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Randomized controlled trial to assess the short-term effectiveness of tailored web- and text-based facilitation of smoking cessation in primary care (iQuit in Practice)

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ABSTRACT

Aims To estimate the short-term effectiveness, feasibility and acceptability of a smoking cessation intervention (the iQuit system) that consists of tailored printed and Short Message Service (SMS) text message self-help delivered as an adjunct to cessation support in primary care to inform the design of a definitive trial. **Design** A stratified two parallel-group randomized controlled trial comparing usual care (control) with usual care plus the iQuit system (intervention), delivered by primary care nurses/healthcare assistants who were blinded to the allocation sequence. **Setting** Thirty-two general practice (GP) surgeries in England, UK. **Participants** A total of 602 smokers initiating smoking cessation support from their local GP surgery were randomized (control $n = 303$, intervention $n = 299$). **Measurements** Primary outcome was self-reported 2-week point prevalence abstinence at 8 weeks follow-up. Secondary smoking outcomes and feasibility and acceptability measures were collected at 4 weeks after quit date, 8 weeks and 6 months follow-up. **Findings** There were no significant between-group differences in the primary outcome [control 40.3%, iQuit 45.2%; odds ratio (OR) = 1.22, 95% confidence interval (CI) = 0.88–1.69] or in secondary short-term smoking outcomes. Six-month prolonged abstinence was significantly higher in the iQuit arm (control 8.9%, iQuit 15.1%; OR = 1.81, 95% CI = 1.09–3.01). iQuit support took on average 7.7 minutes (standard deviation = 4.0) to deliver and 18.9% (95% CI = 14.8–23.7%) of intervention participants discontinued the text message support during the programme. **Conclusions** Tailored printed and text message self-help delivered alongside routine smoking cessation support in primary care does not significantly increase short-term abstinence, but may increase long-term abstinence and demonstrated feasibility and acceptability compared with routine cessation support alone.

Keywords Cessation advice, computer tailoring, primary care, self-help, smoking cessation, text messaging.

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INTRODUCTION

Primary care is an important setting for smoking cessation interventions [1,2]. However, the implementation and intensity of cessation support offered and delivered varies widely between countries [2]. Tailored self-help interventions could be used to augment cessation support in healthcare settings and are recommended for use in primary care [3,4]. A Cochrane Review of self-help interventions for smoking cessation [5] identified a small benefit of tailored self-help materials compared to standard materials or no intervention [$n = 28\,189$; relative risk (RR) = 1.31, 95% confidence interval (CI) = 1.20–1.42]. However, the potential benefit of adding tailored self-help to routine cessation support in primary care has not yet been assessed.

Studies have shown that Short Message Service (SMS) text messaging smoking cessation interventions outside primary care are feasible and acceptable [6,7], but data

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on effectiveness, particularly in the longer term, are limited. A recent Cochrane Review [8] found a benefit for mobile cessation interventions compared with minimal or no intervention controls ($n = 9100$; RR = 1.71, 95% CI = 1.47–1.99). The largest trial included in this review (*txt2stop*) [9] found that abstinence rates in the text messaging arm were twice that of a no intervention control arm at the 6-month follow-up (RR = 2.20, 95% CI = 1.80–2.68). However, among a subgroup of participants who reported using a smoking cessation product or service at baseline there was a non-significant difference between trial arms (RR = 1.51, 99% CI = 0.90–2.55). Currently, there is uncertainty about the potential additive benefits of text message support, alone or combined with other self-help, on top of pharmacological and/or face-to-face cessation support.

The iQuit system evaluated in the current study has been informed by several tailored cessation systems, which have been evaluated in trials with mixed results. Tailored advice letters/reports generated by these earlier systems were found to increase abstinence among smokers when delivered as an adjunct to telephone counselling and generic self-help materials [10], but not significantly when compared to non-tailored information only among smokers recruited via general practice (GP) [11] and online [12]. Expanding intervention delivery to mobile phones, we developed and evaluated a pilot tailored text message intervention for pregnant smokers, which had high acceptability and increased hypothesized determinants of abstinence [7]. These tailored systems demonstrated enhanced perceived personal relevance of the information received and the likelihood that it would be read [7,10,13], in line with hypothesized mechanisms of tailoring [14,15]. The iQuit system builds on these interventions; it is a programme designed to be used by a primary care nurse or other smoking cessation adviser (SCA), which generates a highly tailored advice report and initiates a 90-day programme of automated tailored text messages sent to the smoker's mobile phone. The iQuit system is the first digital self-help tool designed for use by SCAs and, unlike most other text messaging programmes, delivers text support that is highly tailored to the smoker.

