the project email address (details provided on eNgage and within email communication to participants). If such a request occurs, the research team will clarify the name and email of the participant, identify their unique participant ID and

then delete all of their data (1-5 as applicable above). The research team will then inform the participant by email that this action has been performed (giving the date/time). The name/email addresses of participants who have withdrawn will be removed from Qualtrics to prevent further auto-generated emails being sent. A datafile logging the date/time of participant withdrawals will held by the lead researcher.

4.10 Questionnaire Measures

4.10.1 Baseline measures

A baseline questionnaire will include questions regarding demographic information (including age, gender, profession, ethnicity, postcode (for purposes of identifying indices of multiple deprivation score)) current smoking status, previous use of SSS, ease of internet access, and motivation to quit, measured using the one item 'Motivation to Stop Scale', MTSS (Kotz et al., 2013) and a single item Likert scale (Hummel et al.,2017). Health-related quality of life data will be collected using the EQ5D-5L instrument to inform the health economic analysis, and the ICECAP-A (ICEpop CAPability measure for Adults) instrument will be used to measure general wellbeing. In addition, we have developed a bespoke resource use questionnaire to gain insight into the costs both to individuals and to the public purse of resources accessed as a result of participation in the study or use of the Stopapp (see appendix E). Participants will be given measures online via the project website. If they register but do not complete baseline measures within two weeks we will send email reminders. Those recruited through GP practices will be sent a reminder (using same method as initially used by GP surgery) two weeks after the first communication. All smokers who agree to take part in the study and return baseline questionnaire responses will be randomised into either the intervention or control group as described above.

4.10.2 Two month follow-up

Follow up emails will be sent approximately two months after completion of the baseline questionnaire, to invite participation in the follow-up questionnaire. Emails containing a link to the follow-up measures will be sent to all participants to assess feasibility and acceptability of these, and likely attrition rates in a future trial. The questionnaire will also ask them to confirm whether they booked an appointment and attended a SSS, set a quit date and reached a 4-week abstinence, and explain what prompted them to book an appointment. Pinnacle Health Ltd will run a search of the PharmOutcomes and Outcomes4Health systems for our participants (where they consented to this) and provide us with their service use data to test feasibility of sourcing objective evidence of booking, attendance (and did not attends; DNAs), quit dates set, and CO tested 4 week quits. We will also assess feasibility and acceptability of follow-up measures of; motivation using the MTSS and a single item Likert scale (Hummel et al.,2017); the EQ5D-5L instrument; the ICECAP-A instrument and a resource use questionnaire to capture participant use of NHS and other resources for both intervention and control arms. Non-responders to the email will be contacted two weeks later with a reminder to respond. We will send an email with a link to the information leaflet provided to the control group, to anyone who contacts us after the end of the period of recruitment to the study until the end of December 2019.

4.10.3 Data on costs associated with delivering the intervention versus usual care

We will gather, through trial processes, data on the costs associated with delivering the intervention (e.g. web hosting, text messages and usual care (e.g. telephone calls taken to book in appointments). We will also collect data on costs and resource use associated with promoting the intervention and usual care (e.g marketing through social media, posters on buses etc.). Costs and resource use associated with attendance or non-attendance (Did not attend, DNA rates) at SSSs will also be collected from PharmOutcomes or Outcomes4Health system).

B – Nested qualitative process evaluation

Procedure for participant interviews

At baseline, following randomisation, we will ask all participants (using a single yes/no question) if they are interested in participating in a brief follow-up telephone interview at the end of the study, regardless of whether or not they end up completing the study. For all participants that indicate an interest, we will request a contact telephone number and their consent to process this information in addition to personal data already collected. For participants providing this consent, we will create a new Excel database (process evaluation contact database) containing: their unique ID, setting recruited from (GP, community or online), experimental condition allocation, and their responses to a number of demographic questions asked at baseline for the purposes of randomisation i.e. gender, self-report socio-economic status. This database will be stored on the research lead's private password protected OneDrive folder (located on CU server). At the end of data collection (30th June) we will also record in this database, study retention information for each participant (i.e. whether they completed the study or dropped out at baseline or intervention phase) and whether they accessed Stop Smoking Services (using PharmOutcomes/Outcomes for Health data – see above). Using this data, we will select approximately 30 feasibility RCT participants and invite them to participate in the process evaluation interviews.

In order to ensure a good representation from more disadvantaged smokers in particular, we will apply maximum variation sampling and seek to over represent where possible, smokers from lower socio-economic groups, whose voices are not typically included in this type of research (on basis of data stored within this database as listed here). NB the above database will be retained until the end of data processing (data analysed and findings reported) after which point it will be deleted.

