A digital behaviour change intervention to increase booking and attendance at Stop Smoking Services: the MyWay feasibility RCT

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Scientific summary

The MyWay feasibility RCT

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Scientific summary

Smoking is a significant cause of long-term illness and preventable death worldwide. Significant reductions in tobacco smoking in the UK have been achieved, but 14.7% of the adult population still smoke. UK NHS Stop Smoking Services offer free behavioural and pharmacological interventions proven to increase the likelihood of quitting. However, access to such services has steadily declined over recent years and even at the peak of their popularity they reached only 5–10% of smokers. Despite significant budget cuts, sustained investment in Stop Smoking Services is being called for by the All Party Parliamentary Group on Smoking and Health to support the ambition of achieving a smoke-free population by 2030. Cost-effective interventions that reach more smokers who want to quit and draw them into Stop Smoking Services are, therefore, needed.

Digital interventions have the potential to provide cost-effective solutions. Current data suggest that internet and smartphone use is becoming increasingly widespread, with an estimated 96% of those aged 16–24 years, 98% of those aged 25–34 years, 94% of those aged 35–44 years, 87% of those aged 45–54 years and 71% of those aged 55–64 years owning a smartphone. There are innumerable applications (apps) for smartphones that are designed to support people to stop smoking, but no other digital intervention currently exists to increase the use of Stop Smoking Services.

StopApp™ (Coventry University, Coventry, UK) is a brief, digital behaviour change intervention web app that aims to increase booking of and attendance at Stop Smoking Services. Underpinned by theoretical and evidence-based frameworks, it aims to enhance motivation to attend Stop Smoking Services using a series of behaviour change techniques, derived from a systematic assessment of the barriers and facilitators that smokers typically experience. StopApp also supports instant appointment booking by offering flexible time and location options using an app programming interface. It functions by working with pharmacy and general practitioner data management software that is already used extensively nationally by providers of Stop Smoking Services.

In the future, evaluating the effectiveness and cost-effectiveness of StopApp to increase attendance at Stop Smoking Services will be warranted. However, studies involving the recruitment and retention of smokers can face challenges, and the digital nature of this intervention means that there is value in identifying the best recruitment methods, including whether or not online recruitment would be feasible. There are also concerns around increasing health inequalities if users of digital technologies are principally from higher socioeconomic status groups; this requires exploration to avoid promoting a 'digital divide'. This is especially pertinent given that smoking is more prevalent in lower socioeconomic status communities. A feasibility randomised controlled trial was, therefore, proposed with the following research objectives.

Primary objective

The primary objective was to conduct a feasibility randomised controlled trial of StopApp to estimate recruitment and attrition rates of participants across three settings (general practitioner practices, community settings and online) at baseline, intervention access and 2-month follow-up. The study was known as the MyWay feasibility trial.

Secondary objectives

The secondary objectives of the MyWay feasibility trial were to estimate:

- the acceptability of randomisation and the StopApp intervention for participants
- the acceptability of the outcome measures and measures required for cost-effectiveness analyses in a future trial

- the key costs incurred in delivering the intervention and usual care, including a comparison of 'did-not-attend' rates
- the feasibility of accessing Stop Smoking Services data on attendance, quit dates set and 4-week abstinence rates for trial participants
- any differential recruitment and attrition rates across socioeconomic groups, age and sex
- the rate of Stop Smoking Services booking and attendance in the intervention and control groups to estimate the event rate of the primary outcome measure for a future trial and to support sample size calculations.

Methods

This was a two-arm, 1 : 1 allocation, parallel-group, individual-participant randomised feasibility controlled trial comparing StopApp (intervention) with the usual promotion of and provision of contact details for Stop Smoking Services via an online leaflet (control), with a nested qualitative process evaluation involving trial participants and staff supporting the trial.

Eligible participants were smokers aged ≥ 16 years who lived and/or worked in Warwickshire. Participants also needed to understand written English and have access to the internet and a mobile phone. People were not excluded if they had previously used Stop Smoking Services. Participants (1) received an invitation from their general practitioner, (2) viewed information about the study in a community setting or (3) viewed information online via social media channels. For individuals recruited via their general practitioner, in the event that more than one adult at a single address was identified as a smoker, the person whose first name came first alphabetically was invited to take part. To identify the recruitment source, each recruitment setting had a unique URL taking participants to three separate, but identical, study websites. The original target for recruitment was 162 participants; however, challenges with recruitment led to a revised target of 120 participants being agreed with the National Institute for Health Research.

