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Promoting smoking cessation during pregnancy: A feasibility and pilot trial of a digital storytelling intervention delivered via text-messaging

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Declarations of interest

None.

I confirm all patient/personal identifiers have been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details of the story.

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Abstract

Objective—Smoking during pregnancy causes risks to mother and infant health. We investigated the feasibility and likely success of SKIP-IT, a narrative and picture-based smoking cessation intervention delivered via text messages.

Methods—A feasibility and pilot trial. We aimed to recruit 70 pregnant women who smoked, randomised to usual care alone, or usual care and the SKIP-IT intervention, between 12 weeks of pregnancy and 6 weeks post due-date. Outcomes assessed were recruitment, retention, acceptability of, and engagement with the intervention, smoking behaviour, intentions, perceived risk, and self-efficacy.

Results—Of 312 women initially approached by smoking cessation services only 54 (17%) agreed to be contacted by the research team. Twenty were then either ineligible or uncontactable and 28 (82%) participated. Most women reported texts to be entertaining and helpful. The proportion of women not smoking at follow-up was lower in the intervention group, but numbers were too small to draw conclusions about effectiveness.

Conclusion—The intervention was acceptable, but difficulty in making initial and follow-up contacts meant our methods were unfeasible for a larger trial.

Practice implications—Digital Storytelling interventions could help women quit smoking, but further research is required to identify alternative methods for studies with pregnant women who smoke.

Keywords

Smoking; Pregnancy; Behaviour change; Intervention; Text-messaging

1 Introduction

Smoking during pregnancy carries serious risks to mother and infant health including increased rates of intrauterine growth retardation, preterm birth, stillbirth, death within the first year, and babies' longer-term risk of developing heart disease and diabetes [1–4].

Reduction in the rates of smoking in pregnancy has been a long-standing health policy target in the UK, with the ambition to reduce the prevalence to 6% or less by the end of 2022 [5]. However, the rates of maternal smoking at the time of birth in England continue to remain at 10.4% [6] with higher rates in Scotland (14.6%) and Wales (17.3%) [7]. Smoking

in pregnancy is strongly related to health in-equality [8] and age, with a higher percentage of women (26.8%) reported as smoking during pregnancy in the most deprived areas of Scotland, compared to 3.3% from the least deprived areas, and rates as high as 32.6% in women under 20 [9,10]. Women from disadvantaged groups are known to experience poorer outcomes of pregnancy [11] and smoking increases the already considerable burden of health inequality and disease. Around half of women who smoke are reported to make a quit attempt during pregnancy but relapse rates are high, and many continue to smoke through pregnancy [6,12].

Currently in the UK, efforts to reduce smoking during pregnancy involve early identification and referral of women to NHS smoking cessation services on an opt-out basis [13]. All pregnant women routinely receive carbon monoxide (CO) monitoring at the first antenatal appointment with 90% referral to smoking cessation services for smokers or where CO levels are raised. However, while women may initially express interest in cessation support, the actual uptake of, and subsequent engagement with, smoking cessation services, particularly among women from deprived backgrounds, remains low. A study in England found around half of pregnant smokers were interested in cessation support but only around 12% accessed the NHS cessation services [14].

Several interventions have been developed and evaluated for smoking cessation in pregnancy. However, most have had limited effectiveness. A Cochrane review of psycho-social interventions to reduce smoking in pregnancy (including cognitive behavioural therapy, stages of change, incentives, feedback, and pharmacological therapy) showed that together they were effective in helping only 6% of women who smoked to quit [11]. The most effective technique was provision of financial incentives, but these have been criticised for their potential coercive character, risk of cheating [15], concerns around cost-effectiveness and risk of relapse when incentives cease [16]. The lack of effectiveness of individual interventions was attributed to their inability to change generational patterns and environmental factors that increase the risk of smoking, and their potential effect of being judgemental which may alienate women.

There appears to be two main problems: firstly many of the women who continue to smoke during pregnancy do not or cannot engage with standard NHS smoking cessation services for reasons that are likely to be complex. Secondly current smoking cessation interventions appear to have limited impact in this group that may be described as hard to reach and hard to engage [17].

There is growing evidence to suggest that self-help interventions could be a low-cost, wide-reaching adjunct to face to face interventions and services, reducing barriers such as time constraints and women’s sense of feeling judged. A meta-analysis found that self-help interventions were significantly better than usual care at promoting cessation amongst pregnant women who smoke [18]. SMS text messaging has been found to be an effective and acceptable form of delivering self-help in many behavioural contexts including smoking cessation, binge drinking, weight loss, physical activity, and medication adherence [19–21] and in groups that are regarded as hard to reach and retain, such as those from deprived areas, heavy drinkers, or drug users [22,23]. A pilot/feasibility trial in England found a

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text-message based intervention to be feasible and acceptable among pregnant women who smoke [24] and a subsequent multi-centre pilot RCT showed feasibility of recruitment and measurement as well as promise of effectiveness [25]. However, problems were identified in these studies with ensuring the texts remained engaging, the unknown generalizability of findings to all pregnant women who smoke and lack of strategies to prevent post-partum relapse.

Building on the evidence for the potential benefits of self-help interventions delivered via text messages and the potential problems of loss of interest and disengagement, we developed SKIP-IT, an intervention that aimed to assist women to stop smoking when pregnant and to avoid post birth relapse. SKIP-IT used a novel story-telling approach. Story-telling is an increasingly common method of communicating complex health information in ways that are easily understood and can capture the imagination of the audience.

Behaviour Change Techniques (BCT), directly relevant to smoking cessation in pregnancy, were embedded in the story and engaging images were included alongside some of the text messages. This paper describes the SKIP-IT intervention and its initial testing for feasibility of a larger scale trial [26].

2 Aim and objectives

We aimed to investigate the acceptability, feasibility, and like-lihood of success of the SKIP-IT intervention for smoking cessation in pregnant women.

Our objectives were:

- **a.** To assess acceptability and willingness to be randomised to the SKIP-IT intervention or usual care.
- **b.** To assess and compare the feasibility of recruitment strategies, the level of participants' retention in the study and engagement with SKIP-IT.
- **c.** To assess the acceptability and likely impact of SKIP-IT among pregnant women who smoke.
- **d.** To estimate the required sample size for a full trial.

3 Methods

3.1 Design

A two-arm individually randomised controlled feasibility and pilot trial, comparing a narrative story-telling and image-based intervention with usual care for smoking cessation during pregnancy [27].

3.2 Setting and participants

3.2.1 Study setting—Maternity and smoking cessation services in five NHS boards in Scotland and one NHS Trust in England. These sites included a range of deprivation levels, including two with 30% and 26% of people respectively living in Scottish Index of Multiple

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Deprivation (SIMD) quintile 1 (the most disadvantaged group). Recruitment took place between December 2017 and December 2018.