The aims of this study were to estimate the short-term effectiveness of the iQuit intervention compared with usual care alone, to assess the acceptability of the intervention to participants and to assess the feasibility of the intervention and of aspects of the trial design and procedures to inform the design of a definitive trial.

METHOD

Design and randomization

This was a two parallel-group randomized controlled trial with 1 : 1 individual allocation comparing usual care (control) with usual care plus the iQuit system (intervention). Randomization was stratified by SCA. The allocation sequence was generated by a computer-based random number generator using random permuted blocks with block sizes of four and six, stored on a remote web server. The sequence was accessible to the investigators, who had no involvement in recruitment at participating sites. The sequence was not accessible to the SCAs or participants. Allocation was made by the web server during the consultation once Part 1 of the iQuit questionnaire was submitted (see Procedure). At this point, the SCA and the participant were unblinded to allocation.

Recruitment

Recruitment: practices

General practices with at least one SCA (primary care nurse or healthcare assistant, a nursing auxiliary under the guidance of a qualified healthcare professional) trained to give 'level 2' smoking cessation advice (see Interventions) with internet and printer access from their consultation room(s) were eligible. Initially, practices close to Cambridge were approached, but due to slow practice recruitment this area was extended to the whole of the East of England. One hundred and eighteen practices were contacted directly by the researchers between September 2009 and March 2011. Of the 104 eligible practices approached, 32 participated (30.8%) (see Fig. 1). Mean list size for participating practices was 10 538 [standard deviation (SD) = 3638]. A deprivation measure, which combines 37 indicators of deprivation into a summary score (Index of Multiple Deprivation: IMD) [16], indicated that eight practices were in the top 50% of deprived small geographical areas in England (Lower Super Output Areas) (mean IMD score for study practices 13.7; range 3.0–27.7; SD = 7.0).

Recruitment: participants

Patients were eligible for inclusion if they met the following criteria: current smoker (usually smokes at least one cigarette a day, has smoked in the 7 days prior to randomization); able to read English and provide written informed consent; willing to set a quit date within 14 days after randomization; aged 18–75 years; has a mobile phone and is familiar with sending and receiving text messages; not enrolled in another formal smoking cessation study or programme; and not using smoking cessation medications at randomization date.

Participants were primarily recruited opportunistically, through self-referral or referred by a health professional, to receive smoking cessation advice. Practices were also encouraged to post study information to a