The study protocol was approved by the NHS West Midlands – Edgbaston Research Ethics Committee (reference 18/WM/0170) and later published. After accessing the study information on the website, people could choose to sign up and provide consent. Participants completed baseline measures online and the study management software randomised participants using minimisation to ensure balance by age, sex and socioeconomic status. Participants were, accordingly, directed to the intervention or control web-based content and were informed that they could book a Stop Smoking Services appointment if they wanted to (but were under no obligation to do so). All appointments available within StopApp were based at one of 28 participating pharmacies. Reminders were sent to complete the baseline measures and view the content 2 weeks later. Participants were asked if they would be willing to be contacted for a process interview and, if so, to provide contact details for this purpose. At 2 months post baseline, participants were sent an e-mail with a request to complete the follow-up measures online. Reminder e-mails were sent 2 weeks later, after which no further contact was made.

Those who were willing to be contacted for process evaluation interviews were contacted by telephone and/or e-mail to arrange this, after data collection was concluded. Staff from across the different recruitment and Stop Smoking Services pharmacy settings were also invited to participate in a process interview, and individuals who were willing completed consent procedures in advance online, and arranged a convenient time with a researcher for a telephone interview. All process interviews were audio-recorded and transcribed verbatim in readiness for analysis.

Data collected at baseline included age, sex, profession, ethnicity, current smoking status and tobacco products used (type and quantity), electronic cigarette use, previous use of Stop Smoking Services, ease of internet access and motivation to quit. The last was measured using the one-item 'Motivation to Stop Scale' and a single-item Likert scale. Pregnancy status was collected to identify any participants

who would experience a separate NHS care pathway specifically for smoking in pregnancy. Social and economic deprivation was measured in several ways to identify the most suitable method for a full trial. Postcode data were collected and used to calculate the Indices of Multiple Deprivation rank and quintile scores. A five-point version of the National Statistics Socio-economic Classification was also used based on employment status data. Health-related quality-of-life data were measured using the EuroQol-5 Dimensions, five-level version, and the ICEpop CAPability measure for Adults instrument to inform the health economic analysis.

At the 2-month follow-up time point, self-reports of current smoking behaviour, Stop Smoking Services appointment bookings made and how they were made (e.g. StopApp or booked with own general practitioner), attendance at Stop Smoking Services in the last 2 months, quit dates set and 4-week abstinence were collected. If participants reported service use, questions about resource use were also asked to verify costs to individuals and the public purse in conjunction with using StopApp compared with the control.

After the final participant follow-up contact, objective data about service access stored by the owner of the Stop Smoking Services software management system were accessed. Where trial participants accessing participating pharmacy services had provided consent for their service use data to be passed to the research team, these data were shared securely and matched with self-report data. Web analytics data were also collected for the StopApp intervention arm using Matomo (https://matomo.org; accessed March 2021) software linked to individual participant activity.

Results

A total of 838 participants signed up on the study website, consented to take part in the study and completed the baseline measures. No one withdrew consent prior to randomisation. Of these, 715 participants (all accessing the study via social media) were excluded because they did not meet the eligibility criterion of living or working in Warwickshire. A total of 123 eligible participants were recruited over a period of 116 days and were included in the baseline analyses (overall recruitment rate of 1.06 participants per day). Sixty-one participants were recruited via social media (0.53 per day), 36 from community settings (0.31 per day) and 26 from general practitioner practices (0.22 per day). Using text messages and postal letters to recruit people from general practitioners, we were able to identify that only 1.62% of those who received an invitation were recruited. All recruits were recruited via text message. Five participants were identified as not having been computer randomised within the trial and were instead hand randomised by our team statistician. A further seven participants were not randomised. Interrogation of web analytics suggests that these participants completed the baseline measures and closed their browser before being assigned an arm. As a result, a total of 116 participants were randomised (59 to the StopApp arm and 57 to the control arm). Fifteen per cent of participants randomised to StopApp demonstrated meaningful engagement: actively engaging with pages beyond the first page. A total of 60 participants completed the follow-up questionnaire (48.8%) ($n = 32$, 54.2%, in the StopApp arm and $n = 28$, 49.1%, in the control arm) at 2 months post baseline. This reveals an attrition rate of 51.2%. Loss to follow-up by site was as follows: social media ($n = 24$, 39.3%), community settings ($n = 18$, 50%) and general practitioner ($n = 21$, 80.8%).

