Effectiveness of the BabyBreathe intervention for maintaining postpartum smoking cessation: multicentre pragmatic randomised controlled trial

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ABSTRACT

OBJECTIVE

To assess the effectiveness of an interpersonal and digital intervention, BabyBreathe, for maintaining postpartum smoking cessation.

DESIGN

Multicentre pragmatic individually randomised controlled trial.

SETTING

Community health visiting services in the UK.

PARTICIPANTS

887 pregnant women and people who reported quitting smoking in the 12 months before, or during, pregnancy, with abstinence verified by exhaled carbon monoxide readings. A secure web based randomisation sequence, stratified by recruitment hub, partner smoking status, and quit timing (before or during pregnancy), was used to randomise participants (1:1) to receive the intervention or usual care. The trial was unblinded.

INTERVENTION

BabyBreathe comprised in-person or remote smoking cessation maintenance interpersonal support at 28-32 weeks' gestation and 10-14 days post partum. The BabyBreathe box, posted at the time of birth notification, contained theory driven advice for cessation maintenance, a sample of nicotine replacement gum, and motivational tools. Tailored motivational and educational text messages were provided. A website and app provided tailored cessation maintenance advice, social support, motivational tools, and gamification. Control was usual postpartum care.

MAIN OUTCOME MEASURE

The primary outcome was continuous smoking abstinence, verified by exhaled carbon monoxide concentration (≤7 parts per million (ppm)) 12 months post partum.

RESULTS

Between 4 September 2021 and 3 August 2023, 887 participants were randomised: 442 to receive BabyBreathe and 445 to receive usual care. After one post-randomisation exclusion, 886 participants were included in an intention-to-treat analysis. The group difference in smoking abstinence at 12 months post partum was not significant (BabyBreathe 242/441 (54.9%) *v* usual care 222/445 (49.9%); odds ratio 1.23, 95% confidence interval (CI) 0.94 to 1.60, P=0.13, risk difference 4.8% (-1.7% to 11.2%), and number needed to treat (NNT) 21 (NNT to benefit 8.9 to ∞) and NNT to harm 59). A post hoc per protocol analysis favoured the intervention (BabyBreathe 200/347 (57.6%) *v* usual care 222/445 (49.9%); adjusted odds ratio 1.36, 95% CI 1.02 to 1.81, P=0.04), risk difference 7.2% (0.3% to 14.1%), and NNT 13.9 (7.1 to 333.3). No trial related adverse incidents occurred.

CONCLUSIONS

BabyBreathe did not statistically significantly increase sustained smoking abstinence post partum for people who quit smoking in pregnancy. A post hoc per protocol analysis, including only those who received interpersonal support as intended, showed statistically significantly greater benefit from BabyBreathe over usual care. A focus on fidelity and further targeting of BabyBreathe to groups with lower socioeconomic status may be warranted.

TRIAL REGISTRATION

ISRCTN Registry ISRCTN70307341.

Introduction

In England, the prevalence of tobacco smoking is higher among women of reproductive age compared with the general population.[1] Many people successfully quit smoking during pregnancy, but health inequalities are noticeable as those with lower income are less likely to quit and more likely to relapse. Tobacco smoking is a key modifiable risk factor for adverse pregnancy outcomes, and quitting smoking during pregnancy reduces these risks.[2] A unique opportunity exists to help those who stop smoking in pregnancy to quit permanently. Although most pregnant people who quit smoking want to remain abstinent after the birth, as much as three quarters of spontaneous quitters return to smoking within six months.[3] Sustained postpartum smoking abstinence has important health benefits for mothers, as most new mothers are young enough to minimise long term harm, particularly from cancers and cardiovascular disease.[4] In infants and children, maternal smoking is the primary source of second-hand exposure to smoke, a substantial cause of child ill health and mortality.[5] An intergenerational effect is also evident: children of mothers who smoke are twice as likely to smoke themselves in later life.[6]

In the UK NHS, estimates of the total annual costs associated with smoking in pregnancy and postpartum relapse to smoking are wide and substantial, in 2010 ranging between £8.1m ($10.8m; €9.5m) and £64m overall for treating maternal health problems[7]; equating to about £100m in 2025 if the higher estimate was correct. Postpartum smoking relapse is a key global public health problem; yet no evidence based interventions exist and in the UK

there is no routine support for maintaining smoking abstinence.[8] The NHS Long Term Plan prioritises smoking cessation services in pregnancy,[9] and recent policy has commissioned targeted, evidence based interventions, including financial incentives, for smoking cessation in pregnancy,[10] overlooking postpartum support.

