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Short Report

Feasibility of recruitment to a behavioural smoking cessation intervention combined with ongoing online support

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The aim of this randomized controlled trial was to determine whether a behavioural intervention in pregnancy supported by online information would improve smoking cessation rates. However, due to a number of challenges, recruitment to this trial was reluctantly halted. We aimed to recruit 220 maternal smokers within 2 years and after screening 1995 women, just 22 enrolled over a 8-month period. Only three women accessed the online element of the intervention and, at follow up, no women reported quitting. We report our findings as they may inform the design and powering of future smoking cessation interventions in pregnancy.

Introduction

Maternal smoking is arguably the most important modifiable risk factor for pregnancy outcomes as it increases the risk of adverse fetal and maternal outcomes in the short- and long-term. Importantly, cessation in the first half of pregnancy prevents intrauterine fetal growth restriction associated with smoking throughout pregnancy.[1]

Online delivery of smoking cessation information and support may offer an intervention opportunity given that pregnant women from all socioeconomic groups are using digital platforms extensively to access information on pregnancy.[2] However, previous intervention studies in pregnancy have fallen short of their recruitment target or have reported extending recruitment to reach their intended sample size.[3]

The aim of this randomized controlled trial (RCT) was to evaluate the feasibility of an established behavioural intervention supported by ongoing online information and support which was customized for pregnant women and based on current evidence.

Methods

In an RCT, we compared a recognized behavioural counselling intervention supported by online information alongside customary care to help pregnant women quit smoking. The primary outcome was birthweight. The study was approved by the Research Ethics Committee (17-2015).

A sample size of 220 was required to show a difference of 250 g in birthweight between the control and intervention groups using a calculation for comparing means. This sample size accounted for a drop-out rate of 20% based on previous research.[4–6]

Convenience recruitment was conducted in 2016. Scan lists were checked using the medical record system prior to appointments and maternal smokers highlighted for further investigating of eligibility. Self-reported smokers who were aged >18 years, <17 weeks gestation, understood English, had access to the Internet and capacity to give consent were eligible. Data were collected from the computerized medical records and a research only questionnaire. Carbon monoxide breath tests (BCO) were conducted to detect cigarettes smoke exposure using the handheld Bedfont piCO+ Smokerlyzer®.

The intervention group received customary care as well as a 20-minute counselling session at first antenatal appointment, followed by access to a smoking cessation website. The design and delivery of the intervention was provided by the primary researcher (CR), a certified smoking cessation practitioner. The website's structure and information was informed by the findings from a pilot survey of 32 maternal smokers of whom 84% said they would enrol in an online smoking cessation study if it were available.

Results

Figure 1 shows a flow diagram of the screening and recruitment process. Of the 1995 women screened 88 were eligible and 22 enrolled. Supplementary table S1 presents reasons for ineligibility and for declining participation. The most common reason for women declining was disinterest in quitting (37.5%).

Supplementary table S2 shows characteristics of the study population. Of the 22 women recruited, the average number of cigarettes smoked was 8/day, the mean cigarette dependency score was 4 (moderate). Based on the stages of change model, 5% self-reported being in pre-contemplation, 36% in contemplation, 32% in determination and 27% in relapse.

Ninety-five per cent had made a previous quit attempt and the median length of quit attempts was 3.0 months (IQR 5.5). The most common reason for a previous quit attempt was 'I wanted to see if I could quit'. Ninety-five per cent of women had a partner who smoked and 68% felt unsupported to quit during the current pregnancy. The average confidence in quitting score was $5.4 \pm 2.5/10$.

Eight of the 13 women with a previous pregnancy attempted to quit during the pregnancy and none were successful. The most common reasons for unsuccessful quit attempts in pregnancy were 'withdrawals were too bad' and 'too many people around me were smoking'.

