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# BMJ Open

**A tailored digital behaviour change intervention with e-referral system to increase attendance at NHS Stop Smoking Services (The MyWay Project): study protocol for a randomised controlled feasibility trial.**

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Keywords:	Stop Smoking Services, Digital Interventions, Health Behaviour Change, Randomised Controlled Feasibility Trial, Protocol

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Manuscripts

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3 **A tailored digital behaviour change intervention with e-referral system to increase**  
4 **attendance at NHS Stop Smoking Services (The MyWay Project): study protocol for**  
5  
6 **a randomised controlled feasibility trial.**  
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51 Behaviour Change; Digital Intervention  
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## ABSTRACT

**Introduction:** In the UK, smokers who use Stop Smoking Services (SSS) are four times more likely to stop smoking than smokers who do not. Attendance has declined, warranting the development of interventions to address this. StopApp™ is a novel, brief online behaviour change intervention designed to address common barriers to SSS attendance. It links to widely commissioned service management software which enables instant appointment booking at a user's location and time of choice.

**Methods and analysis:** 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 includes a nested qualitative process evaluation to assess the acceptability of the research processes, with a sub-sample of participants. Smokers aged over 16 years will be recruited via three routes: GP practices, community settings and online. After consenting and the collection of baseline data, participants will be randomised to control or intervention groups. Participants in the intervention group receive a link to StopApp™ and those in the control group receive standard web-based information about the SSS. All participants are told they can book a SSS appointment but are under no obligation to do so. Online follow-up 2 months post randomisation includes data on SSS use and carbon monoxide verified 4 week quit rates. The study aims to recruit 162 smokers.

**Ethics and dissemination:** Ethics approval has been granted by the West Midlands - Edgbaston NHS Research Ethics Committee. The findings will be reported in conferences and peer-reviewed publications; and will be used to design the parameters necessary for a definitive trial to ascertain the effectiveness of

1  
2  
3 StopApp™ at increasing booking and attendance at SSSs compared with existing  
4  
5 methods for encouraging uptake.  
6  
7

8 **Trial Registration:** Research Registry: 3995. Trial Registered 18<sup>th</sup> April 2018.  
9  
10

### 11 12 13 14 **Strengths and limitations of this study**

- 15  
16  
17 • A randomised controlled trial with nested qualitative evaluation to ascertain  
18  
19 acceptability of trial processes.  
20  
21
- 22 • Both objective and subjective measures are included to assess 4 week quit  
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24 rates.  
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26
- 27 • Comparison of different sources of recruitment, including GP, community  
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29 settings and online social media.  
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## INTRODUCTION

Smoking remains a leading cause of mortality and morbidity worldwide (ASH, 2015).

In addition, the direct costs of smoking to the UK National Health Service (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). NHS 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 typically 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 (NHS Digital, 2018). 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

1  
2  
3 not view SSS and EC use as mutually exclusive (Beard et al., 2014). A third of smokers  
4  
5 in England have used EC at least once (Brose et al., 2015), and whilst their use is  
6  
7 associated with significant reductions in numbers of cigarettes smoked this has not  
8  
9 led to an overall rise in quit attempts (West and Brown, 2015). Therefore, SSSs are  
10  
11 still needed to support quit attempts.  
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15 A range of studies conducted since the commissioning of SSSs began, suggest  
16  
17 that smokers (in particular those from lower socio-economic status (SES) groups) are  
18  
19 often unaware that SSSs exist, or what type of service they offer (Roddy et al., 2006,  
20  
21 Benson et al., 2014, Copeland et al., 2010, Ussher et al., 2006, Vogt et al., 2010).  
22  
23 Other barriers to accessing SSSs include holding beliefs that the services lack efficacy,  
24  
25 and will be impersonal, judgmental, and not tailored to individual needs.  
26  
27 Additionally seeking help to stop is viewed as a sign of personal weakness (Roddy et  
28  
29 al., 2006, Copeland et al., 2010, Benson et al., 2014; Fulton et al., 2016). Typically,  
30  
31 these barriers to service uptake have not formed the focus of interventions or health  
32  
33 promotion campaigns targeted at smokers, possibly because access to SSSs had been  
34  
35 robust and growing until recently (Langley et al., 2014). Research has shown  
36  
37 however, that booklets explaining the efficacy of services (Matcham et al., 2014) and  
38  
39 proactively recruiting smokers through GP practices can increase attendance at SSSs  
40  
41 and four-week quit rates (Murray et al., 2008). A recent trial (Start2quit) assessing  
42  
43 personalised risk information in the form of a letter from patients' GPs and an offer  
44  
45 of SSS taster sessions, was both effective and cost-effective at increasing SSS uptake  
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47 (Gilbert et al., 2012, 2017).  
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56 StopApp™ is a brief, novel web-based behaviour change intervention,  
57  
58 developed with input from smokers from across the SES spectrum that targets the  
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3 known barriers to service access to improve users' motivation and capability to  
4  
5 access SSS. StopApp™ links to an existing on-line booking and service management  
6  
7 system used by pharmacies offering SSS (PharmOutcomes), providing the  
8  
9 opportunity to instantly book a first appointment at SSSs at a time and location to  
10  
11 suit the user. A feasibility trial of StopApp™ (The MyWay study) is required to  
12  
13 establish whether a future Randomised Controlled Trial (RCT) can be achieved. This  
14  
15 is especially necessary due to i) the novelty of the StopApp™ intervention; ii) the  
16  
17 potential for overlooking health inequalities associated with smoking when using  
18  
19 digital interventions; and iii) the limited extant research employing the required trial  
20  
21 design across recruitment contexts that replicate real-world use of the intervention  
22  
23 (including online and community settings).  
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### 33 **Aims and Objectives**

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36 The aim of the proposed research is to establish the feasibility of a future  
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38 randomised controlled trial of the StopApp™ intervention.  
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### 41 **Primary Objective**

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43  
44 To conduct a feasibility trial of StopApp™ to estimate recruitment and attrition rates  
45  
46 of participants across three settings: GP surgeries, community settings and on-line;  
47  
48 at baseline, intervention access, and two-month follow-up.  
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### 51 **Secondary Objectives**

52  
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54 Secondary objectives of the MyWay feasibility trial are to estimate the:

- 55  
56  
57 **1.** Acceptability of randomisation and the StopApp™ intervention for  
58  
59 participants.  
60



2. Acceptability of the outcome measures and measures required for cost-effectiveness analyses in a future trial.
3. Key costs which would be incurred in delivering the intervention and usual care, including a comparison of 'Did-not-attend' (DNA) rates between each arm of the trial.
4. Feasibility of accessing SSS and GP data (if recruited via GP) on attendance, quit dates set and four-week abstinence rates for trial participants.
5. Any differential recruitment and attrition rates across socio-economic groups, age and gender.
6. Rate of SSSs attendance in the treatment and control groups to estimate the event rate of the primary outcome measure (e.g. 4 week abstinence rate) for a future trial and to support future trial sample size calculations.

## **METHODS AND ANALYSIS**

### **Study design**

This 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 to assess the acceptability of the research processes, randomisation, measures, and the intervention with a sub-sample of participants.

## Study setting

Smokers who are aged 16 years and over will be recruited from 3 settings across Warwickshire including four GP surgeries, a range of community settings (e.g. children's centres, libraries, wellbeing hubs) and online via social media platforms.

## Eligibility criteria

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, regardless of whether they have previously attended SSS. Access to the internet via a computer or smartphone to complete study measures, view intervention or control content, and receive SMS reminders will be a requirement.