3.2.2 Eligibility criteria—Women were eligible to take part in the study if they were 16 years of age or over and were resident in the catchment areas of the participating NHS boards or NHS Trust. Women needed to be up to 14 weeks of pregnancy and currently smoking any number of cigarettes. In order to effectively take part in the study women were required to own or regularly use a mobile phone with media capability, be able to understand written English, and be able to give informed consent.

Women were excluded from the study if they did not meet the eligibility criteria, above, or if they were already enrolled in an alternative formal smoking cessation trial.

3.3 Sample size

The primary objective of the study was to assess feasibility. We determined a sample size large enough to detect unforeseen problems which can occur with 5% probability (e.g. an unanticipated reason for a potential participant being excluded), at a 95% confidence level, equating to 59 participants [28]. Allowing for 15% drop-out requires 70 participants (35 per arm). We therefore aimed to recruit a total of 70 participants, 35 in each group.

3.4 Recruitment procedures

3.4.1 Recruitment—Pregnant women are routinely offered a carbon monoxide (CO) breath test at the antenatal booking appointment by their midwives. Women who test positive (≥4 ppm) are referred to local smoking cessation services and are then contacted and offered the smoking cessation interventions available in the local area. At this point smoking cessation staff were asked to give women brief information about the trial and seek permission to securely pass their contact details to the research team, who sent further study information before contacting potential participants. Rates were monitored weekly and as rates were low, targeted Facebook adverts were used in study areas to supplement recruitment by self-referral.

3.4.2 Consent—Consent was sought over the phone by the research team [25]. Due to the long period between data collection points, the study operated an iterative consent process, with participants asked to verbally consent prior to each data collection questionnaire. All participants were given information about how to stop messages or withdraw from trial participation. Prior to each data collection time point maternity services were asked to confirm that no adverse events (maternal death or pregnancy loss) had occurred.

3.5 Randomisation

Eligible women consenting to take part in the study were randomised to receive the SKIP-IT intervention plus usual care or usual care alone (control). Usual care was included in both trial arms for several reasons. Routine CO monitoring and referral to NHS smoking cessation services was mandatory at the time of the study therefore removal of this offer during the study would have been unacceptable to healthcare staff. Given the clear health

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risks of smoking during pregnancy it would have been unethical to deny participants existing services in favour of an intervention of unknown efficacy. Randomisation was carried out using the secure remote web-based system provided by the Tayside Clinical Trials Unit (TCTU) on a 1:1 basis, using minimisation on age group (16–24/25 + years), recruitment method (smoking cessation service / self-referral) and NHS board. It was not possible to blind researchers to study allocation.

3.6 Study arms

3.6.1 SKIP-IT intervention—SKIP-IT SmoKing In Pregnancy – Intervening with Texts is a novel, narrative, story-telling intervention designed to be delivered via automated text-messages. The intervention was initially designed and tested as a PhD [29]. The intervention aimed to alter participants' perceptions of risk, social norms, outcomes and self-efficacy using three key elements (Table 1):

1) a fictional story of a pregnant young woman, 'Megan' who tries to stop smoking by overcoming a series of commonplace barriers

2) images depicting increasing fetal size and describing its stage of development (Pictures 1&2)

3) a 'help' function to receive a supportive smoking cessation message.

A text message intervention was chosen as it allows flexibility for participants to engage when they wish and reduces the potential for feelings of being judged [30]. Text messages are inexpensive to deliver, and mobile phones are now fairly ubiquitous even in more deprived groups. TEXTApp, a software tool developed by the Health Informatics Centre, University of Dundee was used. The message schedule and any personalisation was programmed into the TEXTApp delivery system which also handled replies and delivery monitoring. The intervention was delivered to the participant's own mobile phone.

The intervention development used the MRC framework for development of complex healthcare interventions [31] and combined: theory from psychology on behaviour change, literature from arts and humanities about storytelling and narrative, and inductively derived theory. The final intervention targeted participants' perceptions of risk, social norms, outcomes and self-efficacy, which have been evidenced to predict smoking behaviour during pregnancy [29]. The intervention embedded BCTs aimed at changing these predictors and behaviour [32]. A storyline was developed, and the story was written in the form of text messages from a fictional character, 'Megan' a pregnant young woman who smokes. Characters embedded within the storyline were designed to display and model coping behaviours evidenced to increase self-efficacy [33]. For example, Megan builds up her motivations to quit smoking and makes an initial attempt. Over the course of the intervention, she relapses, encounters various barriers in her work and personal life to quitting, and explores ways to overcome these, ultimately succeeding in doing so. Megan also relays information from 'her mid-wife', a character who acts as an authority figure to deliver health messages, information, advice and guidance without judgement. We tested the intervention for acceptability and usability by involving key stakeholders - clinical staff

and participants who smoked during pregnancy - in the study during steering and story development groups and incorporating their feedback iteratively.

The text messages were designed to mimic messages coming from a friend (Megan). The messages started at approximately one a day and reduced to 3–4 per week later in the intervention. Participants received the messages at various times of day, and at varying levels per week, to mimic 'real-life' messaging and to ensure that participants did not become accustomed to receiving messages at particular times. Supplementary images which gave information about the participant's stage of pregnancy were delivered at the end of each week along with a summary message explicitly outlining the techniques which 'Megan' had employed that week to enable her behaviour change. Texts started at 14 weeks of pregnancy and ended 6 weeks after the expected date of birth (40 weeks in total). This ensured that support continued to be provided during the post-birth phase, which is typically high risk for smoking relapse [34].

Messages were tailored so that 'Megan' occasionally addressed the participant by name, although feedback from early testing advised us that using the name too frequently felt false. Participants could text 'Help' to receive a message with extra smoking cessation support and could text 'Stop' to opt out. Initial testing of the messages during the development PhD [29] found that the target audience liked the storyline, showing promise for a feasibility trial. No modifications were required to be made to the overall intervention during the study.

3.6.2 Control group—Participants in the control group continued to receive usual care, the offer of the standard NHS smoking cessation services available in their area and did not receive any SKIP-IT study text messages. Usual care varied between sites but generally included the offer of telephone or group support, advisory leaflets and motivational interviewing.

3.7 Outcome measures

Participants were enrolled in the study before 14 weeks and 6 days of pregnancy. After giving informed consent to participation all participants completed a series of structured telephone interviews. A baseline questionnaire was completed over the telephone (time-point 1). This closed ended questionnaire [35] included questions about socio-demographic status, current smoking behaviour and smoking history. The questionnaire, except the socio-demographic questions, was repeated at 4 weeks post randomisation (Time point 2), 36 weeks of pregnancy (Timepoint 3), 6–7 weeks post–due date (Timepoint 4), and 12–13 weeks post-due date (Timepoint 5). The data collected at each of the five time points is described in Table 2.