Invitation will be by telephone and those who wish to participate will be sent a follow-up email directing them to a new study page on eNgage (set up specifically for the process evaluation interviews). Here participants can read and download the participant information details and review the consent statements. Participants will be required to endorse all consent statements to activate the 'join project' button. On clicking 'join project', they will receive a message telling them that they will be contacted by a member of the research team to set up a mutually convenient time for the interview. The interviews will last approximately 30 minutes, and will be audio recorded using telephone interview recording devices. Interview transcripts will be transcribed verbatim in preparation for analysis. Participants will be able to withdraw their consent for up to 2 weeks after participation in the interview. Please refer to appendix H for a copy of the interview schedule. We will allow data analysis to determine saturation point and when to stop, but anticipate conducting up to 30 interviews. We will explore acceptability and user experience in line with each of the identified research objectives.

Procedure for staff interviews within recruitment settings

In addition, we will invite a range of staff from recruitment settings to also comment on acceptability and experience of supporting the trial (see appendix I). The staff contacts made at recruitment sites during data collection will be invited to participate in process evaluation interviews. As above, a separate project page on eNgage will be set up for this purpose. Here participants can read the Participant Information Sheet and will be asked to provide consent. All remaining procedure as for trial participants described above. Data analysis will determine saturation point but we will aim to recruit around 3 members of staff from each setting type (GP, community, online).

All qualitative data will be subject to thematic analysis using Nvivo software.

Procedure for data management
All interviews will be digitally recorded. Once each recording is complete, it will be downloaded on to the shared password protected project folder and named according to the participants' unique ID. The original recording on the recording device will then be deleted. Audio files will then be transcribed by a CU approved transcription service with whom we have a data sharing agreement in place. Identifying data such as names will be removed from transcriptions to ensure anonymity of participants. Once the research team is satisfied that all transcriptions are complete, the audio files will be deleted.

4.10.4 Measurement of potential harms
As this is a behavioural intervention with extremely limited potential for harm or adverse events we do not consider it necessary to measure these.

4.11 Estimated recruitment rate and proposed sample size
The primary objective of this study is to assess the feasibility of recruitment to a potential future definitive RCT and therefore formal power analysis is not appropriate. However, in order to determine the target sample size we have drawn on two sources. Teare et al. (2014) recommend that external pilot and feasibility studies with binary outcome measures (in this case attend vs. does not attend SSS) recruit at least 60 participants in each group (minimum N=120) and a maximum of 100 participants in each group (maximum N=200). In addition, our sample size calculations, based on similar definitive RCT data about recruiting smokers to trials via letters from their GPs, suggested that we would need to enrol 980 smokers to detect a 7% difference between control and intervention arms in a definitive trial. Based on this estimate, any trial would need to recruit 1.8 participants per day to achieve the required recruitment in 18 months. We plan to recruit for three months, and based on needing to recruit 1.8 participants per day, we need to reach a required sample size of **162 participants** (54 per setting). With a sample size of 162, the recruitment rate of smokers for a full RCT will be estimable with a precision (95% CI width) of +/- 5%.

4.12 Statistical analysis plan
Feasibility and acceptability of all measures will be assessed by level of completeness and by follow-up qualitative interviews with a sub-sample of participants (see detail above on nested qualitative study). We will calculate recruitment rate via GP surgeries as a percentage of those recruited from those smokers identified on participating GPs lists. We will calculate recruitment via community and online settings as the time taken and spend required to recruit 54 participants and/or the number recruited and spend over three months. We will

calculate the average recruitment rate per day across the three settings. We will provide percentage rates for attrition across each recruitment setting at each of baseline, intervention/control access, and two-month follow-up.

We will look at the observed difference between intervention and control groups for bookings and attendance at SSS and use this data to support estimates for the required sample size for a definitive trial. Clinical significance will also be used in these estimates and a comparison of the two will help to determine future trial feasibility. We will assess level of completeness of all measures and run missing value analysis to determine whether any missing data are missing at random or whether patterns of missing data may indicate a problem with measures.

We will report observed and self-reported bookings, attendances, quit rates set and four-week quits across the intervention and control groups, and the proportion of participants agreeing to allow access to SSS and GP data (where relevant) relating to smoking status and SSS attendance.

We will report on numbers of higher versus lower SES status participants recruited as well as age and gender, and assess using chi-squared analysis whether SES status, age or gender are associated with attrition at baseline, intervention/control access and two-month follow-up.

