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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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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

StopApp™ at increasing booking and attendance at SSSs compared with existing methods for encouraging uptake.

Trial Registration: Research Registry: 3995. Trial Registered 18th April 2018.

Strengths and limitations of this study

- A randomised controlled trial with nested qualitative evaluation to ascertain acceptability of trial processes.
- Both objective and subjective measures are included to assess 4 week quit rates.
- Comparison of different sources of recruitment, including GP, community settings and online social media.

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

not view SSS and EC use 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 this has not led to an overall rise in quit attempts (West and Brown, 2015). Therefore, SSSs are still needed to support quit attempts.

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 to accessing SSSs include holding beliefs that the services lack efficacy, and will be impersonal, judgmental, and not tailored to individual needs. Additionally seeking help to stop is viewed as a sign of personal weakness (Roddy et al., 2006, Copeland et al., 2010, Benson et al., 2014; Fulton et al., 2016). Typically, these barriers to service uptake have not formed the focus of interventions or health promotion campaigns targeted at smokers, possibly because access to SSSs had been robust and growing until recently (Langley et al., 2014). Research has shown however, that booklets explaining the efficacy of services (Matcham et al., 2014) and 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 and an offer of SSS taster sessions, was both effective and cost-effective at increasing SSS uptake (Gilbert et al., 2012, 2017).

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 and service management system used by pharmacies offering SSS (PharmOutcomes), providing the opportunity to instantly book a first appointment at SSSs at a time and location to suit the user. A feasibility trial of StopApp™ (The MyWay study) is required to establish whether a future Randomised Controlled Trial (RCT) can be achieved. This is especially necessary due to i) the novelty of the StopApp™ intervention; ii) the potential for overlooking health inequalities associated with smoking when using digital interventions; and iii) 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).

Aims and Objectives

The aim of the proposed research is to establish the feasibility of a future randomised controlled trial of the StopApp™ intervention.

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.

Secondary Objectives

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

1. Acceptability of randomisation and the StopApp™ intervention for participants.

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

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

the ICECAP-A (ICEpop CAPability measure for Adults, Al-Janabi et al., 2012, Al-Janabi et al., 2013) instrument to measure general wellbeing.

Two month follow-up measures

An online follow up questionnaire will assess self-reports of whether participants booked an appointment and attended a SSS, set a quit date and reached a 4-week abstinence, and what prompted them to book an appointment. Pinnacle Health Ltd will run a search of the PharmOutcomes system for MyWay participants (where they consented) and provide the researchers with objective service use data. This will allow an assessment regarding the validity of sourcing objective evidence of booking, attendance (DNA rates), quit dates set, and CO tested 4 week quits. We will also assess the feasibility of collecting 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. In addition, a bespoke resource use questionnaire will be administered, to gain insight into the costs both to individuals and to the public purse of resources accessed as a result of use of the StopApp™ compared with the control.

Data on costs associated with 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.).

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

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. For ethical reasons we will not attempt to recruit people under 16 years of age as they would typically require parental consent and parents may not be aware of their child's smoking status. The email/text/letter will include brief information and a web link to the study website.

2. *Recruitment via community settings*

A range of community settings have agreed to promote the study. These include libraries, leisure centres, wellbeing hubs, children's centres, the family information service and the registrar's office. A bus stop and bus based advertising campaign will also be used 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 web address to gain immediate access to the study website for participants. We will train all relevant staff in participating locations about the study to enable them to answer any basic questions and to promote it confidently. We will also offer 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 web link to the project website or via contact with the research team. Where a research assistant recruits on site, immediate access will be provided to the study via tablet computers. Participants will have the option to gain access to the project website without having to commit to participating.

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

will also be sent to all participants two weeks later. 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. Participants in both groups will have continued access to the content, although they have been designed to be used on a single basis. Two months after baseline data collection all participants will be asked via email to complete an online follow-up questionnaire, and invited to take part in a nested qualitative study (telephone interviews) to investigate the acceptability of the MyWay trial. The number of participants from both arms taking part in the interviews will be capped at n=30. 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. Participants will be informed that should they wish to withdraw from the study at any time they should contact the research team using the project email address (details provided on eNgage and within email communication). An email with a link to the information leaflet provided to the control group, will be given to anyone who contacts us after the end of the period of recruitment to the study.