3.7.1 Feasibility outcomes—Feasibility outcomes were recruitment, engagement and retention in order to meet the specific objectives of the study. The recruitment rate was defined as the proportion of participants approached by the study team who consented to study entry, assessed from the recruitment log kept by the study team. Engagement in the intervention was defined as the proportion of participants who chose not to stop the text/picture messages, assessed using data captured by TEXTApp. TEXTApp is able to identify

that texts are received but cannot determine if they are opened. Retention was defined as the proportion of participants who did not withdraw prior to the end of the study.

3.7.2 Acceptability outcomes—Acceptability with the study methods was defined as the rate of completion of all study follow-up assessments, Acceptability of the intervention was assessed by asking additional open-ended questions in the structured telephone interviews [35], conducted with intervention group participants at the follow-up points described below. The questions included asking for feedback on the storyline, timing of text messages, anything good or bad they wanted to tell us about either the text messages or taking part in the study. Women in the control group who had received no text message were asked only for feedback on the study processes. At the final timepoint all women were asked additional open-ended questions, such as whether they had engaged with any other smoking cessation help (e.g. NHS), whether anything in particular helped them, and whether there was anything they felt the study could do to help women give up smoking.

3.7.3 Socio-cognitive determinants—Socio-cognitive determinants of smoking behaviour are important indicators of psychological preparedness to stop smoking. The socio-cognitive determinants targeted by the SKIP-IT intervention (perceived risk, self-efficacy and intention to quit smoking) were assessed (all participants) as follows:

- *Intention to quit smoking:* Informed by the Theory of Planned Behaviour [25], participants' current intention to stop smoking throughout pregnancy and for the rest of their life was assessed using two Likert-type items (e.g. I intend to remain smoke free throughout my pregnancy / for the rest of my life) scored 1 = strongly disagree to 5 = strongly agree). Score range 2–10.
- *Perceived risk:* Informed by The Health Belief Model and the Protection Motivation Theory, participants' perceptions of risk to baby associated with smoking during pregnancy were assessed using two Likert-type items scored 1 = Strongly disagree to 5 = strongly agree). Score range 2–10. One item assessed their belief about the likelihood of serious consequence (my smoking can cause serious risk of harm to my baby) and another assessed the significance of this consequence (I worry a lot about causing serious harm to my baby because of my smoking).
- *Self-efficacy:* Informed by the Social Cognitive Model (Bandura 1998), participants' self-efficacy to resist smoking was assessed using four items, similar to those used in previous studies [26]. One item assessed participants' generic self-efficacy (I am confident that I can resist smoking), while three items assessed their confidence in being able to resist smoking in specific emotional (when feeling anxious or stressed), habitual (when I crave a cigarette), and social situations (when I am with family or friends who smoke). Responses were elicited on a Likert type scale scored 1 = strongly disagree 5 = strongly agree). Score range 4–20.

3.7.4 Smoking outcomes—Assessment of smoking outcomes followed the Russell Standard [36]. The Russell Standard is a widely used set of criteria to define smoking

abstinence, providing an agreed definition for comparison of outcomes across studies. For SKIP-IT we took the 4 week-post randomisation point as the start of the abstinence period. Smoking more than 5 cigarettes since the beginning of the abstinence period classified the participant as a smoker.

3.7.5 Smoking behaviour—At study entry (baseline) all participants were asked about their current and pre-pregnancy smoking and any previous quit attempts. At each subsequent data collection time-point (Table 2) participants were asked:

1. If they had smoked at all since the last data collection point (with answers being reported as: 'no, not a puff; 1–5 cigarettes; more than 5 cigarettes'). [self-reported abstinence]
2. How many times they had purposefully not smoked for more than 24 h since the last data collection time point. [Self-reported 24 h quit attempts]

Self-reported smoking outcomes were also validated at 36 weeks pregnancy and 6–7 weeks post-due date using salivary samples tested for cotinine, a nicotine metabolite (a cut off of 13 ng/ml was used to determine abstinence) and anabasine allowing differentiation between nicotine from tobacco or from NRT or e-cigarettes.

3.7.6 Progression criteria—Progression to a full trial was pre-specified as recruitment ≥ 50%, retention ≥ 70% and evidence of a direction of effect in favour of the intervention.

3.8 Data analysis

Acceptability was assessed by deductive content analysis of the telephone questionnaire data to elicit specific aspects of participants' experience of the SKIP-IT intervention e.g. acceptability of text message. Frequency and descriptive statistics were used to explore recruitment and retention rates. A statistical analysis plan was prespecified for the quantitative analysis, which was conducted according to a modified intention-to-treat principle whereby observed data were analysed by randomised allocation irrespective of adherence to the intervention. Descriptive summaries of smoking outcomes were tabulated for both intervention and control groups. This included proportions for categorical and dichotomous data (e.g. smoking abstinence rates) and means and standard deviations for continuous data (e.g. socio-cognitive determinants of smoking behaviour). The candidate primary outcomes for a full RCT of the intervention were self-reported and validated smoking abstinence at completion of the intervention and self–reported and validated abstinence at 12 weeks post-birth. As this was a pilot trial it was not powered to detect between-groups differences and no estimates of effect size were estimated.

3.9 Ethical conduct of the study

Ethical approval for the study was obtained from the East of Scotland Research Ethics Service (EoSRES) ref: 17/ES/0131.

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4 Results

4.1 Recruitment rates

Overall 646 women were assessed for eligibility of their smoking cessation status by maternity staff. Of those 312 were potentially eligible and given information about the study (either face-to-face, via phone call, or information posted). Overall, 54 women (17%) initially agreed to be contacted by the researchers. Thirty-four were contacted and eligible and 28 consented to participate (82%). Two of these women contacted the study team following the Facebook adverts. One was consented and one woman was ineligible for the study. The CONSORT diagram showing the flow of participants at each stage of the study is shown in Fig. 1.

4.1.1 Participant characteristics—Demographic details of participants at baseline are shown in Table 3.

4.2 Study retention

Most participants remained in the study once randomised. Four participants withdrew (2 intervention and 2 control) due to non-continuing pregnancies. One participant in the control group was lost to follow-up from both treatment and study measures due to a change of contact details. All other participants remained until the end of the study. The retention rate was 87% (13/15) in the intervention group and 77% (10/13) in the control group.

4.2.1 Intervention engagement—Data captured by the TEXTApp software showed that no participants used the additional help function, although some replied to texts from Megan.

4.3 Acceptability of the intervention

Acceptability of the intervention was assessed in sequential interviews with 10 intervention group participants at the timepoints described in Table 2. Not all participants were contactable at each time point and 23 interviews were completed in total. Interviews took an average of five minutes to complete. Participants who gave feedback were generally positive about the texts and said that they had found the text messages helpful and entertaining.