Previously trialled interventions to support sustained smoking abstinence post partum overall did not clearly show effectiveness, because although an effect was identified at 12-17 months post partum (two studies (n=431); average risk ratio 2.20, 95% confidence interval (CI) 1.23 to 3.96), the effect at six to 11 months post partum was only borderline (six studies (n=2458); 1.33, 1.00 to 1.77).[11] A Cochrane review of interventions to prevent relapse included postpartum relapse prevention trials as a subgroup, finding no significant benefit of interventions (15 studies (n=4606); risk ratio 1.02, 95% CI 0.94 to 1.09).[12] A subsequent trial tested the effectiveness of financial incentives for maintaining postpartum smoking cessation, with inconclusive findings.[13] New approaches are urgently needed to address this important public health issue. Our team undertook multiple systematic reviews to inform the logic model underpinning BabyBreathe, an interpersonal intervention for maintaining postpartum smoking cessation.[14] We reviewed qualitative studies exploring the experience and understanding of postpartum smoking relapse,[15] undertook a systematic review of predictors of such a relapse,[16] and identified the most promising behaviour change techniques in preventing return to smoking post partum.[17] Interventions combining multiple techniques were the most promising, suggesting that sustained postpartum smoking cessation requires a complex intervention. We hypothesised intervention components and their functions[18] that would achieve sustained postpartum smoking abstinence. Working with women and people both during pregnancy and post partum, their families, and healthcare professionals, we designed an intervention that could be delivered alongside usual care, would be feasible to implement in practice, and would be acceptable. We tested the effectiveness of BabyBreathe at supporting women and people to maintain smoking cessation after pregnancy.

Methods

Trial design, setting, and participants

This trial was a multicentre, pragmatic, two arm, superiority, parallel group, individually randomised controlled trial, with internal pilot, including embedded economic and process evaluations. The trial protocol was registered and is published elsewhere.[14] Participants were recruited through UK midwifery services during pregnancy, in person or remotely by telephone, and online using social media advertising. Health visitors or trained researchers delivered the intervention in the community, in person or remotely, alongside delivery of usual care.

Between July 2021 and August 2023, research midwives screened pregnant women and people in England and Scotland at their first antenatal booking appointment, discussed the study, and sought written consent to be contacted by the research team. Initially, we excluded many potential participants (n=5231) because they were not in areas with BabyBreathe trained health visitors. This barrier was removed when we extended the intervention to remote delivery, enabling us to recruit participants from across the UK. Participants provided initial consent to be contacted during early pregnancy (n=2774). Potential participants were then contacted by an automated system, through email or text message, at about 26 weeks' gestation, and confirmed eligibility (n=1271 (46%) of participants who had provided consent to contact). Eligibility criteria were pregnant women and people who had stopped smoking completely in the 12 months before pregnancy, or at any time during pregnancy, had not had a single puff of a cigarette for at least four weeks by 26 weeks' gestation or any time after this up until the birth, were able to read and understand English, were willing and able to give informed consent for study participation, were aged at least 16 years, and had an expired carbon monoxide reading of <4 parts per million (ppm).

Potential participants were asked to download a study specific smartphone app (iCOBabyBreathe) so they could use a study-provided individual use carbon monoxide monitor (Smokerlyzer; Bedfont, Maidstone, UK) to take two readings. The highest reading was input into a bespoke REDCap database. When possible, a member of the clinical team took carbon monoxide readings in person at ≥26 weeks' gestation as part of standard care. Following provision of written informed consent and confirmation of eligibility through a carbon monoxide reading, participants received a text or email inviting them to complete the baseline questionnaire. The published protocol outlines the baseline variables.[14]

Randomisation

Submission of the baseline measures triggered randomisation. Between 4 September 2021 and 3 August 2023, we randomised participants (1:1 ratio) to one of the two treatment groups, using a secure web based randomisation sequence. Randomisation was stratified by recruitment hub, partner smoking status, and quit timing (before or during pregnancy). Random block sizes of four and six were used.