At the first appointment stop smoking advisors will be prompted to ask participants: i) to confirm they are taking part in the MyWay study/ trial; and if yes, ii) whether they consent to the research team accessing data on their SSS use, which will be stored anonymously; and iii) how they heard about the SSS. This is to ensure that consent for the access of service use data is collected by the data controller in order that they can create a report on SSS use for trial participants who consent to this.

The report will identify appointments booked via StopApp™, and sent to a secure NHS.net email address, from which names will be cross-referenced against participant ID numbers before the data is transferred into the anonymous database maintained by the research team.

Procedure for qualitative study

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 select approximately 30 feasibility RCT participants and invite them to participate in the process evaluation interviews. We will apply maximum variation sampling using the demographic characteristic data collected, in order to ensure good representation of the range of consenting participants. In addition, staff contacts generated at recruitment sites during data collection will be invited to participate in process evaluation interviews. 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 (separate pages will be generated for staff and trial participants). 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 explore acceptability and user experience in line with each of the identified research objectives. They will last approximately 30 minutes

and be audio recorded. Interview transcripts will be transcribed verbatim. Participants will be able to withdraw their consent for up to 2 weeks after participation in the interview, prior to data analysis. We will allow data analysis to determine saturation point and when to stop, but anticipate conducting up to 30 interviews. All qualitative data will be subject to thematic analysis (Braun & Clarke, 2006) assisted by NVivo software.

Patient and public involvement (PPI)

We have a PPI group of eleven smokers from a range of SES backgrounds who have contributed to the design of this feasibility trial, including the participant information sheet and measures. At least one member of the PPI group will be present at study steering committee meetings throughout the duration of the feasibility trial.

Data Management

Study recruitment, consent, randomisation, provision of intervention or control content, and questionnaire data collection, all takes place within 'eNgage' - Coventry University's bespoke online research software hosted on their secure server. eNgage is an online research platform that includes the research pages, study information, consent and research team contact details. It is developed to work seamlessly with other web applications. On 'joining' a project, participants provide their full name and email address, upon which a unique participant ID is created. Participants are then directed to Qualtrics (a separate questionnaire data inputting software) to complete the baseline, and later the follow-up, measures. Participants are then directed back to eNgage where they are randomised to experimental conditions.

Analytics data on participant use of the research materials (and intervention or control content) is collected by software called 'Matomo'. All data is linked by the unique participant ID.

Statistical Methods

Sample size and justification

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). Teare et al. (2014) 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). In addition, our sample size calculations, based on similar definitive RCT data about recruiting smokers to trials via letters from their GPs (Gilbert et al, 2017), 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.

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

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.

Ethics and dissemination

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

DISCUSSION

The main purpose of the proposed feasibility study is to determine the necessary requirements for successful study design and data collection such that a definitive full trial can be conducted. 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. We will also use data collected about SES, age and gender of those recruited and lost through attrition to understand whether SES is associated with

retention in the trial. 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 service promotion.

Although leaflet and letter based methods are effective for increasing recruitment to SSS's, StopApp™ is unique in that its systematic evidence based development (Fulton et al., 2016; 2018), 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). If effective and cost-effective, StopApp™ is instantly scalable because PharmOutcomes is already used extensively across the UK. Therefore it would likely be delivered at even lower ongoing cost than interventions such as the cost-effective Start2quit letter and taster session (Gilbert et al 2012; 2017), and if well marketed could reach many more than the 5 to 10% of smokers that services have reached so far (Dobbie et al., 2015).

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 therefore maximise effectiveness and help to ensure optimal use of increasingly tight public health resources.