Megan was seen as believable. Participants related to the circumstances she described and they reported feeling better about their own situations.

"It just kind of made me feel like it's ok to have a bit of a bad day, and it's ok to have a good day as well." [Y020].

"I did think it helped a lot, like, getting the texts and having somebody that you could relate, that somehow related to it as well. Just like, obviously with the stress and them being obviously round about other people that were doing it and stuff, and obviously breaks at her work, like all that I could relate to it." [A003].

Some participants found that Megan made them feel less alone as if they had someone there going through the same things as them.

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"You can, like, listen to other people's experiences but like it depends how often you see them, whereas when you are getting these texts regularly it feels like you've got somebody there …it's helpful to have somebody there and imagining that it's a real situation and that it happens to other folk as well, not just you, like the feeling that you're feeling and the things that you're going through, and what makes you want to smoke and what makes you doesn't want to smoke." [A004].

Only one participant reported that she did not like the text messages and indicated that she did not relate to Megan's character.

"I just kinda feel that the text messages are a bit stereotypical. Almost as if people that smoke are living a bit of a chaotic lifestyle." [A018].

Another participant did not find the messages helpful because she did not feel that Megan was an encouraging role model.

"I'm not saying that it wasn't supportive, because of course it was, if that person was three months pregnant, and had said 'right I've cut down to maybe two cigarettes' or something, but when she [Megan] *was still smoking 15 that was like 'I think you need more help than me'."* [T001].

4.4 Study engagement for control and intervention groups

The rate of completion of all study follow-up assessments was low, with many participants not being able to be contacted at the data collection time-points. See CONSORT diagram, Fig. 1.

Regarding the acceptability of study data collection, one woman said she would have liked the researchers to phone more often, and one reported difficult in taking part in study assessments due to problems with her phone.

"I would just like you to give me more phone calls rather than just about five phone calls or something through your pregnant, like through the full thing. I think you should do more phone calls …when you don't phone for a while it kinda does, it like goes to the back of your mind and then you do pick up a fag when you're stressed." [A007 - Control].

"Obviously because my phone was broken I didn't have the charge. And it was kinda annoying me that yous was maybe trying to get in contact with me and I couldn't get in contact with yous and stuff." [A009 - Intervention].

4.5 Smoking outcomes

Table 4 shows the results obtained from participants about how much they were smoking at each time point. The majority of participants were uncontactable at follow-up points. From the participants who did provide results, the proportion not smoking at 36 weeks pregnant was higher in the group who received text messages. This was found to be similar at 1 week and 6 weeks after the text messages stopped. The numbers, however, are too small either to draw conclusions about the effectiveness of the intervention or to provide a robust estimate for a sample size for a full trial.

Fig. 2 shows the Russell Standard Abstinence Rates, which measures the number of participants who have abstained from smoking for several weeks. This shows similar results to Table 3 with all the abstinent participants being in the intervention group (shown in red), although again the study was not designed to be large enough to draw wider conclusions about effectiveness at this stage. The graph also highlights the low number of participants willing to provide data and that this was lowest (only 5 participants at the first time point after participants gave birth). (Table 5).

Perceived risk was high at baseline and this meant that there was a ceiling effect i.e. no higher scores could have been reported. However, perceived risk appears to have declined a little over time. Intention to quit during and post pregnancy was also high (4.3 on a 5-point scale) this appears to decline for intentions to remain smoke free for rest of their lives. Self-efficacy is in the middle ranges and remains so through the study with some small decline in both groups.

5 Discussion

The purpose of this study was two-fold. Firstly, we aimed to test the feasibility of study methods; recruitment strategies and rates and study retention for a future RCT. Secondly, we aimed to assess the acceptability and likelihood of success of the SKIP-IT intervention for smoking cessation in pregnant women.

Recruitment was the biggest challenge and was considerably lower than required to assess the likely impact of SKIP-IT in a larger scale trial. We anticipated that by linking in with existing NHS smoking cessation pathways for pregnant women, rather than asking clinical midwives to introduce the study at the first antenatal appointment, study recruitment would be facilitated. However, it emerged that smoking cessation staff often had difficulty in contacting women referred to them. Only women who were seen face to face by smoking cessation services agreed for their details to be passed to the research team. Smoking cessation services posted study information to a further 130 women who had been referred to them by midwives but whom they had been unable to contact but none of them opted to self-refer to SKIP-IT. Using Facebook to boost recruitment was not successful. Overall, only 54 women agreed to be contacted by researchers and we were ultimately able to contact 34.

Once successfully contacted, however, most (82%) consented to participate in SKIP-IT.

Study retention was also problematic. SKIP-IT was a long intervention delivered over a 40-week period and aimed to support women through their entire pregnancy and the immediate period post birth, when many women who have stopped smoking are known to relapse. This was ambitious, and following recruitment, although most participants remained in the study, it was often very difficult to contact women by telephone or post for the follow-up questionnaires, despite considerable effort. This resulted in some low rates of outcome data collection. Some participants were un-contactable at certain timepoints but continued to provide data at later timepoints and so had not left the study.

We found that women who received the SKIP-IT text messages and images were positive about content and timing of the messages, found them engaging and most found them helpful.

The novelty of this intervention was the storytelling approach. Although evidence shows that narrative can be an effective method of communicating health information [37,38], there are very few past interventions which have used it as a mode of delivery. Story-telling can be engaging and entertaining. Information can be embedded or implicit within a storyline or narrative without the need for stating the information outright [39]. The story can be told through the perspective of the characters, removing the need for instructional elements in information delivery which could other-wise be negatively perceived. As some of the participant quotes above show, the women were receptive to advice coming from ‘Megan’ and saw her as somebody else going through the same experience. This suggests that storytelling has promise as a means of delivering behaviour change methods if barriers to implementation can be overcome.

The proportion of women not smoking at 36 weeks pregnant was higher in the group who received text messages. This was found to be similar at one week and 6 weeks after the text messages stopped. The numbers, however, are too small to draw wider conclusions about the effectiveness of the intervention.

Considering feasibility of study methods, although our progression criteria were met, the results clearly demonstrated that our methods were not feasible for progression to a full-scale trial using the methods tested. Although once successfully contacted by the research team the study consent rate, and retention rates were high, overall recruitment was low.

The translation of promising e-Health innovation is recognised to be challenging, particularly the implementation of e-Health within the NHS [40], Involvement of end users in the development stage is considered essential to the success of translating e-Health [41] While we did involve stakeholders-clinical staff and participants who smoked during pregnancy in the development stage, even at the development stage we found it difficult to involve many pregnant women who were current smokers. Some health boards in Scotland are currently operating text-based systems for reminder and support, e.g. FLORENCE [42], which shows promise for adoption and implementation within NHS structures.