Allocation concealment and blinding

The Clinical Trial Unit's data management team generated the randomisation list, which was securely stored and not revealed until after the participant was randomised to ensure concealment. No blinding was possible owing to the nature of the trial. Only trained healthcare providers or researchers delivered the intervention. To limit contamination, control participants were allocated to healthcare providers not trained to deliver BabyBreathe.

Intervention

BabyBreathe is a complex intervention underpinned by behaviour change theory.[18] It consists of interpersonal support (in person or remotely delivered by video call or telephone) with a trained healthcare provider (health visitor, member of health visiting team, or researcher) at about 28-32 weeks' gestation, to align with scheduled visits for usual care and to prepare for the immediate postnatal period. A relapse prevention kit ("BabyBreathe box") was posted to participants on notification of the birth. The kit contained behaviour change theory driven advice leaflets for mothers and their partners, advice on nicotine alternatives, a sample of nicotine replacement gum, gifts for parents such as a fridge magnet and pen, reminders, encouragement to set goals and self-reward, and motivational tools. An automated text message support system was triggered, delivering supportive, motivational, and educational messages following a reducing schedule, with opportunities to tailor messages by answering "lapse" or "smoke-free." Access was provided to the BabyBreathe website and app, providing tailored and targeted advice and offering the opportunity to engage with social support, motivational tools, and gamification as rewards. A second interpersonal discussion was scheduled at 10-14 days' post partum, aligning with health visiting protocols for usual care in the UK. Digital and remote support through text message, the website, and the BabyBreathe app continued for up to 12 months post partum, and support from healthcare professionals was reiterated at routine

appointments. The intervention is fully described elsewhere, and all intervention components were chosen and developed through preceding co-production research.[14]

Control

The usual care group received standard antenatal and postnatal care according to the NHS maternity care pathway (ie, no routine relapse prevention support). Usual care varies across the UK but commonly includes routine screening for smoking status by a midwife at the first antenatal booking appointment. If patients report currently smoking or have a carbon monoxide reading >4 ppm, they should be automatically referred to NHS commissioned stop smoking services (opt-out referral). These services focus on abstinence in pregnancy, only giving brief advice about maintaining abstinence post partum and in the long term. Before this trial (and in usual care), no information was collected on past smoking status, and neither midwives nor health visitors routinely provided information to address potential postpartum smoking relapse.

Primary outcome

The primary effectiveness outcome was self-reported continuous smoking abstinence from notification of the birth, biochemically validated by carbon monoxide monitoring at 12 months post partum, with a cut-off of ≤7 ppm for those who were not pregnant or with a cut-off of ≤4 ppm if they were pregnant again at this time point, according to the Russell standard.[19] We adapted the Russell standard for the postpartum population, allowing up to five smoking lapses (a one-off instance of smoking) between delivery and the 12 month follow-up, before the outcome was counted as relapse. Participants provided carbon monoxide readings electronically, using the carbon monoxide monitor and iCOBabyBreathe app, enabling the trial to continue during covid-19 restrictions. When it was possible to collect carbon monoxide readings in person, this continued as part of standard care, or a researcher took readings and offered participants help with obtaining a carbon monoxide reading when needed.