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

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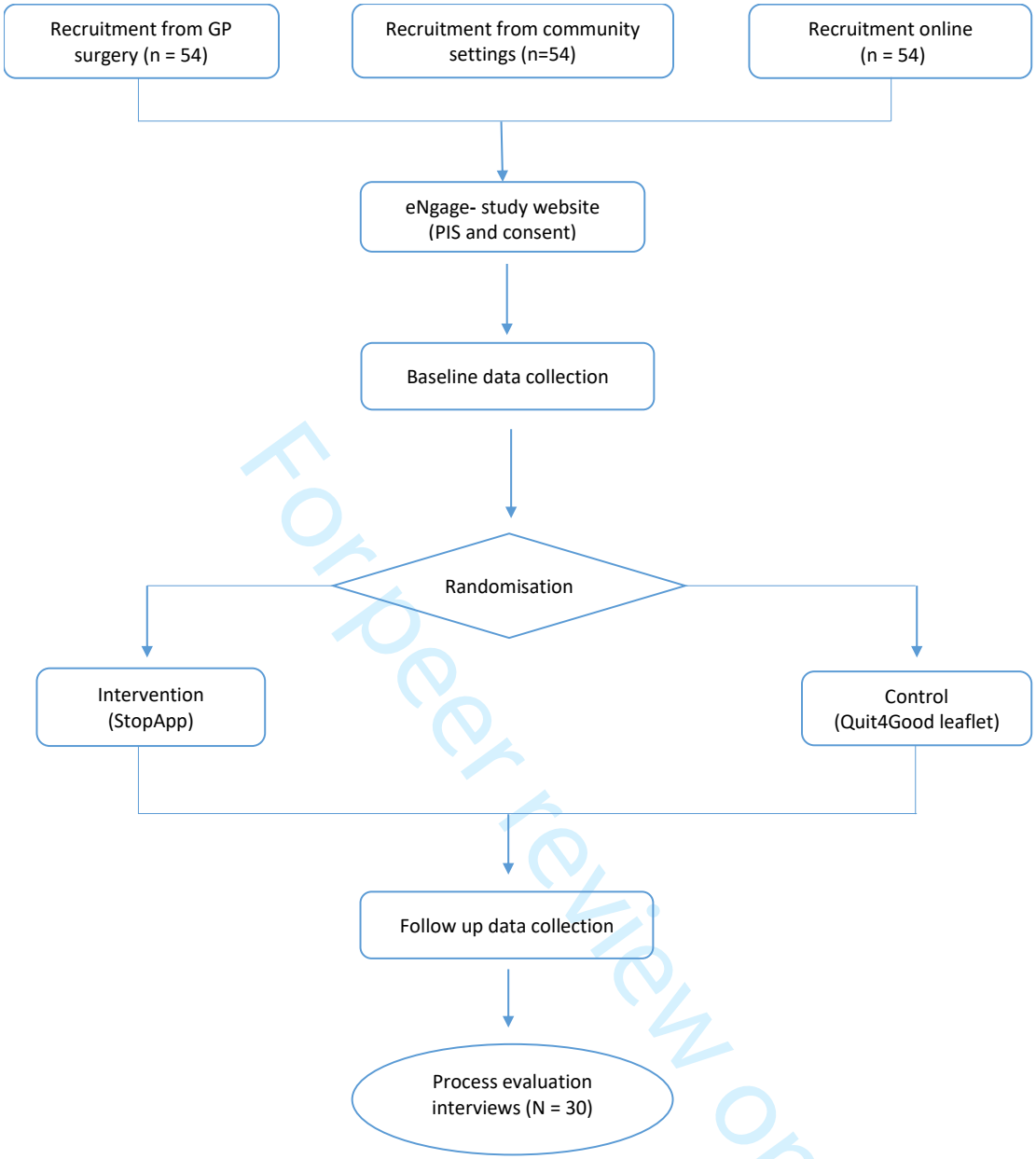

Figure 1: Flow diagram illustrating participant's route through project.

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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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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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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

StopApp™ at increasing booking and attendance at SSSs compared with existing methods for encouraging uptake.

Trial Registration: Research Registry: 3995. Trial Registered 18th April 2018.

Strengths and limitations of this study

- A randomised controlled trial with nested qualitative evaluation to ascertain acceptability of trial processes.
- Both objective and subjective measures are included to assess 4 week quit rates.
- Comparison of different sources of recruitment, including GP, community settings and online social media.
- Potential for selection bias including the requirement for participants to have access to the internet.
- Reliance on self-report data only for those in the control arm.