## Intervention

StopApp™ is a web-based self-administered behaviour change intervention designed to address the barriers that smokers typically face in accessing SSSs (Fulton et al., 2018; 2016). Information about users' previous quit attempts and use of SSSs is used to tailor the way in which subsequent content is framed to address any negative perceptions. Users can instantly book an appointment at a time and location of their choice, or get a reminder to re-access the intervention at a later date. StopApp™ is linked to the online outcomes reporting systems owned by Pinnacle Healthcare Ltd and used by SSSs in pharmacies (Pharmoutcomes) in Warwickshire (and many other local authority areas across the UK). These secure systems support service providers

1  
2  
3 in recording standard SSS outcome data such as quit dates and CO verified 4 week  
4  
5 quit rates. In addition to applying co-production and usability methods, the content  
6  
7 of the StopApp™ intervention was systematically developed using the Behaviour  
8  
9 Change Wheel approach (Michie et al., 2014). Specific content within the app  
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11 delivers 17 BCTs identified as most useful for supporting SSS access behaviour (see  
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Fulton et al., 2018; 2016).

### **Control**

The control group will receive access to a webpage displaying Warwickshire's standard stop smoking service provision information ('Quit4good'). The control website does not link to an online 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.

### **Baseline Measures**

An online baseline questionnaire includes questions regarding demographic information (including age, gender, profession, ethnicity, postcode - for purposes of identifying indices of multiple deprivation score); current smoking status and tobacco products used (type and quantity; including e-cigarette (EC) use, 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 (Devlin et al., 2016); and

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3 the ICECAP-A (ICEpop CAPability measure for Adults, Al-Janabi et al., 2012, Al-Janabi  
4 et al., 2013) instrument to measure general wellbeing.  
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### 10 **Two month follow-up measures**

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12 An online follow up questionnaire will assess self-reports of whether participants  
13 booked an appointment and attended a SSS, set a quit date and reached a 4-week  
14 abstinence, and what prompted them to book an appointment. Pinnacle Health Ltd  
15 will run a search of the PharmOutcomes system for MyWay participants (where they  
16 consented) and provide the researchers with objective service use data. This will  
17 allow an assessment regarding the validity of sourcing objective evidence of booking,  
18 attendance (DNA rates), quit dates set, and CO tested 4 week quits. We will also  
19 assess the feasibility of collecting follow-up measures of motivation using the MTSS  
20 and a single item Likert scale (Hummel et al., 2017); the EQ5D-5L instrument; the  
21 ICECAP-A instrument. In addition, a bespoke resource use questionnaire will be  
22 administered, to gain insight into the costs both to individuals and to the public  
23 purse of resources accessed as a result of use of the StopApp™ compared with the  
24 control.  
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### 49 **Data on costs associated with the intervention versus usual care**

50 We will gather, through trial processes, data on the costs associated with delivering  
51 the intervention (e.g. web hosting, text messages) and usual care (e.g. telephone  
52 calls taken to book in appointments). We will also collect data on costs and resource  
53 use associated with promoting the intervention and usual care (e.g marketing  
54 through social media, posters on buses etc.).  
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### **Assignment of interventions: allocation and blinding**

Randomisation will be carried out through the study website during months 12-14 of the study. For this purpose, a digital bespoke randomisation algorithm (embedded within the study website) has been developed in collaboration with our statistician and 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. The research team and participants will be blind to condition assignment.

### **Recruitment**

Recruitment will take place in three settings: GP practices, community settings and online.

#### *1. Recruitment via GP surgery*

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 (ensuring in this process that we are reaching diverse groups). 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 all other resident(s) will receive the control intervention after the study has ended.

Smokers (one 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

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3 in the 'MyWay' study. This will inform them that the study will investigate the best  
4 ways of using the internet to help people to stop smoking. Where a GP practice's  
5 preferred method of contact with patients is via postal letter, 'Docmail' services will  
6 be used to distribute letters. For ethical reasons we will not attempt to recruit  
7 people under 16 years of age as they would typically require parental consent and  
8 parents may not be aware of their child's smoking status. The email/text/letter will  
9 include brief information and a web link to the study website.  
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## 23 *2. Recruitment via community settings*

24 A range of community settings have agreed to promote the study. These include  
25 libraries, leisure centres, wellbeing hubs, children's centres, the family information  
26 service and the registrar's office. A bus stop and bus based advertising campaign will  
27 also be used to aid recruitment. We will supply each participating community setting  
28 with posters to display in prominent locations advertising the 'MyWay' study with  
29 contact details of the research team and a community-setting specific web address  
30 to gain immediate access to the study website for participants. We will train all  
31 relevant staff in participating locations about the study to enable them to answer  
32 any basic questions and to promote it confidently. We will also offer ad hoc research  
33 assistant presence for active promotion and recruitment on site. Where staff provide  
34 a leaflet, access to the study will be either through web link to the project website or  
35 via contact with the research team. Where a research assistant recruits on site,  
36 immediate access will be provided to the study via tablet computers. Participants  
37 will have the option to gain access to the project website without having to commit  
38 to participating.  
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### 3. *Online recruitment*

The marketing and communications team at Warwickshire County Council (WCC) are supporting all online recruitment activities. Specifically, they are providing 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. 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 will promote the study online via their social media channels. Anyone hearing about the study via this method will be able to link directly to the study website via an online-setting specific web address.

#### **Procedure**

Please refer to Figure 1 for a flow diagram illustrating participants' routes through the study. Eligible smokers will be recruited from one of three settings and provided with a link to the study webpage. The study webpage is delivered via Coventry University's secure bespoke study management software ('eNgage'). Participants will be required to endorse mandatory consent statements. Participants then complete a baseline questionnaire which will take approximately 20 minutes to complete.

Following randomisation, both groups will receive a link with near identical content, taking participants to either the control website or to the StopApp™ (intervention group). At the same time, an email containing the link will also be sent to participants to allow them to access the material at a later date. A reminder email

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3 will also be sent to all participants two weeks later. Participants in both conditions  
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5 will be told that if they wish to book an appointment at the SSS, then they are free to  
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7 do so, but in taking part are under no obligation to do so. Participants in both groups  
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9 will have continued access to the content, although they have been designed to be  
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11 used on a single basis. Two months after baseline data collection all participants will  
12  
13 be asked via email to complete an online follow-up questionnaire, and invited to  
14  
15 take part in a nested qualitative study (telephone interviews) to investigate the  
16  
17 acceptability of the MyWay trial. The number of participants from both arms taking  
18  
19 part in the interviews will be capped at n=30. Consenting participants will complete  
20  
21 one telephone interview after follow-up. Staff from recruitment settings (community  
22  
23 and GP) will also be invited to participate in telephone interviews about their  
24  
25 involvement in the study. Participants will be informed that should they wish to  
26  
27 withdraw from the study at any time they should contact the research team using  
28  
29 the project email address (details provided on eNgage and within email  
30  
31 communication). An email with a link to the information leaflet provided to the  
32  
33 control group, will be given to anyone who contacts us after the end of the period of  
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35 recruitment to the study.  
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47 At the first appointment stop smoking advisors will be prompted to ask participants:

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49 i) to confirm they are taking part in the MyWay study/ trial; and if yes, ii) whether  
50  
51 they consent to the research team accessing data on their SSS use, which will be  
52  
53 stored anonymously; and iii) how they heard about the SSS. This is to ensure that  
54  
55 consent for the access of service use data is collected by the data controller in order  
56  
57 that they can create a report on SSS use for trial participants who consent to this.  
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3 The report will identify appointments booked via StopApp™, and sent to a secure  
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5 NHS.net email address, from which names will be cross-referenced against  
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8 participant ID numbers before the data is transferred into the anonymous database  
9  
10 maintained by the research team.  
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### 15 **Procedure for qualitative study**

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17 At baseline, following randomisation, we will ask all participants (using a single  
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19 yes/no question) if they are interested in participating in a brief follow-up telephone  
20  
21 interview at the end of the study, regardless of whether or not they end up  
22  
23 completing the study. For all participants that indicate an interest, we will request a  
24  
25 contact telephone number and their consent to process this information in addition  
26  
27 to personal data already collected. For participants providing this consent, we will  
28  
29 select approximately 30 feasibility RCT participants and invite them to participate in  
30  
31 the process evaluation interviews. We will apply maximum variation sampling using  
32  
33 the demographic characteristic data collected, in order to ensure good  
34  
35 representation of the range of consenting participants. In addition, staff contacts  
36  
37 generated at recruitment sites during data collection will be invited to participate in  
38  
39 process evaluation interviews. Invitation will be by telephone and those who wish to  
40  
41 participate will be sent a follow-up email directing them to a new study page on  
42  
43 eNgage (separate pages will be generated for staff and trial participants). On clicking  
44  
45 'join project', they will receive a message telling them that they will be contacted by  
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47 a member of the research team to set up a mutually convenient time for the  
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49 interview. The interviews will explore acceptability and user experience in line with  
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51 each of the identified research objectives. They will last approximately 30 minutes  
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3 and be audio recorded. Interview transcripts will be transcribed verbatim.  
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5 Participants will be able to withdraw their consent for up to 2 weeks after  
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7 participation in the interview, prior to data analysis. We will allow data analysis to  
8  
9 determine saturation point and when to stop, but anticipate conducting up to 30  
10  
11 interviews. All qualitative data will be subject to thematic analysis (Braun & Clarke,  
12  
13 2006) assisted by NVivo software.  
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### 17 18 19 20 **Patient and public involvement (PPI)** 21

22 We have a PPI group of eleven smokers from a range of SES backgrounds who have  
23  
24 contributed to the design of this feasibility trial, including the participant information  
25  
26 sheet and measures. At least one member of the PPI group will be present at study  
27  
28 steering committee meetings throughout the duration of the feasibility trial.  
29  
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### 32 33 34 **Data Management** 35

36 Study recruitment, consent, randomisation, provision of intervention or control  
37  
38 content, and questionnaire data collection, all takes place within 'eNgage' - Coventry  
39  
40 University's bespoke online research software hosted on their secure server. eNgage  
41  
42 is an online research platform that includes the research pages, study information,  
43  
44 consent and research team contact details. It is developed to work seamlessly with  
45  
46 other web applications. On 'joining' a project, participants provide their full name  
47  
48 and email address, upon which a unique participant ID is created. Participants are  
49  
50 then directed to Qualtrics (a separate questionnaire data inputting software) to  
51  
52 complete the baseline, and later the follow-up, measures. Participants are then  
53  
54 directed back to eNgage where they are randomised to experimental conditions.  
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3 Analytics data on participant use of the research materials (and intervention or  
4 control content) is collected by software called 'Matomo'. All data is linked by the  
5  
6 unique participant ID.  
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## 10 11 12 13 **Statistical Methods**

### 14 15 *Sample size and justification*

16  
17 The primary objective of this study is to assess the feasibility of recruitment to a  
18 potential future definitive RCT and therefore formal power analysis is not  
19  
20 appropriate. However, in order to determine the target sample size, we have drawn  
21  
22 on two sources based on the primary outcome of attendance at SSS (attend vs. does  
23 not attend SSS). Teare et al. (2014) recommend that external pilot and feasibility  
24  
25 studies with binary outcome measures recruit at least 60 participants in each group  
26  
27 (minimum N=120) and a maximum of 100 participants in each group (maximum  
28  
29 N=200). In addition, our sample size calculations, based on similar definitive RCT data  
30  
31 about recruiting smokers to trials via letters from their GPs (Gilbert et al, 2017),  
32  
33 suggested that we would need to enrol 980 smokers to detect a 7% difference in  
34  
35 attendance at SSS between control and intervention arms in a definitive trial. Based  
36  
37 on this estimate, any trial would need to recruit 1.8 participants per day to achieve  
38  
39 the required recruitment in 18 months. We plan to recruit for three months, and  
40  
41 based on needing to recruit 1.8 participants per day, we need to reach a required  
42  
43 sample size of 162 participants (54 per setting). With a sample size of 162, the  
44  
45 recruitment rate of smokers for a full RCT will be estimable with a precision (95% CI  
46  
47 width) of +/- 5%. We will compare recruitment rates across the 3 recruitment  
48  
49 sources.  
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### *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, and to help to determine future trial efficacy. 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

1  
2  
3 participants agreeing to allow access to SSS and GP data (where relevant) relating to  
4  
5 smoking status and SSS attendance.  
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10 We will report on numbers of higher versus lower SES status participants recruited  
11  
12 as well as age and gender, and assess using chi-squared analysis whether SES status,  
13  
14 age or gender are associated with attrition at baseline, intervention/control access  
15  
16 and two-month follow-up.  
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### 23 **Ethics and dissemination**

24  
25 Ethical approval for this study was granted by West Midlands - Edgbaston Research  
26  
27 Ethics Committee (NRES reference 18/WM/0170). To date we have recruited 4 GP  
28  
29 practices and 56 community settings to recruit participants to the study.  
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33 Recruitment is due to commence in January 2019. Data collection takes place until  
34  
35 the end of March 2019. Analysis of data is due to be complete for dissemination in  
36  
37 September 2019. Data will be reported at conferences and in peer reviewed  
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39 journals.  
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### 45 **DISCUSSION**

46  
47 The main purpose of the proposed feasibility study is to determine the necessary  
48  
49 requirements for successful study design and data collection such that a definitive  
50  
51 full trial can be conducted. This will largely be determined by whether one or more  
52  
53 of the recruitment settings is able to produce the required sample size for a future  
54  
55 main trial. We will also use data collected about SES, age and gender of those  
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57 recruited and lost through attrition to understand whether SES is associated with  
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3 retention in the trial. A future potential randomised controlled trial will enable us to  
4  
5 establish whether and to what extent StopApp™ is effective and cost-effective at  
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7 increasing SSS bookings and attendance in comparison to standard methods of  
8  
9 service promotion.  
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12  
13 Although leaflet and letter based methods are effective for increasing  
14  
15 recruitment to SSS's, StopApp™ is unique in that its systematic evidence based  
16  
17 development (Fulton et al., 2016; 2018), aimed to address all identified barriers to  
18  
19 accessing SSSs whilst also taking account of (or will take account of during  
20  
21 evaluation) affordability, practicability, effectiveness (and cost-effectiveness),  
22  
23 acceptability, side-effects (and safety), and equity (Michie, 2014). If effective and  
24  
25 cost-effective, StopApp™ is instantly scalable because PharmOutcomes is already  
26  
27 used extensively across the UK. Therefore it would likely be delivered at even lower  
28  
29 ongoing cost than interventions such as the cost-effective Start2quit letter and taster  
30  
31 session (Gilbert et al 2012; 2017), and if well marketed could reach many more than  
32  
33 the 5 to 10% of smokers that services have reached so far (Dobbie et al., 2015).  
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39

40 Given that public health budgets are under increasing pressure, and evidence  
41  
42 suggests smokers seeking help themselves are more successful at stopping than  
43  
44 those referred by others (Borland et al., 2012), it will become increasingly important  
45  
46 that SSSs are used by more of those making quit attempts each year to enhance their  
47  
48 chances of success. Implementing inexpensive strategies to help this to happen will  
49  
50 therefore maximise effectiveness and help to ensure optimal use of increasingly tight  
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52 public health resources.  
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52 **Figure 1:** Flow diagram illustrating participant's route through project.