Secondary outcomes

Secondary outcomes were measured at six and 12 months post partum by online self-report or follow-up by researcher. Outcomes included self-reported point prevalence abstinence and time to relapse, participant reported partner smoking status, self-reported breastfeeding status, self-efficacy (single item, self-report), Edinburgh Postnatal Depression Scale score,[20] behavioural support use (eg, support from a stop smoking service), use of a nicotine-containing product, perceived stress,[21] Alcohol Use Disorders Identification Test - Consumption (AUDIT-C) score,[22] and health related quality of life using the EQ-5D-5L.[23] Infant health outcomes (eg, minor infections requiring visits to a general practitioner, and more serious ill health requiring hospital admission), participant and infant health resource use, and cost effectiveness were measured at 12 months post partum using participant self-report. Participants were reimbursed for their time (£15 shopping voucher) on completion of the 12 month follow-up. Fidelity of the intervention was assessed with digital analytics data and recording of interpersonal contacts. The interpersonal care element included any intervention contact with a healthcare professional (BabyBreathe manualised advice given at antenatal or postpartum contact, either in person or remotely). The protocol reports assessments for the full process evaluation and for cost effectiveness,[14] and findings will be reported elsewhere. Adverse events and serious adverse events were not recorded as part of the trial. Healthcare practitioners were, however, able to record adverse incidents.

Statistical analysis

Analysis followed a prespecified statistical analysis plan (OSF | Babybreathe SAP V1.2 28-11-24.pdf). Based on existing relapse estimates and smoking cessation in pregnancy trial outcomes, we estimated that if the primary outcome occurred in 25% of the control group (based on an estimated relapse rate of 75%), compared with 35% in the intervention group, then we would need 880 participants to have 90% power to detect this 10% difference at the 5% significance level. We estimated that this difference between control and intervention groups was realistic based on recent trials.[24] Loss to follow-up or withdrawal was not considered within the sample size calculation, as all those lost to follow-up (or those with unverified carbon monoxide readings) were counted as having returned to smoking, as is standard in smoking cessation trials. Analysis of smoking status was based on the intention-to-treat principle, by analysing individuals according to their allocated group. All analysis was completed using STATA version 19.

We descriptively summarised baseline data by group. Analysis of the primary outcome was based on a logistic regression model, adjusting for recruitment hub, quit timing (before versus during pregnancy), and smoking status of partner in the minimally adjusted model; however, in a fully adjusted model we also adjusted for e-cigarette use in previous week (yes or no), a factor known to predict relapse. The odds ratios were estimated from these models, and risk difference was estimated using an identity link function—when the model failed to converge, we estimated risk differences using approximate equations based on the control rate and the odds ratio. Subgroup analyses were conducted for deprivation (using the index of multiple deprivation), timing of quit, e-cigarette use at baseline, and partner smoking status, by including an interaction between subgroup and intervention or control term in the model. Secondary outcomes were analysed in a similar way using logistic regression models for binary outcomes. For continuous outcomes, we used linear regression when the full adjusted models adjusted for both e-cigarette use in the past week and baseline value of the outcome. Owing to the ordinal nature of the AUDIT-C outcome, we used a Mann-Whitney test. For the number of visits to a general practitioner, we used a negative binomial regression model. For the time to relapse, we analysed only individuals who had relapsed and provided a valid date of relapse at 12 months using a Kaplan-Meier curve and Cox's proportional hazard model, adjusting for the factors recruitment hub, quit timing, partner smoking status (minimally adjusted model), and additionally e-cigarette use in the past week (fully adjusted model). Additionally, we completed a non-prespecified per protocol analysis for the primary outcome using the same model specifications as we did for the intention-to-treat analysis, restricting the intervention participants to only those who received interpersonal care (a major aspect of the intervention). A compliance adjusted causal effect analysis was undertaken at a reviewer's request, by dividing the estimated effect by the rate of compliance, for the risk difference and the log-odds ratio for both the minimally adjusted and the fully adjusted models.

Patient and public involvement

The intervention tested was co-developed with patient and public involvement (PPI). Two PPI members contributed to the funding proposal for the trial. They remained involved throughout the trial and attended all trial steering committee meetings. PPI members partnered with us to design study recruitment materials and provided feedback on data collection instruments, assessing the burden to patients and advising on language used. At the end of the study, PPI members commented on the findings, contributed

to the dissemination plan, and attended the final trial findings meeting.

Results

A total of 887 participants were randomised from September 2021 to September 2023, with the last follow-up visit in December 2024. Sixteen participants discontinued the intervention (all intervention components were stopped) but were included in the intention-to-treat analysis for the primary outcome (fig 1). One participant was excluded after randomisation and not included in the intention-to-treat analysis (this participant had been randomised to the intervention group but was found to be a current smoker). Thus, data for 886 participants (441 in the BabyBreathe group, 445 in the usual care group) were analysed.