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

associated with significant reductions in numbers of cigarettes smoked this has not led to an overall rise in quit attempts[11]. Therefore, SSSs are still needed to support quit attempts.

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[12-16]. Other barriers to accessing SSSs include holding beliefs that the services lack efficacy, and will be impersonal, judgmental, and not tailored to individual needs. Additionally seeking help to stop is viewed as a sign of personal weakness[12-14,17]. Typically, these barriers to service uptake have not formed the focus of interventions or health promotion campaigns targeted at smokers, possibly because access to SSSs had been robust and growing until recently[18]. Research has shown however, that booklets explaining the efficacy of services[19] and proactively recruiting smokers through GP practices can increase attendance at SSSs and four-week quit rates[20]. A recent trial (Start2quit) assessing personalised risk information in the form of a letter from patients' GPs and an offer of SSS taster sessions, was both effective and cost-effective at increasing SSS uptake[21,22].

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 and service management system used by pharmacies offering SSS (PharmOutcomes), providing the opportunity to instantly book a first appointment at SSSs at a time and location to suit the user. A feasibility trial of StopApp™ (The MyWay study) is required to

establish whether a future Randomised Controlled Trial (RCT) can be achieved. This is especially necessary due to i) the novelty of the StopApp™ intervention; ii) the potential for overlooking health inequalities associated with smoking when using digital interventions; and iii) 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).

Aims and Objectives

The aim of the proposed research is to establish the feasibility of a future randomised controlled trial of the StopApp™ intervention.

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.

Secondary Objectives

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

1. Acceptability of randomisation and the StopApp™ intervention for participants.
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.

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

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

Participants

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.

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.

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 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. For ethical reasons we will not attempt to recruit people under 16 years of age as they would typically require parental consent and parents may not be aware of their child's smoking status. The email/text/letter will include brief information and a web link to the study website.

2. *Recruitment via community settings*

A range of community settings have agreed to promote the study. These include libraries, leisure centres, wellbeing hubs, children's centres, the family information service and the registrar's office. A bus stop and bus based advertising campaign will also be used 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 web address to gain immediate access to the study website for participants. We will train all relevant staff in participating locations about the study to enable them to answer any basic questions and to promote it confidently. We will also offer 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 web link to the project website or via contact with the research team. Where a research assistant recruits on site, immediate access will be provided to the study via tablet computers. Participants will have the option to gain access to the project website without having to commit to participating.

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.

Interventions

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 will also be sent to all participants two weeks later. 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. Participants in both groups will have continued access to the content, although they have been designed to be used on a single basis. Two months after baseline data collection all participants will be asked via email to complete an online follow-up questionnaire, and invited to take part in a nested qualitative study (telephone interviews) to investigate the acceptability of the MyWay trial. The number of participants from both arms taking part in the interviews will be capped at n=30. 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. Participants will be informed that should they wish to withdraw from the study at any time they should contact the research team using the project email address (details provided on eNgage and within email communication). An email with a link to the information leaflet provided to the control group, will be given to anyone who contacts us after the end of the period of recruitment to the study.

At the first appointment stop smoking advisors will be prompted to ask participants: i) to confirm they are taking part in the MyWay study/ trial; and if yes, ii) whether they consent to the research team accessing data on their SSS use, which will be stored anonymously; and iii) how they heard about the SSS. This is to ensure that consent for the access of service use data is collected by the data controller in order that they can create a report on SSS use for trial participants who consent to this. The report will identify appointments booked via StopApp™, and sent to a secure NHS.net email address, from which names will be cross-referenced against participant ID numbers before the data is transferred into the anonymous database maintained by the research team.

Qualitative study

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 select approximately 30 feasibility RCT participants and invite them to participate in the process evaluation interviews. We will apply maximum variation sampling using the demographic characteristic data collected, in order to ensure good representation of the range of consenting participants. In addition, staff contacts generated at recruitment sites during data collection will be invited to participate in process evaluation interviews. 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 (separate pages will be generated for staff and trial participants). 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 explore acceptability and user experience in line with each of the identified research objectives. They will last approximately 30 minutes and be audio recorded. Interview transcripts will be transcribed verbatim. Participants will be able to withdraw their consent for up to 2 weeks after participation in the interview, prior to data analysis. We will allow data analysis to determine saturation point and when to stop, but anticipate conducting up to 30 interviews. All qualitative data will be subject to thematic analysis[23] assisted by NVivo software.