Demographic profiles of participants were broadly similar at follow-up and at baseline across the two trial arms, suggesting that randomisation did not significantly affect participant satisfaction. Process interviews also asked about the acceptability of randomisation and the StopApp intervention. Participants understood the need for randomisation and thought that it was an acceptable part of the study design. One participant expressed disappointment at being allocated to the control arm when this information was disclosed in the interview. StopApp was considered acceptable by those randomised to receive this, although some suggested that improvements could be made.

Missing data were interrogated in order to assess acceptability of measures. Most questionnaire items had complete or near-complete data (< 5% missing data). Missing data were evident at > 5% on the following items: self-report on appointment bookings with Stop Smoking Services at follow-up (48.8% of participants did not respond) and questions about job status (16.3–33.3% missing on three items). Data on whether or not female participants were pregnant were missing for 31.7% of participants. Two items regarding smoking status had 17.1% missing data. There were also very few data entered in open-text boxes, and because of low frequencies of data in some of the ethnicity categories, which would impair statistical analysis, the variable was reduced to four categories: 'white British', 'white other', 'all mixed background' and 'African/Asian background'. Acceptability of measures was also discussed during the process interviews. Participants in the trial who took part in the process evaluation interview found the measures acceptable.

The costs to recruit participants to the study were highest among community-based recruits at £184.42 per recruit, followed by general practitioner recruits at £123.39 per recruit. Social media represented the most cost-efficient method of recruitment at £50.20 per recruit. A number of costs were incurred by participants. They self-reported a wide range of resource use, often at their own personal cost. These costs and the resource use was higher for participants accessing StopApp.

Female participants were over-represented in the sample (84/123, 68.3%). A large proportion of the sample was also white British (98/123, 79.7%). The most recent population census data show, however, that the population of Warwickshire is 93% white British, suggesting that we have over-represented black, Asian and minority ethnic groups. The mean age was 38.3 years (standard deviation 12.6 years), with a good representation across age groups (range 16–70 years). Deprivation scores based on postcode (Indices of Multiple Deprivation quintiles) were evenly distributed between least and most deprived, with 38 (30.9%) participants in the two most deprived quintiles. Demographic profiles of participants were broadly similar at baseline and follow-up, suggesting relative health equity of follow-up methods, but the data did suggest that black, Asian and mixed-ethnicity participants may have dropped out in slightly greater numbers, requiring attention in a future trial.

Some issues related to accessing the objective Stop Smoking Services data about booking, attendance and quit dates were identified. These related to the combination of not all Stop Smoking Services venues being able or willing to participate in offering services via StopApp and requirements to re-collect consent from trial participants within services. A mid-study decision by the data controller to require data-sharing agreements from all participating pharmacies that had taken Stop Smoking Services bookings during the trial also delayed data access. Objective service data provided evidence of five Stop Smoking Services bookings made in StopApp (two did not attend). A further five intervention arm participants self-reported booking and accessing Stop Smoking Services (outside StopApp) versus two control arm participants. Event rate calculations for the intervention arm were 8% (objective data) and 17% (including self-reports) and 3.5% from control arm self-reports.

Discussion and conclusions

A conservative estimate of a 6% difference in effect size between the intervention and control arms was identified from the event rate data, which appears to be consistent with other similar smoking trials. Sample size calculations indicate that 840 smokers would be needed to detect this effect in a future definitive randomised controlled trial of StopApp. Data collected on recruitment and attrition suggest that, if using social media alone, over 18 months in six local authority areas with a similar population size to Warwickshire, it may be possible to achieve as many as 1830 baseline recruits and 1116 participants' self-report data at follow-up (based on 61% follow-up achieved in the present study). Given that few problems were identified with the acceptability and health equity of the study methods and the StopApp intervention, it is concluded that a full trial may be feasible. In planning a multisite randomised controlled trial, however, the challenges identified with accessing objective service data need careful attention and a targeted social media campaign is required. Some improvements to measures and a more intensive follow-up procedure are also recommended.

Trial registration

Research Registry: 3995. The trial was registered on 18 April 2018.

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