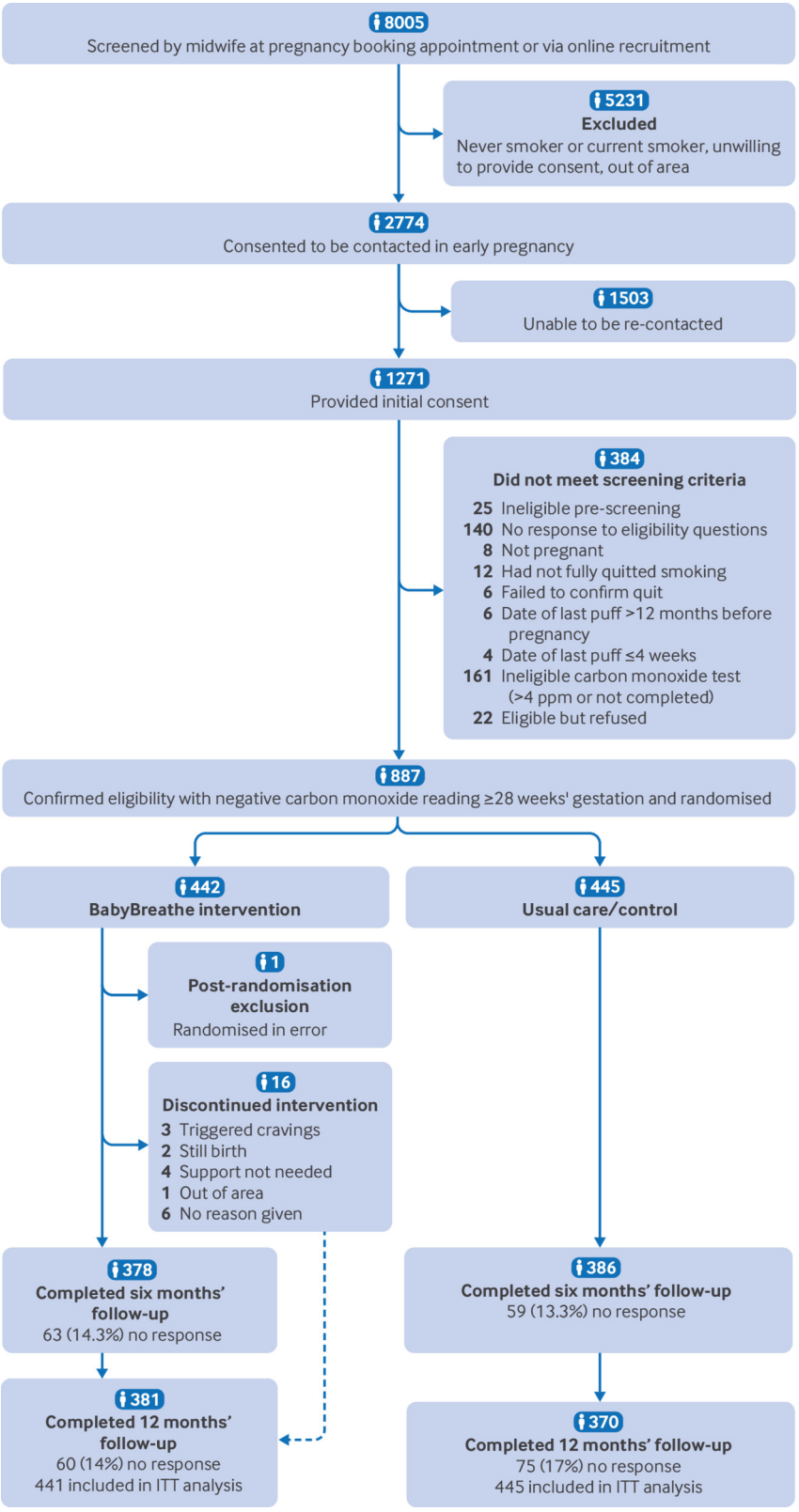


Fig 1 | Participant flow diagram. It was not possible to provide a numerical breakdown of reasons for exclusion at screening owing to the way screening was conducted. Full screening logs were not kept, and reasons for not meeting inclusion criteria were not recorded for those screened remotely

Baseline characteristics of participants in the two groups were similar for the intention-to-treat population (table 1). About one third (32.2%) of participants had stopped smoking in the 12 months before pregnancy, and the remainder (67.7%) reported stopping smoking during early pregnancy. Around one third (35.0%) of participants reported living with a partner who smoked tobacco.