Intervention arm

StopApp™ is a web-based self-administered behaviour change intervention designed to address the barriers that smokers typically face in accessing SSSs[17,24]. 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 in recording standard SSS outcome data such as quit dates and CO verified 4 week quit rates. In addition to applying co-production and usability methods, the content of the StopApp™ intervention was systematically developed using the Behaviour Change Wheel approach[25]. Specific content within the app delivers 17 BCTs identified as most useful for supporting SSS access behaviour[17,24].

Control arm

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.

Data Management

Study recruitment, consent, randomisation, provision of intervention or control content, and questionnaire data collection, all takes place within 'eNgage' - Coventry University's bespoke online research software hosted on their secure server. eNgage is an online research platform that includes the research pages, study information, consent and research team contact details. It is developed to work seamlessly with other web applications. On 'joining' a project, participants provide their full name and email address, upon which a unique participant ID is created. Participants are then directed to Qualtrics (a separate questionnaire data inputting software) to complete the baseline, and later the follow-up, measures. Participants are then directed back to eNgage where they are randomised to experimental conditions. Analytics data on participant use of the research materials (and intervention or control content) is collected by software called 'Matomo'. All data is linked by the unique participant ID.

Outcomes

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[26] and a single item Likert scale[27]. Health-related quality of life data will be collected using the EQ5D-5L instrument to inform

the health economic analysis[28]; and the ICECAP-A (ICEpop CAPability measure for Adults)[29,30] instrument to measure general wellbeing.

Two month follow-up measures

An online follow up questionnaire will assess self-reports of whether participants booked an appointment and attended a SSS, set a quit date and reached a 4-week abstinence, and what prompted them to book an appointment. Pinnacle Health Ltd will run a search of the PharmOutcomes system for MyWay participants (where they consented) and provide the researchers with objective service use data. This will allow an assessment regarding the validity of sourcing objective evidence of booking, attendance (DNA rates), quit dates set, and CO tested 4 week quits. We will also assess the feasibility of collecting follow-up measures of motivation using the MTSS and a single item Likert scale[27]; the EQ5D-5L instrument; the ICECAP-A instrument. In addition, a bespoke resource use questionnaire will be administered, to gain insight into the costs both to individuals and to the public purse of resources accessed as a result of use of the StopApp™ compared with the control.

Data on costs associated with 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.).

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

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.

Statistical methods

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 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.

Patient and public involvement (PPI)

We have a PPI group of eleven smokers from a range of SES backgrounds who have contributed to the design of this feasibility trial, including the participant information sheet and measures. At least one member of the PPI group will be present at study steering committee meetings throughout the duration of the feasibility trial.

DISCUSSION

The main purpose of the proposed feasibility study is to determine the necessary requirements for successful study design and data collection such that a definitive full trial can be conducted. 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. We will also use data collected about SES, age and gender of those recruited and lost through attrition to understand whether SES is associated with retention in the trial. 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 service promotion.

Although leaflet and letter based methods are effective for increasing recruitment to SSS's, StopApp™ is unique in that its systematic evidence based development[17,24], 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[25]. If effective and cost-effective, StopApp™ is instantly scalable because PharmOutcomes is already used extensively across the UK. Therefore it would likely be delivered at even lower ongoing cost than interventions such as the cost-effective Start2quit letter and taster session[21,22], and if well marketed could reach many more than the 5 to 10% of smokers that services have reached so far[7].

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[32], 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 therefore maximise effectiveness and help to ensure optimal use of increasingly tight public health resources.

Trial Registration

The trial is registered as: researchregistry3995.

Funding

The feasibility trial is funded by the National Institute of Health Research (NIHR) Public Health Research (PHR) Programme (NIHR Portfolio number: 38004).