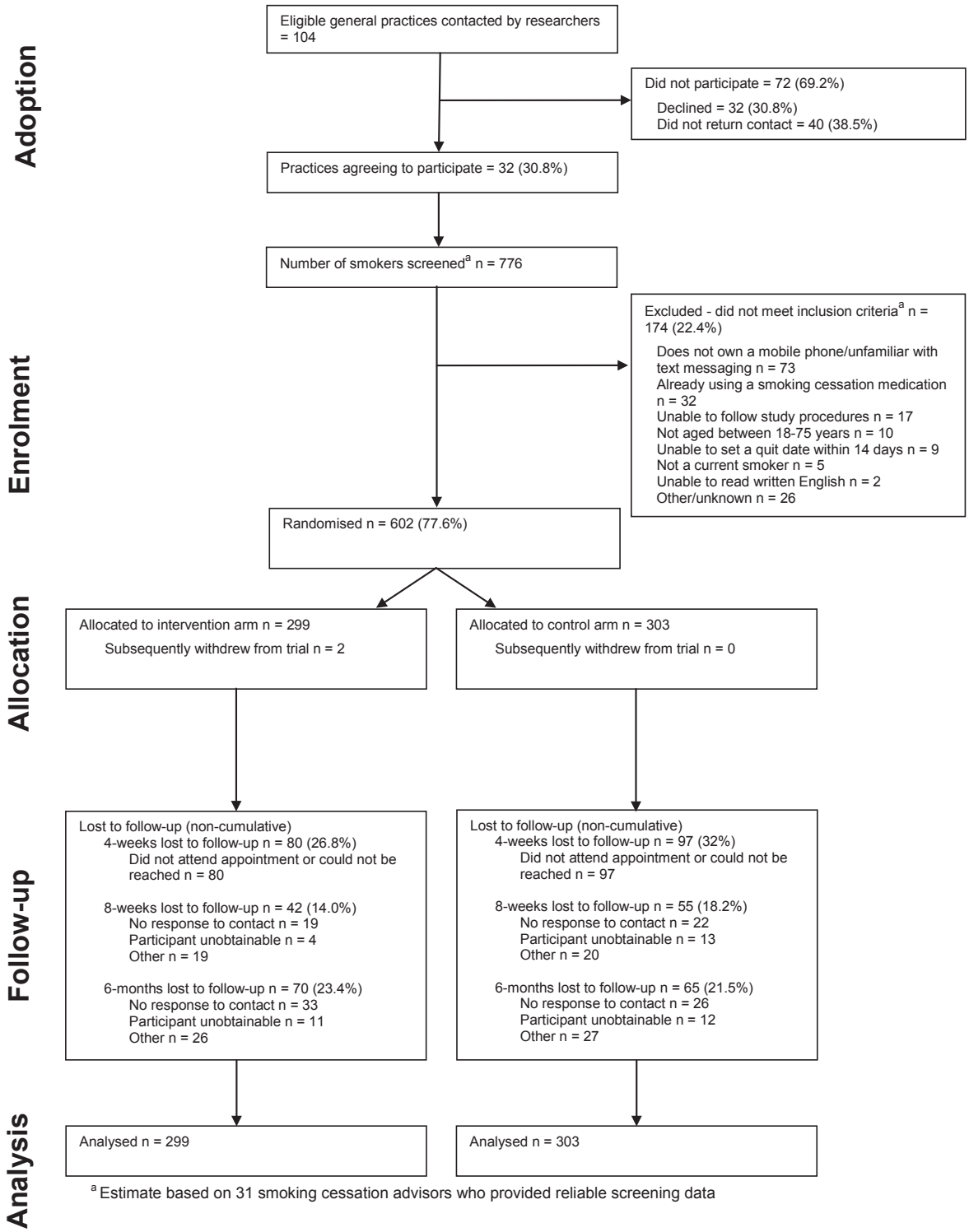

Figure 1 Trial flow.

random selection of patients identified as smokers from their practice database. See Protocol for further information [17].

Interventions

Control

'Usual care' consisted of routine 'level 2' smoking cessation advice delivered by SCAs [18]. This included a brief discussion about smoking habits and history, measurement of expired-air carbon monoxide (CO) (using a supplied Bedfont piCO Smokerlyzer, Maidstone, UK), brief advice to quit, setting a quit date within the next 14 days, options for pharmacotherapy, a prescription and arranging a follow-up visit. Usually the opportunity for multiple follow-up visits was offered.

Intervention

The intervention consisted of usual care, as described above, plus a tailored advice report and a programme of tailored text messages generated by the iQuit system. The content of the report and text messages were based on relevant theories of smoking cessation and behaviour change, including social cognitive theory [19] and the perspectives on change model [20], and informed by previous research [10] and extensive qualitative work with smokers [21,22]. The iQuit programme was piloted in five general practices in Cambridgeshire. See Supporting information for detailed information about iQuit support.

Advice report. The four-page advice report contained detailed advice on quitting tailored to 25 items from the programme's 30-item questionnaire including: smoking habits and history; motivation and determination to quit; reasons for quitting; dependence; self-image; pros and cons of quitting; perceived difficult situations; children; living with other smokers; social support; and current health problems.