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**Contributors:** EF, KB, KN, KK and KG contributed to the literature review, development of the original study protocol and drafting the initial manuscript. EF, KB, KN, LJ, FN and TC contributed to the trial design and outcome measures. LJ, FN and TC offered further feasibility trial advice and contributed to the statistical and health economic analysis plan. All authors approved the final version of the manuscript.

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**Competing interests statement:** None declared

**Sponsor:** The trial is sponsored by Coventry University.

**Trial status:** Recruitment begins in January 2019. This article is based on protocol version 5. Dated July 11, 2019.

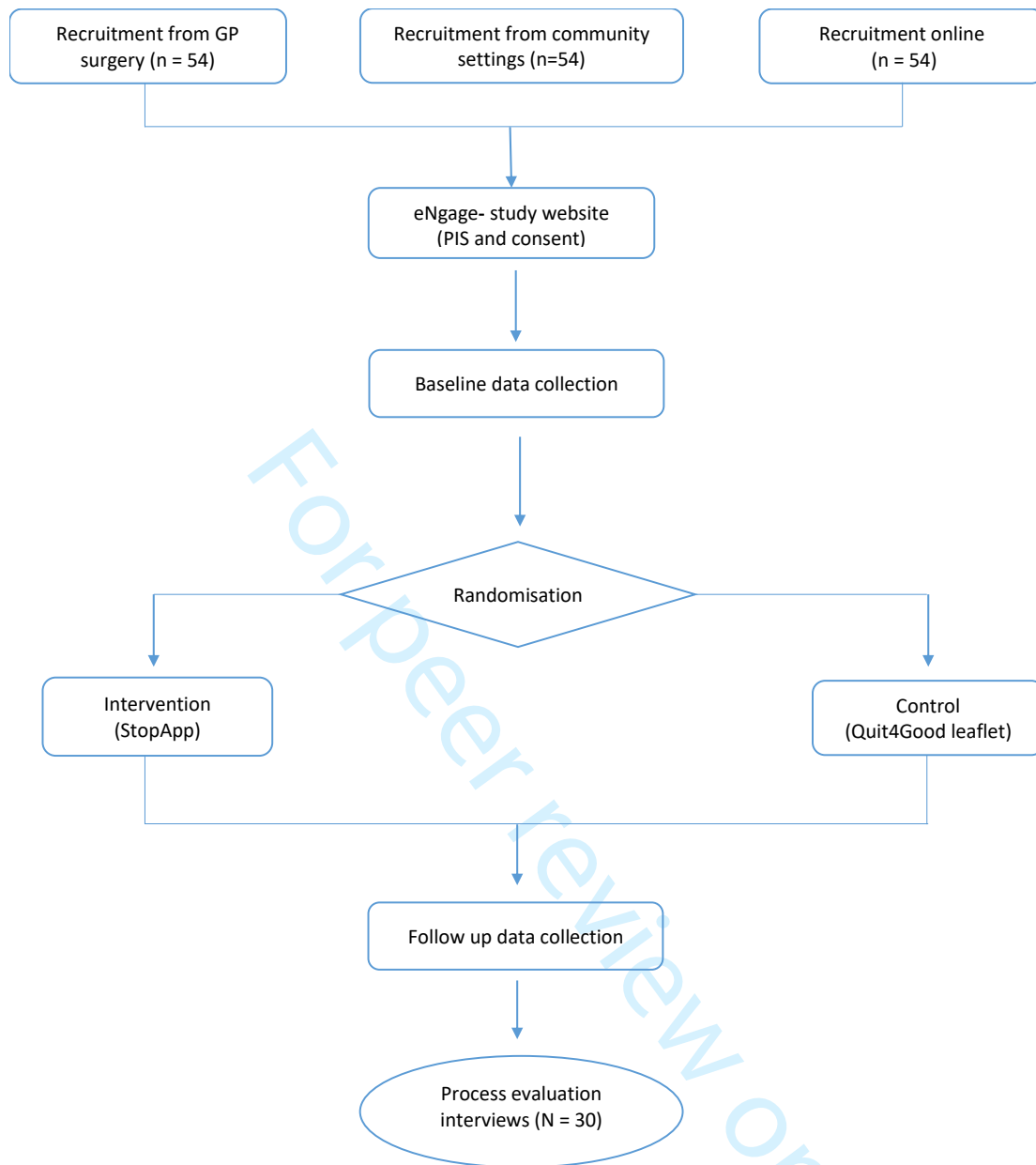


Figure 1: Flow diagram illustrating participant's route through project.

# BMJ Open

## A tailored digital behaviour change intervention with e-referral system to increase attendance at NHS Stop Smoking Services (The MyWay Project): study protocol for a randomised controlled feasibility trial.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-028721.R1
Article Type:	Protocol
Date Submitted by the Author:	29-Jan-2019
Complete List of Authors:	Fulton, Emily; Coventry University, Centre for Advances in Behavioural Science; Newby, Katie; Coventry University, Centre for Advances in Behavioural Science Gokal, Kajal; Coventry University, Centre for Advances in Behavioural Science Kwah, Kayleigh; Coventry University, Centre for Advances in Behavioural Science Schumacher, Lauren; Coventry University Faculty of Health and Life Sciences, Centre for Innovative Research Across the Lifespan Jackson, Louise; University of Birmingham, Health Economics Unit Naughton, Felix; University of East Anglia Faculty of Medicine and Health Sciences, School of Health Sciences Coleman, Tim; University of Nottingham, Division of General Practice Brown, Katherine; Coventry University, Centre for Advances in Behavioural Science
<b>Primary Subject Heading</b>:	Smoking and tobacco
Secondary Subject Heading:	Public health
Keywords:	Stop Smoking Services, Digital Interventions, Health Behaviour Change, Randomised Controlled Feasibility Trial, Protocol

SCHOLARONE™  
Manuscripts

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3 **A tailored digital behaviour change intervention with e-referral system to increase**  
4 **attendance at NHS Stop Smoking Services (The MyWay Project): study protocol for**  
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6 **a randomised controlled feasibility trial.**  
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48 **Keywords:** Randomised Controlled Trial; Smoking cessation; Stop Smoking Services;  
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51 Behaviour Change; Digital Intervention  
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53 **Word count:** 4,311  
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## ABSTRACT

**Introduction:** In the UK, smokers who use Stop Smoking Services (SSS) are four times more likely to stop smoking than smokers who do not. Attendance has declined, warranting the development of interventions to address this. StopApp™ is a novel, brief online behaviour change intervention designed to address common barriers to SSS attendance. It links to widely commissioned service management software which enables instant appointment booking at a user's location and time of choice.