Ethics and dissemination

Ethical approval for this study was granted by West Midlands - Edgbaston Research Ethics Committee (NRES reference 18/WM/0170). Recruitment commenced in January 2019. Data collection takes place until the end of March 2019. Analysis of data is due to be complete for dissemination in September 2019. Data will be reported at conferences and in peer reviewed journals.

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

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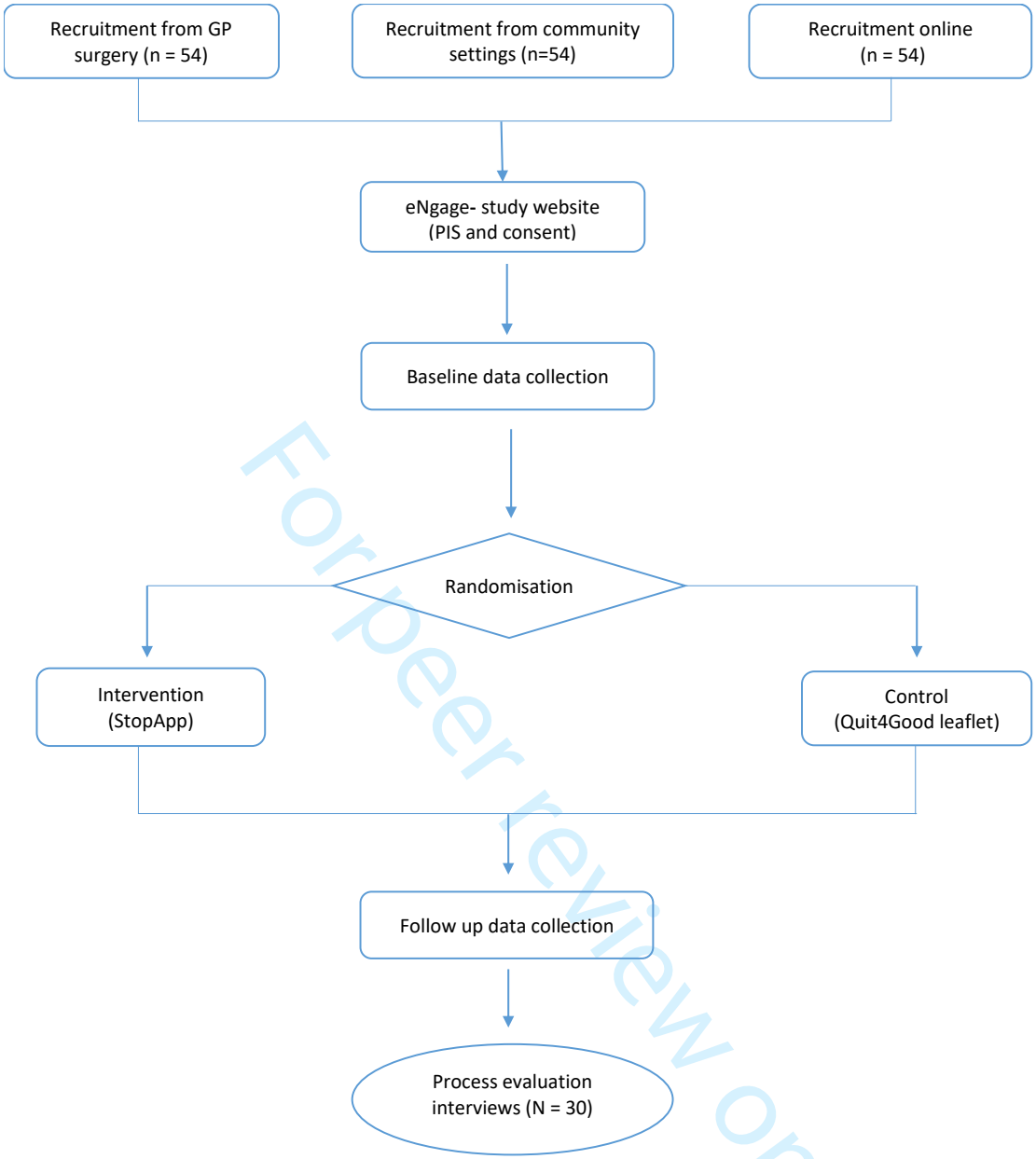

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