Text messaging. The text messaging component consisted of a 90-day programme of automated text messages sent to the smoker's mobile phone. The messages started the day before the participant's quit date. The number of messages sent each day varied according to the predetermined schedule (see Supporting information) and was either 0, 1 or 2 (mean per day over 90 days 1.2). The messages were designed to advise smokers on their quit attempt, provide information about the consequences of smoking and expectations for quitting, provide encouragement, boost self-efficacy, maintain motivation to quit and remind smokers how to cope with difficult situations.

The text messages were tailored individually using 24 items from the iQuit questionnaire and information obtained from query messages about smoking status sent to the participant at 3 and 7 weeks after their quit date. Intervention participants could also text HELP or SLIP to immediately receive a support message if they were tempted to smoke (HELP) or had just had a lapse (SLIP). Intervention participants could text STOP to discontinue all text messages.

Procedure

After the patient had been screened for eligibility by the SCA and consent taken, the SCA provided smoking cessation advice, as per usual practice. The SCA then logged on to the online iQuit program via the practice computer using a unique login and completed part 1 of the iQuit questionnaire with all participants. This included basic demographic and smoking-related information, quit date and CO level. Once part 1 of the iQuit questionnaire was completed, the participant was randomized by the online program either to the control group and asked no further questions or to the intervention group and asked a second set of questions (part 2), focusing on key tailoring variables. Once part 2 was completed, the iQuit program generated a tailored advice report. The report was then printed out by the SCA, handed to the intervention participant and the consultation concluded. Subsequent appointments were undertaken by an SCA as per usual care.

Participants were followed-up by an SCA, although not always the same one seen at the first visit, 4 weeks after their quit date, as per usual care, and by postal questionnaire from the study centre at 8 weeks and 6 months after randomization. Non-responders to the postal questionnaire were contacted by telephone by a researcher, initially blinded to allocation, and given a choice of returning the questionnaire by post or completing it over the telephone. Participants unwilling to complete the full questionnaire were asked to complete the smoking outcomes questions only. Up to six attempts were made to contact participants by telephone at each follow-up.

To compensate for any study-related text messaging costs, intervention participants were sent a £5 voucher with the 8-week follow-up questionnaire.

Outcome measures

Effectiveness

The primary outcome measure was self-reported 2-week point prevalence abstinence at 8-week follow-up from randomization date. This outcome was chosen because it represented a short-term period which would not interfere with the routine 4-week follow-up from quit date. Secondary outcome measures included CO-verified abstinence at 4-week follow-up from quit date for at least 2

weeks, assessed by an SCA [using the England NHS Stop Smoking Services (SSS) definition [23]: a CO reading assessed 25 to 42 days from quit date that is less than 10 parts per million]. Self-reported 3-month prolonged abstinence at 6-month follow-up from randomization date was also a secondary outcome measure. In addition to pre-specified outcome measures, two longer-term smoking outcome measures were assessed [24]; 6-month prolonged abstinence at 6-month follow-up and a strict continuous abstinence measure using all outcome time-points: CO-validated 2-week point prevalence abstinence at 4 weeks, 4-week point prevalence abstinence at 8 weeks and 6-month prolonged abstinence at 6 months. These long-term measures deviated from the Russell Standard, as we did not allow participants to have smoked any cigarettes during the abstinence period, abstinence was not verified biochemically and we could not avoid the possibility that some assessors at the 6-month follow-up became unblinded to allocation. Use of cessation medication was also assessed at all follow-ups.

Feasibility and acceptability

Feasibility measures included the number of smokers per practice recruited, response rates to follow-up questionnaires, time taken to complete the online questionnaire, increase in length of consultation and participant's perceived ease of answering the iQuit questionnaire.

Acceptability measures included evaluation of the advice report and text messages and the proportion of intervention participants who discontinued text support by texting STOP.

Sample size and analysis

For effectiveness, the study was powered on point prevalence abstinence for 2 weeks at the 8-week follow-up. A sample size of 300 per group would give 80% power to detect an increase in abstinence from 20 to 30% (alpha = 0.05, two-sided test), informed by a systematic review showing a relative increase in abstinence among smokers receiving tailored materials versus no materials of 40% at 6 months [5]. The 20% control rate at 8 weeks was estimated from the same review's subgroup analysis where controls, who received face-to-face advice without self-help, had a pooled long-term quit rate of 8% [5]. This sample size was also chosen because it provided a 95% CI width of ± 5% for the between-arm difference in 6-month abstinence, based on an anticipated control group rate of 8% [5]. This CI was used to calculate the probability that the intervention would produce an intervention effect equivalent to a relative risk of at least 1.2 (small effect size), or at least 1.5 (medium effect size), to inform the decision to proceed to a definitive trial.