5. Ethical Considerations

5.1 Risks and benefits

Risks - Participating in the proposed research has limited risk associated with it for participants. Consenting to participate will require participants to complete questionnaire measures and to access either an online information leaflet or the StopApp intervention. They will be required to make a decision about whether or not to book and then attend a SSS appointment and may then choose to go to that appointment, set a quit date and attempt to stop smoking. Risks associated with these actions are in line with normal every day risk and we will provide all study participants with information about how to access support for anything related to their participation in the study. Some smokers may attempt to quit and fail and this may have some negative psychological impacts in the short-term. Participants will also need to provide consent for data held about them and their smoking status by their GP and SSS to be accessed during the study. All such data will be handled in accordance with the latest data protection legislation and anonymised for the purposes of data analysis and reporting.

Potential benefits - There is the potential that some smokers who participate may actually quit smoking which has benefits to them and society. In addition, each quit attempt a smoker makes means they are a step closer to quitting for good (West, 2013) and so there is an overall long-term net benefit to this outcome should it occur.

5.2 Ethical arrangements

Ethical approval will be obtained via the Health Research Authority (HRA), Warwickshire County Council (who commission the SSS) and Coventry University. No potential participants will be contacted until all ethical and R&D approvals are in place.

As outlined above, there are no major risks associated with participating in the research. Participating GP surgeries will receive funding via the CRN to send out recruitment communications to smokers on their patient lists. Participant Information

details and clear consent statements will be available on the eNgage study websites (for feasibility study and qualitative process evaluation) providing a full explanation of the research and what participation involves. Only those who actively opt in to the study and provide full informed consent to participate will able to participate. Participants in the feasibility RCT will be asked explicitly to consent to access to information about their smoking status and records via their GP and/or SSS (this is not mandatory for participation). Only where they have explicitly provided written consent for this will the research team gain access to this information. Participants will be made fully aware of their right to withdraw from the research up to the point of data analysis without needing to give a reason. They will be made aware of exactly how to go about this and all data provided by them will be withdrawn from the dataset and destroyed. Information about the confidentiality and anonymity of their data will be made absolutely clear to participants and we will tell people how their information will be treated and stored and what we will be doing with this. We will ensure that all use of data complies with the most recent data protection requirements and that information governance protocols are strictly adhered to. Participants will be given sources of information, advice and support in relation to issues that being involved may raise for them.

6. Stop/go criteria

The main purpose of the proposed feasibility study is to determine whether the main trial can be done. This will largely be determined by whether one or more of the recruitment settings is able to produce the required sample size for a future main trial. Based on the information discussed above we estimate that we need to recruit an average of at least 1.8 participants per day to make a future trial feasible. We will also use data collected about SES, age and gender of those recruited and lost through attrition to understand the health equity of the trial methodology.

7. Research Governance

The nominated sponsor for this research is Prof Olivier Sparagano, Associate Pro Vice Chancellor of Research at Coventry University. Prof Sparagano has confirmed he is prepared to take on sponsorship of the study on behalf of Coventry University. The university has an Information Protection Unit that provides support and information to staff in ensuring they are fully compliant with all Information Governance requirements.

We have a Study Steering Committee (SSC) in place that will operate independently of the research team to assess research governance issues. This includes an independent chair, Professor Tony Stewart who is also the public health speciality lead for the West Midlands Clinical Research Network (CRN), Professor Janet Dunn, a statistician form the Clinical Trials Unit (CTU) at the University of Warwick, members of our PPI group, Sue Wild, the tobacco control lead from Public Health Warwickshire, and Nigel Smith, the tobacco control lead from Public Health England (West Midlands). The SSC will meet at project outset and shortly before each progress report is due to assess progress, data management and research governance issues.

All data accessed and retrieved from the SSSs systems will be dealt with on secure servers and stored on password protected files accessible only to members of the research team. We will only seek data for those participants who have provided their expressed consent for us to do so. The outcome measures of this project are routinely collected and recorded by the IT systems in the SSS. The owners of PharmOutcomes and Outcomes4health (Pinnacle Health Ltd) have worked with us to ensure StopApp sends the relevant referral data (only name and mobile telephone number) to the system and stores no data on StopApp itself (user information) that would contravene Information Governance requirements. Instead all data is sent via a secure server to the existing Pinnacle Health system.

We have a consultation and PPI group of eleven smokers from a range of SES backgrounds that includes people from lower SES groups and for whom English is not their first language. They have been involved in co-design activities and end-user testing of the StopApp throughout development. We have responded to our PPI group feedback and input to improve StopApp. We have continued to consult and engage this group (including recruiting new members) in the design of this feasibility study. The PPI group will continue to work with the project team throughout the delivery of this feasibility trial. They will meet bi annually, to be involved in aspects of study governance and decision-making, and be consulted regularly throughout the study for contributions via online and electronic communications. At least one member of the PPI group will be present at study steering committee meetings.

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