**Methods and analysis:** 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 includes a nested qualitative process evaluation to assess the acceptability of the research processes, with a sub-sample of participants. Smokers aged over 16 years will be recruited via three routes: GP practices, community settings and online. After consenting and the collection of baseline data, participants will be randomised to control or intervention groups. Participants in the intervention group receive a link to StopApp™ and those in the control group receive standard web-based information about the SSS. All participants are told they can book a SSS appointment but are under no obligation to do so. Online follow-up 2 months post randomisation includes data on SSS use and carbon monoxide verified 4 week quit rates. The study aims to recruit 162 smokers.

**Ethics and dissemination:** Ethics approval has been granted by the West Midlands - Edgbaston NHS Research Ethics Committee. The findings will be reported in conferences and peer-reviewed publications; and will be used to design the parameters necessary for a definitive trial to ascertain the effectiveness of

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3 StopApp™ at increasing booking and attendance at SSSs compared with existing  
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5 methods for encouraging uptake.  
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8 **Trial Registration:** Research Registry: 3995. Trial Registered 18<sup>th</sup> April 2018.  
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### 11 12 13 14 **Strengths and limitations of this study**

- 15  
16 • A randomised controlled trial with nested qualitative evaluation to ascertain  
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18 acceptability of trial processes.  
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- 21  
22 • Both objective and subjective measures are included to assess 4 week quit  
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24 rates.  
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- 27  
28 • Comparison of different sources of recruitment, including GP, community  
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30 settings and online social media.  
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- 32  
33 • Potential for selection bias including the requirement for participants to have  
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35 access to the internet.  
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38 • Reliance on self-report data only for those in the control arm.  
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## INTRODUCTION

Smoking remains a leading cause of mortality and morbidity worldwide[1]. In addition, the direct costs of smoking to the UK National Health Service (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[2]. NHS 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 typically 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[3]. 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[4]. 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[5].

Although most smokers want to quit, and between 22 and 31% of them will make at least one attempt to quit each year[6], SSSs currently only reach 5-10% of the smoking population[7]. In addition, despite the effectiveness of SSSs[6], relative to the number of smokers, uptake has declined in recent years[8]. 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 and EC use as mutually exclusive[9]. A third of smokers in England have used EC at least once[10], and whilst their use is

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3 associated with significant reductions in numbers of cigarettes smoked this has not  
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5 led to an overall rise in quit attempts[11]. Therefore, SSSs are still needed to support  
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7 quit attempts.  
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10 A range of studies conducted since the commissioning of SSSs began, suggest  
11  
12 that smokers (in particular those from lower socio-economic status (SES) groups) are  
13  
14 often unaware that SSSs exist, or what type of service they offer[12-16]. Other  
15  
16 barriers to accessing SSSs include holding beliefs that the services lack efficacy, and  
17  
18 will be impersonal, judgmental, and not tailored to individual needs. Additionally  
19  
20 seeking help to stop is viewed as a sign of personal weakness[12-14,17]. Typically,  
21  
22 these barriers to service uptake have not formed the focus of interventions or health  
23  
24 promotion campaigns targeted at smokers, possibly because access to SSSs had been  
25  
26 robust and growing until recently[18]. Research has shown however, that booklets  
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28 explaining the efficacy of services[19] and proactively recruiting smokers through GP  
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30 practices can increase attendance at SSSs and four-week quit rates[20]. A recent trial  
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32 (Start2quit) assessing personalised risk information in the form of a letter from  
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34 patients' GPs and an offer of SSS taster sessions, was both effective and cost-  
35  
36 effective at increasing SSS uptake[21,22].  
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44 StopApp™ is a brief, novel web-based behaviour change intervention,  
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46 developed with input from smokers from across the SES spectrum that targets the  
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48 known barriers to service access to improve users' motivation and capability to  
49  
50 access SSS. StopApp™ links to an existing on-line booking and service management  
51  
52 system used by pharmacies offering SSS (PharmOutcomes), providing the  
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54 opportunity to instantly book a first appointment at SSSs at a time and location to  
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56 suit the user. A feasibility trial of StopApp™ (The MyWay study) is required to  
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3 establish whether a future Randomised Controlled Trial (RCT) can be achieved. This  
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5 is especially necessary due to i) the novelty of the StopApp™ intervention; ii) the  
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7 potential for overlooking health inequalities associated with smoking when using  
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9 digital interventions; and iii) the limited extant research employing the required trial  
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11 design across recruitment contexts that replicate real-world use of the intervention  
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15 (including online and community settings).  
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### 21 **Aims and Objectives**

22  
23 The aim of the proposed research is to establish the feasibility of a future  
24  
25 randomised controlled trial of the StopApp™ intervention.  
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27

### 28 **Primary Objective**

29  
30 To conduct a feasibility trial of StopApp™ to estimate recruitment and attrition rates  
31  
32 of participants across three settings: GP surgeries, community settings and on-line;  
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34 at baseline, intervention access, and two-month follow-up.  
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### 39 **Secondary Objectives**

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41 Secondary objectives of the MyWay feasibility trial are to estimate the:  
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- 44  
45 **1.** Acceptability of randomisation and the StopApp™ intervention for  
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47 participants.
- 48  
49 **2.** Acceptability of the outcome measures and measures required for cost-  
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51 effectiveness analyses in a future trial.
- 52  
53 **3.** Key costs which would be incurred in delivering the intervention and  
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55 usual care, including a comparison of 'Did-not-attend' (DNA) rates  
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57 between each arm of the trial.  
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4. Feasibility of accessing SSS and GP data (if recruited via GP) on attendance, quit dates set and four-week abstinence rates for trial participants.
  5. Any differential recruitment and attrition rates across socio-economic groups, age and gender.
  6. Rate of SSSs attendance in the treatment and control groups to estimate the event rate of the primary outcome measure (e.g. 4 week abstinence rate) for a future trial and to support future trial sample size calculations.

## METHODS AND ANALYSIS

### Study design

This 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 to assess the acceptability of the research processes, randomisation, measures, and the intervention with a sub-sample of participants.

### Important changes to methods after pilot trial commencement

Shortly after the trial commenced, it was clear that recruitment, in particular via GP practices, was slow. Observation of analytics data regarding visits to the research platform indicated that many potential participants were clicking though but not registering and taking part. In response to this, we decided to offer a financial

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2  
3 incentive (reimbursement) to participants joining the study via community settings  
4  
5 and social media, for their time to complete both measures in the form of a £10 e-  
6  
7 gift token. It was intended that this would also reduce drop-out at follow up. The  
8  
9 changes were approved by both the funder and ethics board. Recruitment in GP  
10  
11 practices had ended at this stage so the financial incentive was not offered to  
12  
13 participants via this route. Participants already recruited to the study via social  
14  
15 media and community settings were contacted and offered the voucher.  
16  
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21  
22

## 23 **Participants**

### 24 *Eligibility criteria*

25  
26 All current smokers aged over 16 years registered with participating GP practices in  
27  
28 Warwickshire, or accessing participating community services or viewing advertising  
29  
30 for the study online, will be invited to take part, regardless of whether they have  
31  
32 previously attended SSS. Access to the internet via a computer or smartphone to  
33  
34 complete study measures, view intervention or control content, and receive SMS  
35  
36 reminders will be a requirement.  
37  
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44

### 45 *Setting*

46  
47 Smokers who are aged 16 years and over will be recruited from 3 settings across  
48  
49 Warwickshire including four GP surgeries, a range of community settings (e.g.  
50  
51 children's centres, libraries, wellbeing hubs) and online via social media platforms.  
52  
53  
54  
55