Groups were compared using χ^2 tests and logistic regression analysis for binary outcome measures, and independent *t*-tests, analysis of variance and linear regression analysis for continuous measures and Fisher's exact test and 95% CI by the Clopper–Pearson method for between-group proportions. Single arm proportions were estimated with exact 95% CI using the binomial distribution. The group difference in prolonged abstinence at 6-month follow-up was assessed using a Bayesian posterior 95% credibility interval for the absolute difference between trial arms. The smoking outcome analyses were intention-to-treat, where all those randomized were analysed with participants lost to follow-up assumed to be smoking. We also conducted sensitivity analyses using a range of less severe assumptions, namely a complete-case analysis and relaxation of the 4-week abstinence definition [25].

RESULTS

Recruitment, baseline characteristics and attrition

Of the 53 SCAs who recruited participants, 31 provided reliable screening logs. Between these 31 SCAs, 455 individuals were screened, of whom 353 were eligible and were recruited (77.6%). Assuming similar eligibility rates among SCAs who did not provide reliable screening logs, we estimate that 776 individuals would have been screened to have recruited 602 individuals (Fig. 1). All 602 participants recruited were randomized. Participants had a mean age of 41.8 years (SD = 13.0) at baseline and 52.7% were female. Two-thirds smoked within 30 minutes of waking and the mean daily smoking rate was 18.3 (SD = 8.0) cigarettes (Table 1). Two participants withdrew from the trial. Attrition (non-cumulative), defined as not obtaining smoking status or a completed questionnaire by post or over the telephone was 30.1% (4 weeks), 15.9% (8 weeks) and 22.3% (6 months) (Fig. 1). There were no between-group differences in attrition.

Smoking outcomes

There were no significant between-group differences in 2-week point prevalence abstinence at the 8-week primary end-point [control 40.3%, iQuit 45.2%; odds ratio (OR) = 1.22, 95% CI = 0.88–1.69] or in any secondary short-term abstinence outcomes (Table 2). Statistically significant group differences were found for 6-month prolonged abstinence at 6 months (control 8.9%, iQuit 15.1%; OR = 1.81, 95% CI = 1.09–3.01) and for 6-month continuous abstinence (control 6.3%, iQuit 11.4%; OR = 1.92, 95% CI = 1.07–3.45). A meta-analysis indicated no observed heterogeneity between practices of the intervention effect on 6-month prolonged abstinence (Cochrane's Q = 15.84, $P = 0.99$;

Table 1 Baseline sample characteristics.

	Control arm[a] *n (%)*	*Intervention*[a] *arm n (%)*	*Total*[a] *n (%)*
Female	158 (52.1)	159 (53.2)	317 (52.7)
Mean (SD) age	41.3 (13.0)	42.3 (13.0)	41.8 (13.0)
White ethnic group	297 (98.0)	293 (98.0)	590 (98.0)
Occupation category			
Not working (student/home carer/retired)	45 (14.9)	53 (17.7)	98 (16.3)
Never worked/long-term unemployed	19 (6.3)	21 (7.0)	40 (6.6)
Sick/disabled	16 (5.3)	26 (8.7)	42 (7.0)
Routine and manual	89 (29.4)	93 (31.1)	182 (30.2)
Intermediate	30 (9.9)	21 (7.0)	51 (8.5)
Managerial/professional	82 (27.1)	74 (24.7)	156 (25.9)
Unknown	22 (7.3)	11 (3.7)	33 (5.5)
Mean (SD) number of cigarettes smoked per day	18.2 (8.2)	18.4 (7.9)	18.3 (8.0)
Smoked first cigarette within 30 minutes	196 (64.7)	213 (71.2)	409 (67.9)
Mean (SD) carbon monoxide in exhaled air p.p.m.	20.8 (11.5)	21.1 (12.7)	21.0 (12.1)
How much do you want to quit? (five-point scale)	4.5 (0.6)	4.5 (0.7)	4.5 (0.6)
Previously quit smoking for 3 months or longer	185 (61.1)	158 (52.8)	343 (57.0)

[a]Percentages may not add up to 100 due to rounding. SD = standard deviation; p.p.m. = parts per million.