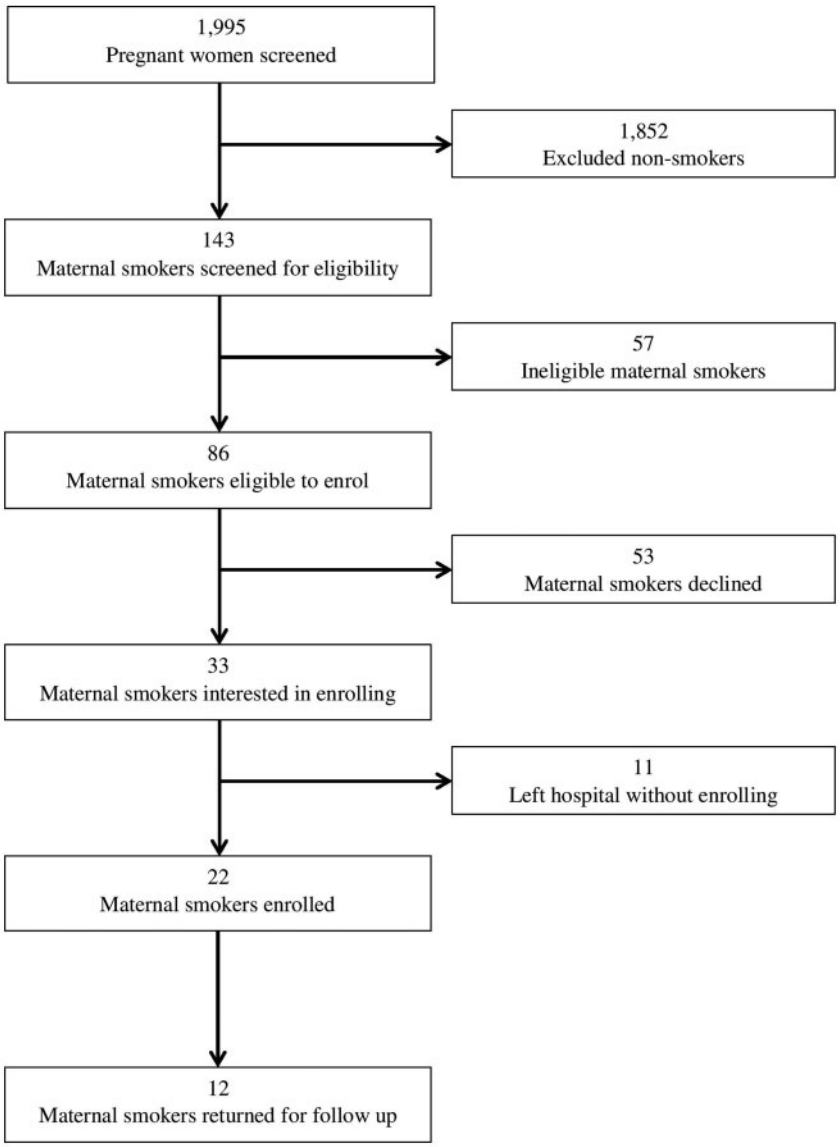

Figure 1 Flow diagram of recruitment

Of the 13 women randomized to the intervention group, three visited the website. There were no return visits. Supplementary table S3 presents website traffic analysis. In total just 12 women (55%) returned for follow-up, despite the appointment coinciding with their antenatal anomaly scan.

The level of interest and participation rate in the study as well as the level of engagement with the intervention was lower than expected. We estimated that it would take at least 6 years to recruit the sample size required, thus, given that the hospital's fundraising arm could only fund the project for 2 years a decision was taken reluctantly to halt the RCT.

Discussion

Although this RCT on smoking cessation in pregnancy was unsuccessful, we report our findings because we believe there are learning points for researchers and maternity services. We found that women who are persistent smokers when they present for hospital antenatal care have little interest in quitting. Although the intervention was evidence-based, customized and accessible, patient engagement was poor. Those who are not motivated to quit appear reluctant to seek advice, however brief, or to access ongoing online support, however customized.

Previous studies that successfully recruited and retained maternal smokers generally included only women who were motivated or incentivised to quit.[7] Our intention to create a more 'real world scenario', and increase the external validity of the work, by offering participation to all maternal smokers may have been impacted negatively on the attrition rate.

Furthermore, the use of a single centre and researcher may have hindered our capabilities to achieve sufficient numbers. Nurse involvement may have also aided reach and uptake to the trial. In addition, due to maternal smokers' tendency to enter prenatal care later in pregnancy, changing the eligibility criteria of gestation to later in pregnancy could have increased our recruitment by 33% (of all maternal smokers excluded $n = 19/57$).

UK services implemented an 'opt-out' referral pathway to improve engagement with stop smoking services (SSS).[8] This pathway recommends giving all identified smokers (by self-report or BCO verification) brief advice and referral to SSS without seeking consent. Before the introduction of this pathway, an opt-in pathway was used whereby women were only referred should they seek support and just one in seven maternal smokers utilized these services.[8] Studies that evaluated the opt-out pathway found that as few as 39% of those referred attended their appointment, 16% set a quit date and only 5%

reported quitting. Thus, despite the opt-out pathway increasing referrals, it did not increase utilization or smoking cessation rates.[8]

There is evidence that if women have not quit before their first hospital visit, they are unlikely to do so later in pregnancy. Women who quit, usually unaided, at confirmation of pregnancy, are commonly referred to as 'spontaneous quitters'. These women are highly motivated by their pregnancy with 65–81% maintaining abstinence throughout pregnancy.[9] A UK longitudinal study found the rate of smoking decreased from 27% before pregnancy to 12% after confirmation of pregnancy with only 1% quitting subsequently.[10]

Concern has been expressed that the failure to publish unsuccessful research trials leads to publication bias. Our study shows that women who have not stopped smoking before presenting for hospital care show little interest in either brief or sustained online behavioural interventions to help them quit. This makes recruitment difficult. More extensive recruitment methods may be required to obtain an adequate sample size. Methods to increase recruitment and retention may include multiple centre involvement, wider staff involvement, biochemical screening to identify non-disclosers, longer recruitment periods and recruiting only women who are motivated to quit. We believe our study has important learning points for the statistical powering of future trials targeting smoking cessation during pregnancy.

Supplementary data

Supplementary data are available at *EURPUB* online.

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Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Ethical approval was received from the Hospital Research Ethics Committee (17-2015).

Informed consent: Informed consent was obtained from all individual participants included in the study.

Conflicts of interest: None declared.

Key points

- Maternal smokers who have not quit spontaneously before their first hospital antenatal visit showed little interest to quit subsequently.
- Future trials may need to consider a longer trial period, biochemical screening of all women, amenable eligibility criteria and multiple centres and staff involvement to achieve sufficient numbers.
- For retention of participants recruitment of only women motivated to quit should be considered.
- Our unsuccessful randomized controlled trial on a smoking cessation intervention during pregnancy has important learning points for the design and powering of future research.

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