Difficulty in recruitment to trials has been seen in other studies of text message interventions for women who smoke in pregnancy, which have used a variety of recruitment methods. For example, Naughton et al. [24] used community midwives to recruit and achieved their target recruitment, despite low referral rates, but felt that recruits were not representative of the general smoking population. In Naughton et al. [43] the researcher also attended clinics and community groups to help with recruitment. Naughton et al. [25] used research midwives to attend clinics with considerable recruitment success. Forinash [44] used screening of patient records and recruitment through pharmacists and reported slow enrolment and challenges with recruitment and retention. Sutton et al. [45] and Naughton et al. [46] report a similar text-message based study but open to all people who smoke, not just pregnant women. They used a mixture of self-referral, letter sent by GP, and recruitment by smoking cessation

advisors. As seen in Naughton et al. [25] the most effective method of recruitment was using research midwives or occasionally members of the research team themselves. This tallies with our findings that recruitment on top of a clinical 'day' job, e.g. by midwives or smoking cessation advisors is less effective than by staff dedicated to recruitment. This has implications for study resources but may be cost effective if required study numbers are achieved. However, as with our study, these studies have also reported substantial loss to follow up of trial participants with Naughton et al. [25] reporting 57% of recruits providing data at both time points. Naughton et al. [24] offered a £5 incentive for completion of each study follow-up questionnaire.

Our study is not alone in finding it very difficult to engage pregnant women who smoke. The difficulty in contacting women was not specifically trial related. We found that of women initially screened as eligible, less than half were able to be contacted by routine smoking cessation services. This population could be described as 'hard to reach' and Forinash [44] describes pregnant women who smoke as a difficult population, because those who are motivated to quit have likely already done so before their first appointment with a clinician. It is also possible that the focus on risks/ dangers of smoking in pregnancy have contributed to the problem by increasing moral approbation, leading to stigmatisation and ultimately marginalisation of these women [47,48] contributing to their reluctance to be contacted.

The lack of self-referral from women who did not meet with smoking cessation services suggests that personal contact (face to face or telephone) is key. Around a quarter of women who initially agreed to discuss the study with the research team were then unable to be contacted despite repeated attempts. Once women were successfully contacted by study researchers, most agreed to participate, seemingly the major challenge to be overcome was in making that initial contact. Naughton et al. [24] also reported that phone/postal contact was sufficient for recruitment and follow-up, after the initial approach had been made face to face by midwives at the booking appointment.

Considering the acceptability and potential likelihood of success of SKIP-IT, the number of women recruited was too small to draw any firm conclusions. However, we feel that the narrative story-telling approach is promising and warrants further investigation. Twenty-three short interviews were undertaken with ten women receiving the SKIP-IT intervention. Their responses showed that women generally found the text messages interesting and found the timings and frequency acceptable. This is in contrast to Naughton et al. [24] where 24% of participants found the text annoying and 26% too numerous.

It is important to distinguish between the intervention and the research participation effects [22]. Whilst women may not have engaged with the study data collection, the intervention itself showed promise. There were no withdrawals from participants who had a continuing pregnancy, which is promising for intervention acceptability. Despite the challenge of collecting follow-up data, most participants continued the intervention until the end of the text messages. This shows good promise for retention of participants to the intervention, if recruitment and data collection issues can be overcome.

Other studies have used a similar digital narrative approach successfully to bring about behaviour change in other socially disadvantaged groups. In the Game of Stones trial, narrative SMS with embedded key messages and BCT were used to support weight loss for men with high levels of disadvantage [49]. The intervention was acceptable to many men who successfully met or partially met weight loss targets, and was feasible to deliver. Similarly, the TRAM study [22] demonstrated that it was possible to recruit and retain large numbers of socially disadvantaged men. The text message intervention in that study fostered enthusiastic engagement and produced a modest, but statistically non-significant effect on the reduction of binge drinking. It appears that the digital narrative approach is feasible, acceptable and engaging and so has the potential to reduce health inequalities in men.

Some participants of this study reported a variety of social situations including domestic abuse, social services involvement, and relationship breakdowns that impacted on their ability to engage with the study and with their intentions to stop smoking. Some of the participants moved address multiple times during the study. Many participants reported poor mental health and using smoking as a way of dealing with mental health problems. Some reported being unaware that certain types of antidepressants were safe for use during pregnancy and had made the choice to continue smoking rather than seeking professional assistance. Whilst these unstable home situations contribute to recruitment difficulty they also demonstrate the potential value of the delivery of the intervention in a text-message format, as these women might otherwise struggle to access regular, continuous smoking cessation advice and support.

This study highlights the importance of undertaking well conducted feasibility studies prior to undertaking a full-scale trial to test both the intervention and the study methods. Our findings and observations point to several recommendations for engaging women in future smoking cessation trials.

Use of dedicated recruiters in the form of study teams or research midwives have been successful in other studies [24,43] and produced the highest recruitment rates in SKIP-IT. Our study has also highlighted the importance of initial contact in person or by telephone, rather than posted material.

The SKIP-IT study protocol placed no restrictions on how many times a participant could be contacted by the study team, other than the team’s judgement of what was acceptable. Some participants who subsequently joined and engaged with the study required numerous attempts before initial contact could be made. This appeared to be due to a mixture of unstable work situations, frequent house moves, and childcare responsibilities. Participants also reported not having mobile credit to return voicemails and being reluctant to answer calls from unknown or withheld numbers. The team often texted a participant to alert them that they would phone and giving the number that the call would come from. This approach was sometimes successful, but very labour intensive. Smoking Cessation Advisers reported having similar difficulties in contacting women referred to their services however, they were limited to the number of contact attempts they could make, for example two phone calls and one text message, before information was posted to the woman about smoking cessation services.

Naughton et al., [14] used incentives for completion of study time-points, which may overcome similar issues with research participation that overshadow the acceptability of the actual intervention. Removing participation issues may also be seen by targeting studies at an NHS level, for example by introducing text messages as standard in particular health boards, as has been seen with the introduction of simple.uk's 'Flo' text system for healthcare self-management [42].

Further work is needed on recruitment strategies and reaching women from lower socioeconomic groups. Strategies used in other studies, such as community outreach [49] and time-space sampling [22] are unlikely to be effective in our population due to women not wanting to be seen talking to recruiters in public and potentially disclosing if they are pregnant/smoking.

5.1 Conclusions

Recruitment to the SKIP-IT intervention was challenging, mainly due to low engagement between pregnant participants and SCS. Engagement with the study data collection was also low, although acceptability of the intervention was high and study retention was also good. Overcoming barriers to uptake of the intervention would be crucial to its success, but qualitative evidence suggests that the intervention itself is acceptable and may be helpful to participants trying to quit smoking.