Table 2 Smoking outcomes and use of cessation medication.

	Control arm n (%)	*Intervention arm n (%)*	*Absolute difference (95% CI)*	*Odds ratio (95% CI)*[a,b]
Primary outcome				
Self-reported 2-week point prevalence abstinence at 8-week follow-up	122 (40.3)	135 (45.2)	4.9% (−3.0 to 12.7%)	1.22 (0.88–1.69)
Secondary outcomes				
CO-verified 2-week point prevalence abstinence at 4-week follow-up after quit date[c]	71 (23.4)	81 (27.1)	3.7% (−3.3 to 10.6%)	1.21 (0.84–1.76)
Self-reported 3-month prolonged abstinence at 6-month follow-up	70 (23.1)	76 (25.4)	2.3% (−4.5 to 9.1%)[d]	1.13 (0.78–1.65)
Additional outcomes				
Self-reported 6-month prolonged abstinence at 6-month follow-up	27 (8.9)	45 (15.1)	6.1% (0.9 to 11.4%)	1.81 (1.09–3.01)
Continuous abstinence (4-week, 8-week and 6-month follow-ups)[e]	19 (6.3)	34 (11.4)	5.1% (0.6 to 9.8%)	1.92 (1.07–3.45)
Smoking cessation medication				
SCA reported usage at 4-week follow-up after quit date[f]	166 (79.4)	174 (79.5)	0.0% (−7.6 to 7.7%)	1.00 (0.63–1.60)
Self-reported usage at 8-week follow-up[f]	114 (55.6)	144 (62.3)	6.7% (−2.5 to 15.8%)	1.32 (0.90–1.94)
Self-reported usage at 6-months follow-up[f]	46 (21.6)	43 (20.9)	−0.7% (−8.5 to 7.1%)	0.96 (0.60–1.53)

[a]Unadjusted odds ratios for smoking outcomes. Adjusting for baseline characteristics made no noticeable difference to findings. [b]Sensitivity analyses did not result in any noticeable differences in the findings. [c]Participants whose self-reported abstinence was not carbon monoxide (CO)-validated or where CO-validated smoking abstinence was recorded outside the National Health Service (NHS) 4-week assessment window (28 days after quit date, −3 to +14) were counted as smokers. [d]Bayesian posterior 95% credibility interval for the absolute difference between trial arms 2.3% (−4.5 to 9.2%). [e]CO validated 2-week point prevalence abstinence at 4 weeks, 4-week point prevalence abstinence at 8 weeks and 6-month prolonged abstinence at 6 months. [f]Denominator restricted to those followed-up. SCA = smoking cessation adviser; CI = confidence interval.

I-squared = 0.0%). No group differences were found in reported cessation medication use.

Feasibility

Per practice, the mean number of SCAs was 1.7 (range 1–3), the mean monthly recruitment rate was 1.9 (SD = 1.6) and the mean number of participants recruited was 18.8 (range 1–40) (Table 3). Among participants followed-up, a greater proportion in the intervention group, compared to controls, completed follow-up information by post (rather than by telephone) (8 weeks: control 42.1%, iQuit 57.9%; $P = 0.01$; 6

Table 3 Feasibility outcomes.