### 56 *Recruitment*

57  
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1  
2  
3 Recruitment will take place in three settings: GP practices, community settings and  
4  
5 online.  
6  
7

8 *1. Recruitment via GP surgery*  
9

10 The Clinical Research Network (CRN) are supporting recruitment via GP surgeries.  
11  
12 GP practices in Warwickshire have been invited to participate and of those who are  
13 interested, we will select four for the feasibility trial (ensuring in this process that we  
14 are reaching diverse groups). To remove the chances of contamination, we will  
15 contact one smoker per household only. Where two or more smokers cohabit, the  
16 resident whose first name is alphabetically first will be selected for invitation to the  
17 study and all other resident(s) will receive the control intervention after the study  
18 has ended.  
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32 Smokers (one per household) will be sent an email and/or text or letter (dependent  
33 on GP and patient communications set up) from their GP inviting them to take part  
34 in the 'MyWay' study. This will inform them that the study will investigate the best  
35 ways of using the internet to help people to stop smoking. Where a GP practice's  
36 preferred method of contact with patients is via postal letter, 'Docmail' services will  
37 be used to distribute letters. For ethical reasons we will not attempt to recruit  
38 people under 16 years of age as they would typically require parental consent and  
39 parents may not be aware of their child's smoking status. The email/text/letter will  
40 include brief information and a web link to the study website.  
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57 *2. Recruitment via community settings*  
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3 A range of community settings have agreed to promote the study. These include  
4  
5 libraries, leisure centres, wellbeing hubs, children's centres, the family information  
6  
7 service and the registrar's office. A bus stop and bus based advertising campaign will  
8  
9 also be used to aid recruitment. We will supply each participating community setting  
10  
11 with posters to display in prominent locations advertising the 'MyWay' study with  
12  
13 contact details of the research team and a community-setting specific web address  
14  
15 to gain immediate access to the study website for participants. We will train all  
16  
17 relevant staff in participating locations about the study to enable them to answer  
18  
19 any basic questions and to promote it confidently. We will also offer ad hoc research  
20  
21 assistant presence for active promotion and recruitment on site. Where staff provide  
22  
23 a leaflet, access to the study will be either through web link to the project website or  
24  
25 via contact with the research team. Where a research assistant recruits on site,  
26  
27 immediate access will be provided to the study via tablet computers. Participants  
28  
29 will have the option to gain access to the project website without having to commit  
30  
31 to participating.  
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### 42 3. *Online recruitment*

43  
44 The marketing and communications team at Warwickshire County Council (WCC) are  
45  
46 supporting all online recruitment activities. Specifically, they are providing support  
47  
48 for online promotion of the study via social media, targeted email marketing, Google  
49  
50 advertising and all WCC internal and external channels such as press releases and  
51  
52 electronic newsletters. These ads will appear to anyone in the Warwickshire area  
53  
54 searching for health-related products or services. We will run a three-month long  
55  
56 campaign to advertise the study. In addition, participating community settings will  
57  
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1  
2  
3 promote the study online via their social media channels. Anyone hearing about the  
4  
5 study via this method will be able to link directly to the study website via an online-  
6  
7 setting specific web address.  
8  
9

### 10 11 12 **Interventions**

13  
14  
15 Please refer to Figure 1 for a flow diagram illustrating participants' routes through  
16  
17 the study. Eligible smokers will be recruited from one of three settings and provided  
18  
19 with a link to the study webpage. The study webpage is delivered via Coventry  
20  
21 University's secure bespoke study management software ('eNgage'). Participants will  
22  
23 be required to endorse mandatory consent statements. Participants then complete a  
24  
25 baseline questionnaire which will take approximately 20 minutes to complete.  
26  
27

28  
29 Following randomisation, both groups will receive a link with near identical content,  
30  
31 taking participants to either the control website or to the StopApp™ (intervention  
32  
33 group). At the same time, an email containing the link will also be sent to  
34  
35 participants to allow them to access the material at a later date. A reminder email  
36  
37 will also be sent to all participants two weeks later. Participants in both conditions  
38  
39 will be told that if they wish to book an appointment at the SSS, then they are free to  
40  
41 do so, but in taking part are under no obligation to do so. Participants in both groups  
42  
43 will have continued access to the content, although they have been designed to be  
44  
45 used on a single basis. Two months after baseline data collection all participants will  
46  
47 be asked via email to complete an online follow-up questionnaire, and invited to  
48  
49 take part in a nested qualitative study (telephone interviews) to investigate the  
50  
51 acceptability of the MyWay trial. The number of participants from both arms taking  
52  
53 part in the interviews will be capped at n=30. Consenting participants will complete  
54  
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1  
2  
3 one telephone interview after follow-up. Staff from recruitment settings (community  
4 and GP) will also be invited to participate in telephone interviews about their  
5 involvement in the study. Participants will be informed that should they wish to  
6 withdraw from the study at any time they should contact the research team using  
7 the project email address (details provided on eNgage and within email  
8 communication). An email with a link to the information leaflet provided to the  
9 control group, will be given to anyone who contacts us after the end of the period of  
10 recruitment to the study.  
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25 At the first appointment stop smoking advisors will be prompted to ask participants:

26 i) to confirm they are taking part in the MyWay study/ trial; and if yes, ii) whether  
27 they consent to the research team accessing data on their SSS use, which will be  
28 stored anonymously; and iii) how they heard about the SSS. This is to ensure that  
29 consent for the access of service use data is collected by the data controller in order  
30 that they can create a report on SSS use for trial participants who consent to this.  
31  
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40 The report will identify appointments booked via StopApp™, and sent to a secure  
41 NHS.net email address, from which names will be cross-referenced against  
42 participant ID numbers before the data is transferred into the anonymous database  
43 maintained by the research team.  
44  
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#### 54 *Qualitative study*

55  
56 At baseline, following randomisation, we will ask all participants (using a single  
57 yes/no question) if they are interested in participating in a brief follow-up telephone  
58  
59  
60

1  
2  
3 interview at the end of the study, regardless of whether or not they end up  
4  
5 completing the study. For all participants that indicate an interest, we will request a  
6  
7 contact telephone number and their consent to process this information in addition  
8  
9 to personal data already collected. For participants providing this consent, we will  
10  
11 select approximately 30 feasibility RCT participants and invite them to participate in  
12  
13 the process evaluation interviews. We will apply maximum variation sampling using  
14  
15 the demographic characteristic data collected, in order to ensure good  
16  
17 representation of the range of consenting participants. In addition, staff contacts  
18  
19 generated at recruitment sites during data collection will be invited to participate in  
20  
21 process evaluation interviews. Invitation will be by telephone and those who wish to  
22  
23 participate will be sent a follow-up email directing them to a new study page on  
24  
25 eNgage (separate pages will be generated for staff and trial participants). On clicking  
26  
27 'join project', they will receive a message telling them that they will be contacted by  
28  
29 a member of the research team to set up a mutually convenient time for the  
30  
31 interview. The interviews will explore acceptability and user experience in line with  
32  
33 each of the identified research objectives. They will last approximately 30 minutes  
34  
35 and be audio recorded. Interview transcripts will be transcribed verbatim.  
36  
37 Participants will be able to withdraw their consent for up to 2 weeks after  
38  
39 participation in the interview, prior to data analysis. We will allow data analysis to  
40  
41 determine saturation point and when to stop, but anticipate conducting up to 30  
42  
43 interviews. All qualitative data will be subject to thematic analysis[23] assisted by  
44  
45 NVivo software.  
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### *Intervention arm*