The purpose of this study was to develop an engaging story that would be delivered as text messages to encourage pregnant women to stop smoking and to test whether we could recruit and retain enough women in the study to make a larger study feasible. The text messages were well received by participants however few women were willing to be contacted by phone initially or at follow-up. Smoking during pregnancy presents a significant risk to the health of the women who smoke and to their infants, compounding the already increased burden of disease experienced by this generally more disadvantaged group. This merits continued effort to overcome the grand challenge of engaging and retaining pregnant smokers in smoking cessation interventions.

5.2 Practice implications

Women who continue to smoke during pregnancy may be reluctant to engage with smoking cessation services. Repeated attempts at contact may be required. Smoking cessation interventions delivered via text messages are acceptable to women and have the potential to aid smoking cessation.

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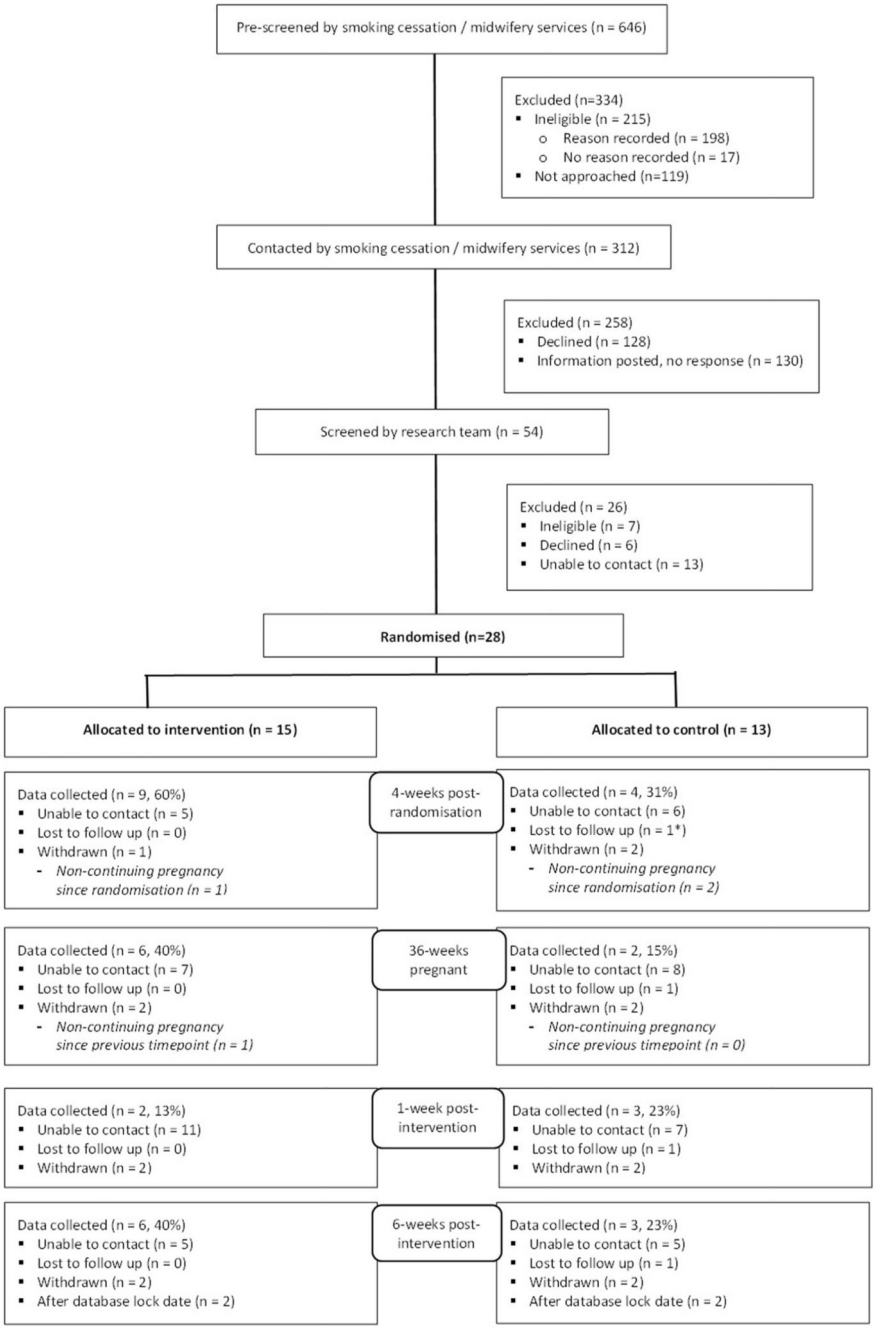

Fig. 1. SKIP-IT CONSORT Diagram.