	Mean (SD)	*95% CI*
Number of active SCAs per practice[a]	1.7 (0.5)	1.5–1.9
Monthly recruitment rate per participating practice	1.9 (1.6)	1.4–2.5
Number of participants recruited per practice	18.8 (11.0)	15.0–22.6
Number of participants recruited per active SCA[a]	11.4 (9.4)	8.8–13.9
Time in minutes taken to complete iQuit questionnaire and generate report (intervention group only)[b]	7.7 (4.0)	7.3–8.2
Ease of answering online questionnaire during consultation (five point scale) (intervention group only)	4.6 (0.7)	4.5–4.7

[a]Active smoking cessation advisers (SCAs) were those who recruited at least one participant into the trial ($n = 53$). [b]Based on data collected by the iQuit program. SD = standard deviation; CI = confidence interval.

months: control 44.0%, iQuit 56.0%; $P = 0.01$). The additional consultation time taken for intervention participants using controls as a reference was 3.5 minutes for the first visit and 0.4 minutes for the 4-week visit, based on SCA self-report. The mean time taken by SCAs to complete the online questionnaire, as recorded by the programme, was 7.7 (SD = 4.0) minutes for intervention participants and 3.0 (SD = 2.4) minutes for control participants (mean difference 4.7, 95% CI = 4.2–5.2). Most participants reported that completing the iQuit questionnaire with the SCA was extremely easy (mean on five-point scale 4.6, SD = 0.7).

Acceptability

Most intervention participants reported that they found the advice report useful (79.2%, see Table 4 for 95% CIs), easy to understand (88.0%) and that it helped them to quit smoking (65.2%). They found the text messages an acceptable way of receiving smoking cessation support (67.7%), useful (64.1%), easy to understand (93.7%) and just fewer than half found that they helped them to quit smoking (44.8%), although one in four found them

Table 4 Acceptability, perceived value and use of iQuit support (intervention group only); proportion of participants who scored 4 or 5 on a five-point scale (1 = not at all, 5 = extremely) unless stated otherwise.

	Percentages (frequencies)	*95% CI*[a]
Tailored advice report assessment at 8 weeks follow-up (denominator)		
Found information useful ($n = 202$)	79.2 (160)	73.1–84.2
Felt the report was effective in helping them quit smoking ($n = 204$)	65.2 (133)	58.4–71.4
Found the report easy to understand ($n = 200$)	88.0 (176)	82.8–91.8
Read all the report at least once ($n = 207$)	69.6 (144)	63.0–75.4
Felt the report was too long ($n = 201$)	11.4 (23)	7.8–16.6
Tailored text messages assessment at 6 months follow-up (denominator)		
Felt receiving support by text message acceptable ($n = 192$)	67.7 (130)	60.8–73.9
Found information in texts useful ($n = 192$)	64.1 (123)	57.1–70.5
Felt the texts were effective in helping them quit smoking ($n = 192$)	44.8 (86)	37.9–51.9
Found the texts easy to understand ($n = 223$)[b]	93.7 (209)	89.7–96.2
Felt they received too many texts ($n = 192$)	18.8 (36)	13.9–24.9
Found the texts irritating ($n = 192$)	25.5 (49)	19.9–32.1
Wish they never received any text messages ($n = 192$)	7.3 (14)	4.4–11.9
Felt the duration of the text programme was too long ($n = 189$)	13.2 (25)	9.1–18.9
Requested an instant support text ($n = 297$)	18.5 (55)	14.5–23.3
Number of instant support texts requested ($n = 55$)		
Mean (SD)	4.2 (7.6)	2.2–6.3[c]
Median	2.0	NA
Found instant support texts useful ($n = 49$)	61.2 (30)	47.3–73.6
Discontinued the texts by texting STOP ($n = 297$)	18.9 (56)	14.8–23.7
Mean (SD) number of days into programme that STOP was sent by text	52.5 (18.9)	47.5–57.6[c]
Reasons why STOP was sent by text ($n = 31$)		
Did not need any further support	25.8 (8)	13.7–43.3
The texts were beginning to annoy me	25.8 (8)	13.7–43.3
The texts were no longer benefitting me	29.0 (9)	16.1–46.6
Other	19.4 (6)	9.2–36.3

[a]95% confidence interval (CI) of the proportion. [b]Collected at 8-week follow-up. [c]95% CI of the mean; SD = standard deviation; NA = not applicable.

annoying to some extent (25.5%). Of intervention participants, 18.9% sent a STOP text message, on average 52.5 (SD = 18.9) days into the 90-day programme. Around one-quarter of those who sent a STOP message (representing approximately 5% of all intervention participants) reported doing so due to annoyance.