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2  
3 StopApp™ is a web-based self-administered behaviour change intervention designed  
4  
5 to address the barriers that smokers typically face in accessing SSSs[17,24].  
6

7  
8 Information about users' previous quit attempts and use of SSSs is used to tailor the  
9  
10 way in which subsequent content is framed to address any negative perceptions.  
11

12  
13 Users can instantly book an appointment at a time and location of their choice, or  
14  
15 get a reminder to re-access the intervention at a later date. StopApp™ is linked to  
16  
17 the online outcomes reporting systems owned by Pinnacle Healthcare Ltd and used  
18  
19 by SSSs in pharmacies (Pharmoutcomes) in Warwickshire (and many other local  
20  
21 authority areas across the UK). These secure systems support service providers in  
22  
23 recording standard SSS outcome data such as quit dates and CO verified 4 week quit  
24  
25 rates. In addition to applying co-production and usability methods, the content of  
26  
27 the StopApp™ intervention was systematically developed using the Behaviour  
28  
29 Change Wheel approach[25]. Specific content within the app delivers 17 BCTs  
30  
31 identified as most useful for supporting SSS access behaviour[17,24].  
32  
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#### 40 *Control arm*

41  
42 The control group will receive access to a webpage displaying Warwickshire's  
43  
44 standard stop smoking service provision information ('Quit4good'). The control  
45  
46 website does not link to an online booking system and does not provide tailored  
47  
48 routing according to the types of barriers a smoker may have to SSS access. It has not  
49  
50 been systematically designed to address barriers to service access and is not  
51  
52 underpinned by a theory of behaviour change or identified BCTs.  
53  
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#### 60 **Data Management**

1  
2  
3 Study recruitment, consent, randomisation, provision of intervention or control  
4  
5 content, and questionnaire data collection, all takes place within 'eNgage' - Coventry  
6  
7 University's bespoke online research software hosted on their secure server. eNgage  
8  
9 is an online research platform that includes the research pages, study information,  
10  
11 consent and research team contact details. It is developed to work seamlessly with  
12  
13 other web applications. On 'joining' a project, participants provide their full name  
14  
15 and email address, upon which a unique participant ID is created. Participants are  
16  
17 then directed to Qualtrics (a separate questionnaire data inputting software) to  
18  
19 complete the baseline, and later the follow-up, measures. Participants are then  
20  
21 directed back to eNgage where they are randomised to experimental conditions.  
22  
23 Analytics data on participant use of the research materials (and intervention or  
24  
25 control content) is collected by software called 'Matomo'. All data is linked by the  
26  
27 unique participant ID.  
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## 38 **Outcomes**

### 39 *Baseline Measures*

40  
41 An online baseline questionnaire includes questions regarding demographic  
42  
43 information (including age, gender, profession, ethnicity, postcode - for purposes of  
44  
45 identifying indices of multiple deprivation score); current smoking status and  
46  
47 tobacco products used (type and quantity; including e-cigarette (EC) use, previous  
48  
49 use of SSS, ease of internet access; and motivation to quit, measured using the one  
50  
51 item 'Motivation to Stop Scale', MTSS[26] and a single item Likert scale[27]. Health-  
52  
53 related quality of life data will be collected using the EQ5D-5L instrument to inform  
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1  
2  
3 the health economic analysis[28]; and the ICECAP-A (ICEpop CAPability measure for  
4 Adults)[29,30] instrument to measure general wellbeing.  
5  
6  
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8  
9

### 10 *Two month follow-up measures*

11  
12  
13 An online follow up questionnaire will assess self-reports of whether participants  
14  
15 booked an appointment and attended a SSS, set a quit date and reached a 4-week  
16  
17 abstinence, and what prompted them to book an appointment. Pinnacle Health Ltd  
18  
19 will run a search of the PharmOutcomes system for MyWay participants (where they  
20  
21 consented) and provide the researchers with objective service use data. This will  
22  
23 allow an assessment regarding the validity of sourcing objective evidence of booking,  
24  
25 attendance (DNA rates), quit dates set, and CO tested 4 week quits. We will also  
26  
27 assess the feasibility of collecting follow-up measures of motivation using the MTSS  
28  
29 and a single item Likert scale[27]; the EQ5D-5L instrument; the ICECAP-A instrument.  
30  
31 In addition, a bespoke resource use questionnaire will be administered, to gain  
32  
33 insight into the costs both to individuals and to the public purse of resources  
34  
35 accessed as a result of use of the StopApp™ compared with the control.  
36  
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### 45 *Data on costs associated with the intervention versus usual care*

46  
47 We will gather, through trial processes, data on the costs associated with delivering  
48  
49 the intervention (e.g. web hosting, text messages) and usual care (e.g. telephone  
50  
51 calls taken to book in appointments). We will also collect data on costs and resource  
52  
53 use associated with promoting the intervention and usual care (e.g marketing  
54  
55 through social media, posters on buses etc.).  
56  
57  
58  
59  
60

## 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 based on the primary outcome of attendance at SSS (attend vs. does not attend SSS). Researchers have recommend that external pilot and feasibility studies with binary outcome measures recruit at least 60 participants in each group (minimum N=120) and a maximum of 100 participants in each group (maximum N=200)[31]. In addition, our sample size calculations, based on similar definitive RCT data about recruiting smokers to trials via letters from their GPs[22], suggested that we would need to enrol 980 smokers to detect a 7% difference in attendance at SSS 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%. We will compare recruitment rates across the 3 recruitment sources.

## Randomisation

### *Sequence generation, allocation & blinding*

Randomisation will be carried out through the study website during months 12-14 of the study. For this purpose, a digital bespoke randomisation algorithm (embedded

1  
2  
3 within the study website) has been developed in collaboration with our statistician  
4  
5 and the Clinical Trials Unit (CTU) at the University of Warwick. This will auto-  
6  
7 randomise at the individual level (1:1) using minimisation to ensure balance. The  
8  
9 research team and participants will be blind to condition assignment.  
10  
11  
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15

### 16 *Statistical methods*

17  
18  
19 Feasibility and acceptability of all measures will be assessed by level of completeness  
20  
21 and by follow-up qualitative interviews with a sub-sample of participants (see detail  
22  
23 above on nested qualitative study). We will calculate recruitment rate via GP  
24  
25 surgeries as a percentage of those recruited from those smokers identified on  
26  
27 participating GPs lists. We will calculate recruitment via community and online  
28  
29 settings as the time taken and spend required to recruit 54 participants and/or the  
30  
31 number recruited and spend over three months. We will calculate the average  
32  
33 recruitment rate per day across the three settings. We will provide percentage rates  
34  
35 for attrition across each recruitment setting at each of baseline, intervention/control  
36  
37 access, and two-month follow-up.  
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45

46 We will look at the observed difference between intervention and control groups for  
47  
48 bookings and attendance at SSS and use this data to support estimates for the  
49  
50 required sample size for a definitive trial, and to help to determine future trial  
51  
52 efficacy. We will assess level of completeness of all measures and run missing value  
53  
54 analysis to determine whether any missing data are missing at random or whether  
55  
56 patterns of missing data may indicate a problem with measures. We will report  
57  
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1  
2  
3 observed and self-reported bookings, attendances, quit rates set and four-week  
4  
5  
6 quits across the intervention and control groups, and the proportion of participants  
7  
8 agreeing to allow access to SSS and GP data (where relevant) relating to smoking  
9  
10 status and SSS attendance. We will report on numbers of higher versus lower SES  
11  
12 status participants recruited as well as age and gender, and assess using chi-squared  
13  
14 analysis whether SES status, age or gender are associated with attrition at baseline,  
15  
16 intervention/control access and two-month follow-up.  
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### 23 **Patient and public involvement (PPI)**