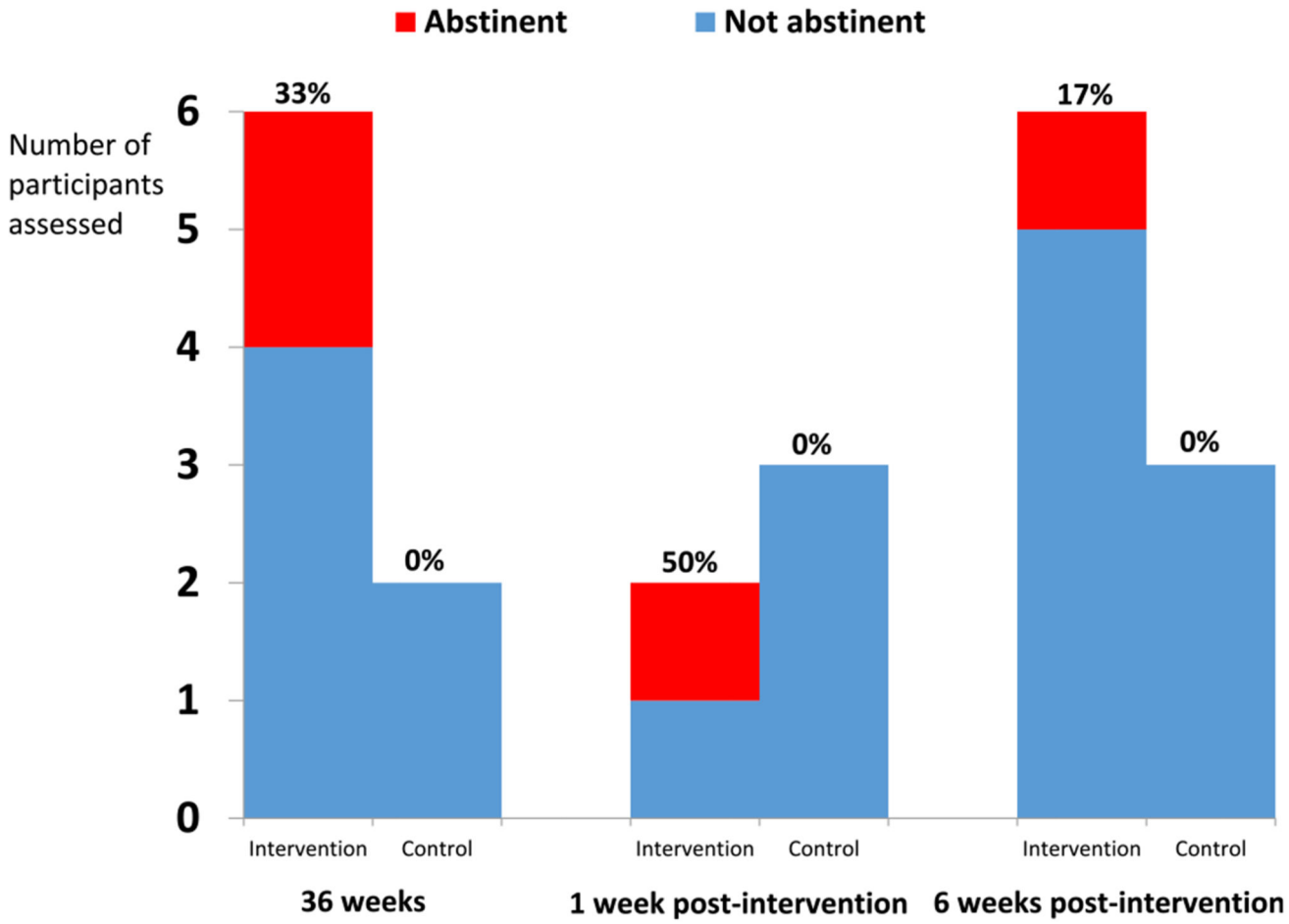

Fig. 2. Russell Standard Abstinence Rates.

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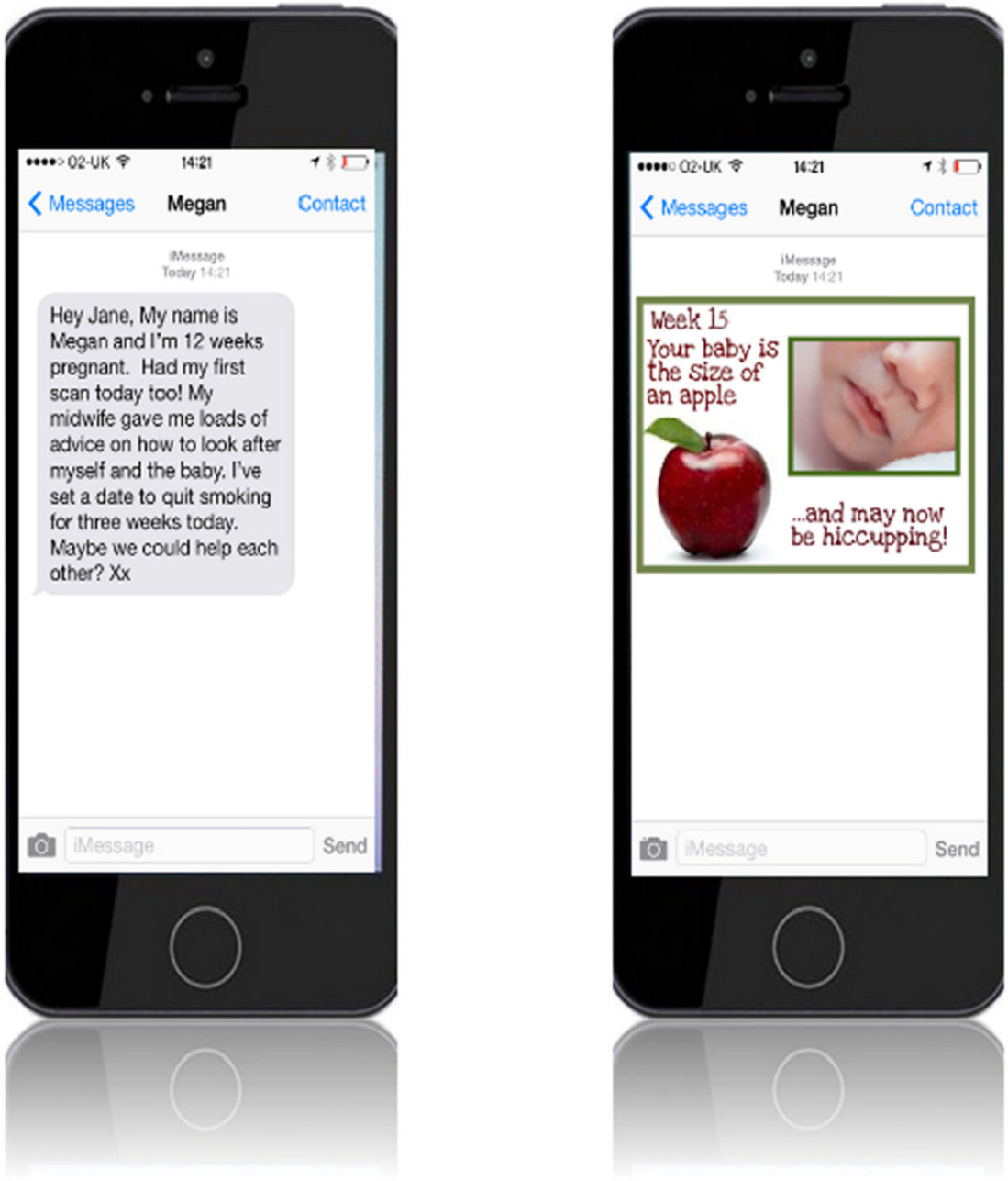

Picture 1. Example text messages.

Picture 2. Example of picture messages showing size of fetus.

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Table 1
Examples of text messages and embedded elements.