Proceeding to a definitive trial

The relative risk for the long-term intervention effect at 6 months was 1.69 (95% CI = 1.08–2.65). Consequently, the estimated probability that the intervention would produce a small intervention effect equivalent to a RR of at least 1.2 is 93%, and the probability of a medium effect size of 1.5 is 70%.

DISCUSSION

This was the first study to evaluate the potential benefit of adding a printed and text message cessation intervention to routine smoking cessation support in primary care. We did not find evidence of a short-term benefit of iQuit support. However, longer-term abstinence at 6 months was clinically and statistically significantly higher among iQuit participants compared with controls. This suggests that there was a benefit to receiving iQuit support for the quit attempt planned at enrolment. The findings also showed that iQuit support was acceptable to most participants and was feasible to deliver within the context of a primary care consultation.

Our 6-month prolonged abstinence findings are consistent with the findings from a meta-analysis of mobile phone cessation intervention trials [8]. Several trials in this meta-analysis found short-term effects for text messaging interventions. Unlike these trials, however, the usual care received by the control group in our trial was fairly intensive. Therefore, the absence of a significant short-term effect may be due to the effect of usual care. It is less clear why there were no significant group differences in 3-month abstinence at the 6-month follow-up. Given that many quitters in this category would have experienced an early relapse, it may be that iQuit support was less helpful for those starting another quit attempt when a significant portion of iQuit support had already been delivered.

Self-reported abstinence at 4 weeks in the control arm, based on the UK Department of Health (DH) definition, was lower than that reported nationally for primary care settings (2011–12) (trial 26.4%; national 47.8%) [1]. The possibility that the practices participating in the study did not represent primary care settings nationally may explain this discrepancy. However, we observed errors in the data collected from SCAs in our trial which may have contributed to this discrepancy (errors were corrected for trial analyses). On 26.0% of occasions (74 of 285 participants self-reporting abstinence), study SCAs indicated that they would report a participant as a quitter to the DH when the 4-week follow-up was undertaken outside the allowed time-frame. Furthermore, for 10.2% of participants (29 of 285) SCAs said they would report them as quitters despite them reporting smoking in the last 14 days, contravening the DH definition. Given that similar discrepancies between research-based and national abstinence figures have been observed elsewhere [26], and that it is suspected that leniency is applied to how service throughput is defined [27], national primary care abstinence figures for the England SSSs may be artificially inflated.

A study limitation was that we were not able to capture accurately the number of individuals approached informally about the study who subsequently decided not to participate. Overall, however, participants were similar to those who access the SSSs nationally [1], although they had higher rates of employment (trial 64.6%; national 43.4%) and white ethnic group (trial 98.0%; national 88.3%).

As the final 6-month follow-up was undertaken by post/telephone and it was not practical to bring participants into the GP surgery for an additional CO measure, we did not validate abstinence biochemically at this time-point. Saliva samples for cotinine assay can be obtained by post, but there are disadvantages to this, including being unable to validate prolonged abstinence when collected at one time-point only and unable to validate quitters who continue to use nicotine replacement therapy (NRT) at follow-up (16.5% of trial participants reporting 6-month prolonged abstinence). While there is little evidence of differential misreporting between trial arms in smoking intervention studies [28], a risk of bias remains. One potential solution for a future definitive trial would be to undertake a verification visit for self-reported quitters using both CO and salivary cotinine assessments.

This trial has established the feasibility and acceptability to smokers in primary care of integrating tailored printed and text message self-help into routine cessation support. The findings from a nested acceptability survey and qualitative interview study, not reported here, also indicate high acceptability among SCAs in delivering this intervention during routine consultations (in preparation). While short-term effectiveness of the iQuit system was not demonstrated, longer-term smoking outcomes suggest a clinically significant benefit of adding this type of tailored self-help to routine care. Overall, the findings support proceeding to a large definitive trial to establish long-term effectiveness and cost-effectiveness.

Clinical trial registration

ISRCTN 56702353.

Declaration of interests

None.

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Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Table S1 Behaviour change techniques applied in the iQuit in Practice tailored intervention. Based on Michie *et al*. [5] Table 1.
Table S2 Text message schedule.
Appendix S1 Tailored advice report.
Appendix S2 Examples of tailored text messages.