24  
25 We have a PPI group of eleven smokers from a range of SES backgrounds who have  
26  
27 contributed to the design of this feasibility trial, including the participant information  
28  
29 sheet and measures. At least one member of the PPI group will be present at study  
30  
31 steering committee meetings throughout the duration of the feasibility trial.  
32  
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### 40 **DISCUSSION**

41  
42 The main purpose of the proposed feasibility study is to determine the necessary  
43  
44 requirements for successful study design and data collection such that a definitive  
45  
46 full trial can be conducted. This will largely be determined by whether one or more  
47  
48 of the recruitment settings is able to produce the required sample size for a future  
49  
50 main trial. We will also use data collected about SES, age and gender of those  
51  
52 recruited and lost through attrition to understand whether SES is associated with  
53  
54 retention in the trial. A future potential randomised controlled trial will enable us to  
55  
56 establish whether and to what extent StopApp™ is effective and cost-effective at  
57  
58  
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1  
2  
3 increasing SSS bookings and attendance in comparison to standard methods of  
4  
5 service promotion.  
6

7  
8 Although leaflet and letter based methods are effective for increasing  
9  
10 recruitment to SSS's, StopApp™ is unique in that its systematic evidence based  
11  
12 development[17,24], aimed to address all identified barriers to accessing SSSs whilst  
13  
14 also taking account of (or will take account of during evaluation) affordability,  
15  
16 practicability, effectiveness (and cost-effectiveness), acceptability, side-effects (and  
17  
18 safety), and equity[25]. If effective and cost-effective, StopApp™ is instantly scalable  
19  
20 because PharmOutcomes is already used extensively across the UK. Therefore it  
21  
22 would likely be delivered at even lower ongoing cost than interventions such as the  
23  
24 cost-effective Start2quit letter and taster session[21,22], and if well marketed could  
25  
26 reach many more than the 5 to 10% of smokers that services have reached so far[7].  
27  
28  
29  
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31

32 Given that public health budgets are under increasing pressure, and evidence  
33  
34 suggests smokers seeking help themselves are more successful at stopping than  
35  
36 those referred by others[32], it will become increasingly important that SSSs are  
37  
38 used by more of those making quit attempts each year to enhance their chances of  
39  
40 success. Implementing inexpensive strategies to help this to happen will therefore  
41  
42 maximise effectiveness and help to ensure optimal use of increasingly tight public  
43  
44 health resources.  
45  
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### 51 **Trial Registration**

52  
53 The trial is registered as: researchregistry3995.  
54  
55

### 56 **Funding**

57  
58  
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60

1  
2  
3 The feasibility trial is funded by the National Institute of Health Research (NIHR)  
4  
5 Public Health Research (PHR) Programme (NIHR Portfolio number: 38004).  
6  
7

### 8 **Ethics and dissemination**

9

10 Ethical approval for this study was granted by West Midlands - Edgbaston Research  
11  
12 Ethics Committee (NRES reference 18/WM/0170). Recruitment commenced in  
13  
14 January 2019. Data collection takes place until the end of March 2019. Analysis of  
15  
16 data is due to be complete for dissemination in September 2019. Data will be  
17  
18 reported at conferences and in peer reviewed journals.  
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23 **Figure 1:** Flow diagram illustrating participant's route through project.  
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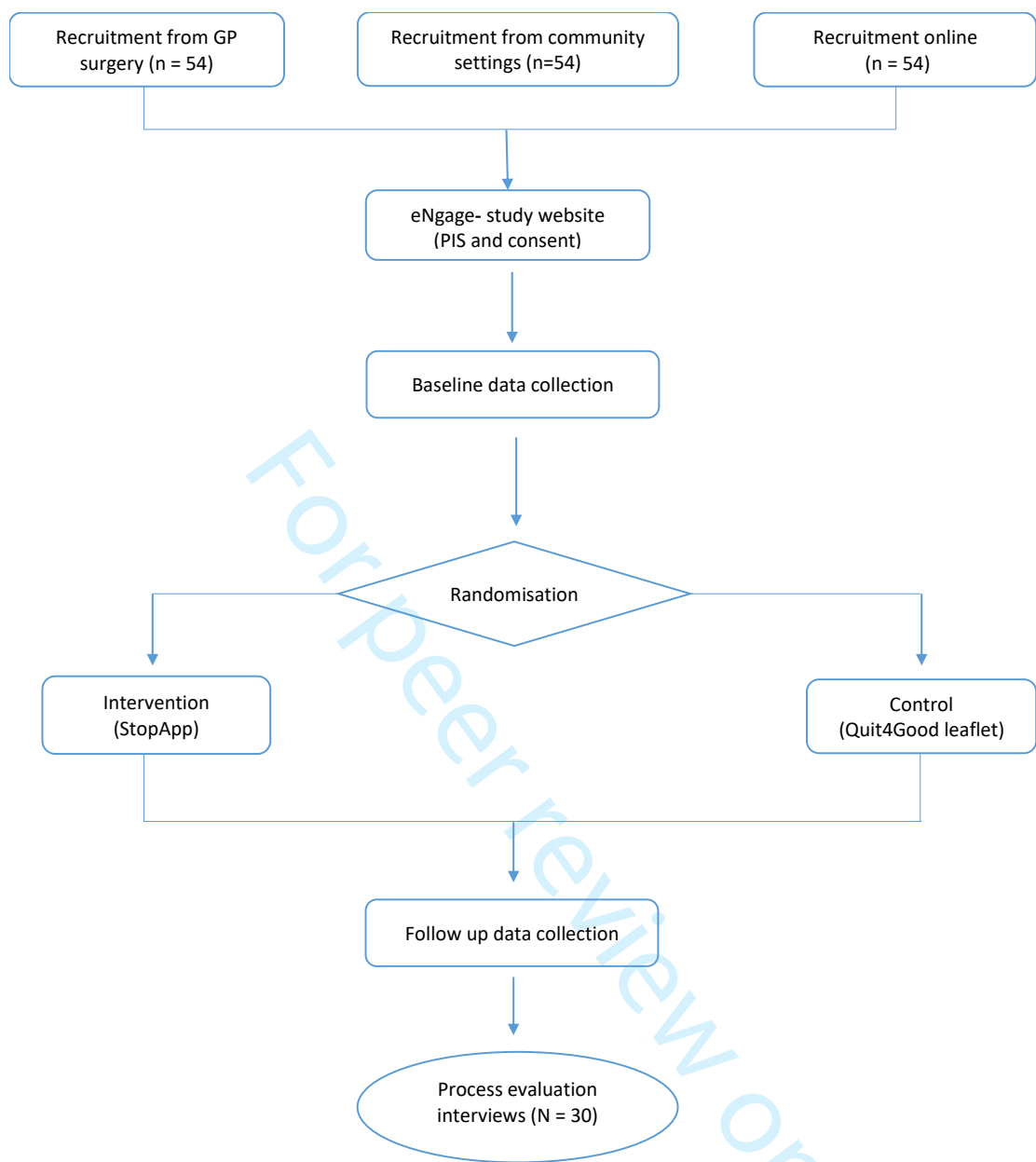


Figure 1: Flow diagram illustrating participant's route through project.