Aims	Method by which it is operationalised	How it is embedded in the story	Example text messages
Raise risk perceptions by:			
Induce cognitive dissonance	Ensuring information is not open to interpretation and is not easily ignored. Identifying and challenging commonly held misconceptions.	Information embedded in the storyline includes Megan discovering that some of her own beliefs are incorrect and talks through her thought processes.	My midwife said Caitlin's not right. The baby won't have bad effects if I quit and it's nicotine withdrawal (not stress) that I'll feel. C won't listen though:(
Create concrete/ experiential risk representations	Arousal of fear/worry. Providing a clear, perceptual understanding of the risks.	The character of Caitlin continues smoking throughout her pregnancy. Her baby is born prematurely.	I saw Caitlin today. Lily is so cute. The nurses have said her lungs are really tiny and even a little bit of smoke could damage them. X
Increase self-efficacy by:			
Enactive mastery	Encourage recollection of past successes or failures of modelling the behaviour (self-modelling).	Megan talks about her past attempts at quitting. She reminds herself that the first 3 days of a quit attempt are the most difficult.	Not coping today. Keep thinking that quitting gets easier after the first 3 days. Doesn't help the girls are joking everyone should avoid me cos I'm in a mood.
Vicarious experience	Using a 'coping model' who struggles with, and achieves realistic goals.	Megan is a 'coping model' developed to increase self-efficacy. Megan has similar attributes to the target group. She will struggle with, and overcome, barriers to smoking cessation throughout the storyline.	Weekly summary text: This week Megan has: Quit on her quit date! Started a 'quit jar'. Used past quitting experiences to help her. Distracted herself from smoking (lollipops, cleaning, walking the dog). Avoided situations where people are smoking.
Verbal persuasion	Encouraging, positive advice and information.	Information about the benefits of quitting smoking embedded in the storyline and delivered from the character of the midwife who is seen as a trusted source of information.	I've decided to quit again. I always thought NRT wasn't safe when pregnant but the midwife says it's better for the baby than smoking. And I can get it free!
Physiological and affective states	Induced positive mood.	Weekly images updating woman about her baby's stage of development	See Pictures 1&2

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Table 2

Data collection.

Timepoint	1	2	3	4	5
Weeks of pregnancy	**12–14**	**16–18**	**36**	**6–7 weeks post-due date**	**12–13 weeks post-due date**
Socio-demographic	X				
Past smoking behaviour/ environment	X				
Current smoking behaviour	X	X	X	X	X
Socio-cognitive determinants of smoking behaviour					
Intention to quit smoking	X		X	X	X
Perceived risk	X		X	X	X
Self-efficacy	X		X	X	X
Experience of intervention (open-ended)		X	X	X	X
Validated smoking outcomes			X	X	

Table 3
Socio-demographic characteristics at baseline

		Intervention	Control
Age in years; n (%)	16-20	2, 13.4%	4, 30,8%
	21-25	5, 33.3%	4, 30,8%
	26-30	3, 20.0%	3, 23,1%
	31-35	3, 20.0%	2, 15,3%
	>35	2, 13.3%	0, 0%
Gestation in weeks;			
N, Mean (SD)		15, 12.8 (2.5)	13, 11.7 (2.7)
Parity; n (%)	First baby	8, 53.3%	7, 53.9%
	Previous births		
Educational level; N, n (%)	Still at school	0, 0,0%	0, 0,0%
	No formal qualification	3, 20.0%	1, 8.3%
	Standard Grade or equivalent	2, 13.3%	7, 58.4%
	Higher Grade or equivalent	2, 13.3%	0, 0,0%
	Apprenticeship	0, 0,0%	0, 0,0%
	Other vocational qualification	5, 33.4%	4, 33.3%
	Degree	3, 20.0%	0, 0,0%
Employment; n (%)	In paid employment	7, 46.7%	2, 15.4%
	Home-maker/full-time parent or carer	3, 20.0%	6, 46.2%
	Retired	0, 0,0%	0, 0,0%
	No known/missing	0, 0,0%	1, 7.7%
	Full-time student	0, 0,0%	0, 0,0%
	Unemployed	2, 13.3%	1, 7.7%
	Permanently sick or disabled	3, 20.0%	3, 23.1
Usual area of work;	Simplified NS-SEC status	12, 5.0 (2.3)	11, 5.1 (1.8)
N, Mean (SD)			
Three-level ONS classification	Routine and manual occupations	8, 66.7%	7, 63.6%
	Intermediate occupations	1, 8.3%	3, 27.7%
	Higher managerial, administrative and professional occupations	3, 25.0%	1, 9.1%
SIMD/IMD (quintile); n (%)	1 (most deprived)	7, 46.7%	4, 33.3%
	2	3, 20.0%	2, 16.7%
	3	2, 13.3%	4, 33.3%
	4	1, 6.7%	0, 0.0%
	5 (least deprived)	2, 13.3%	2, 16.7%
Current partner; n (%)	Yes	12, 80.0%	9, 75,0%
Partner at home; n (%)	Yes	9, 60.0%	7, 59.3%
	No	3, 20.0%	2, 16.7%
	Not applicable	3, 20.0%	3, 25.0%

		Intervention	Control
Other people in household; n (%)	Yes	1, 6.7%	2, 16.7%

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Table 4

Smoking outcomes.

Self-reported smoking behaviour		Women who received the text messages					Women who did not receive the text messages				
		Base-line	4 weeks post-randomisation	36 weeks pregnant	1 week post-intervention	6 weeks post-intervention	Base-line	4 weeks post-randomisation	36 weeks pregnant	1 week post-intervention	6 weeks post-intervention
		N * = 15	N = 9	N = 6	N = 2	N = 6	N = 12	N = 4	N = 2	N = 3	N = 3
Number of cigarettes	None	3 (20%)	3 (33%)	4 (67%)	1 (50%)	1 (17%)	3 (25%)	2 (50%)	0 (0%)	1 (33%)	0 (0%)
currently smoked	1–5	7 (47%)	4 (44%)	1 (17%)	0 (0%)	2 (33%)	4 (33%)	1 (25%)	2 (100%)	0 (0%)	2 (67%)
each day	6–10	3 (20%)	1 (11%)	0 (0%)	1 (50%)	2 (33%)	3 (25%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	11–15	1 (7%)	0 (0%)	1 (17%)	0 (0%)	0 (0%)	0 (0%)	1 (25%)	0 (0%)	1 (33%)	0 (0%)
	16 +	1 (7%)	1 (11%)	0 (0%)	0 (0%)	1 (17%)	2 (17%)	0 (0%)	0 (0%)	1 (33%)	1 (33%)

N* is the number of women who answered the questionnaire at that time point

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Table 5
Socio-cognitive determinants of smoking behaviour.

Item Mean (SD)	Intervention				Control			
	Time Point	Time Point	Time Point	Time Point	Time Point	Time Point	Time Point	Time Point
	1 n=15	3 n=6	4 n=2	5 n=5	1 n=12	3 n=2	4 n=3	5 n=3
Perceived risk (2-10)	9.5 (0.7)	10.0 (0.0)	9 (1.4)	8.8 (1.8)	9.2 (1.1)	10.0 (0.0)	10.0 (0.0)	8.3 (2.1)
Intention (pregnancy) (1-5)	4.3 (0.7)	3.7 (1.8)			4.3 (0.9)	3.0 (2.8)		
Intention (post-birth) (1-5)	3.9 (1.0)	3.2 (1.5)	3 (2.8)	2.6 (1.8)	3.9 (1.3)	4 (1.4)	4.3 (1.2)	3.3 (1.5)
Self-efficacy (4-20)	12.2 (4.8)	10.8 (5.0)	19 (3.2)	10.0 (6.8)	11.6 (5.4)	6.5 (0.7)	10.7 (3.2)	9 (4.4)