Education level was high overall, with 42.2% of participants educated to degree level. Thirty eight per cent reported having used an e-cigarette to help with smoking cessation. For the per protocol population (see supplementary appendix table 1), fidelity was noted to be lower in the northeast of England and in remote delivery sites, among single parents, and in those of lower socioeconomic status, as measured by index of multiple deprivation, and with lower educational attainment.

Table 1 | Baseline characteristics of trial participants. Values are number (percentage) unless stated otherwise

Characteristics	Usual care (n=445)	BabyBreathe (n=441)	Total (n=886)
Mean (SD) age (years)	29.3 (5.2)	29.1 (5.5)	29.2 (5.3)
Mean (SD) pregnancy duration when recruited (days)	175 (56.5)	170 (51.2)	172 (54.0)
Timing of smoking cessation:			
Before pregnancy	142 (31.9)	143 (32.4)	285 (32.2)
During pregnancy	302 (67.9)	298 (67.6)	600 (67.7)
Missing	1 (0.2)	0	1 (0.1)
Partner smoking status:			
No partner	27 (6.1)	32 (7.3)	59 (6.7)
Smokes tobacco	155 (34.8)	155 (35.1)	310 (35.0)
Does not smoke tobacco	262 (58.9)	254 (57.6)	516 (58.2)
Missing	1 (0.2)	0	1 (0.1)
Highest qualification:			
None	6 (1.4)	6 (1.4)	12 (1.4)
GCSE	117 (26.3)	115 (26.1)	232 (26.2)
A level	127 (28.5)	118 (26.8)	245 (27.7)
Degree	181 (40.7)	193 (43.8)	374 (42.2)
Prefer not to say	13 (2.9)	9 (2.0)	22 (2.5)
Missing	1 (0.2)	0	1 (0.1)
Ethnicity:			
White	409 (91.9)	405 (91.8)	814 (91.9)
Mixed	12 (2.7)	14 (3.2)	26 (2.9)
Asian or Asian British	7 (1.6)	6 (1.4)	13 (1.5)
Black, African, Caribbean, or black British	9 (2.0)	11 (2.5)	20 (2.3)
Arab	0	2 (0.5)	2 (0.2)
Other ethnicity	5 (1.1)	3 (0.7)	8 (0.9)
Prefer not to say	2 (0.5)	0	2 (0.2)
Missing	1 (0.2)	0	1 (0.1)
Marital status:			
Single	79 (17.8)	83 (18.8)	162 (18.3)
Cohabiting	203 (45.7)	189 (42.9)	392 (44.2)
Civil partnership	19 (4.3)	20 (4.5)	39 (4.4)
Married	126 (28.3)	128 (29.0)	254 (28.7)
Divorced	1 (0.2)	5 (1.1)	6 (0.7)
Widowed	0	0	0
Prefer not to say	16 (3.6)	16 (3.6)	32 (3.6)
Missing	1 (0.2)	0	1 (0.1)
Confidence in continuing not to smoke until baby's first birthday:			
Not at all	18 (4.0)	18 (4.1)	36 (4.1)
Slightly	88 (19.8)	77 (17.5)	165 (18.6)
Moderately	171 (38.4)	156 (35.4)	327 (36.9)
Very	113 (25.4)	115 (26.1)	228 (25.7)
Extremely	54 (12.1)	75 (17.0)	129 (14.6)
Missing	1 (0.2)	0	1 (0.1)
NRT product used to help stop smoking:			
No	399 (89.7)	388 (88.0)	787 (88.8)
Yes	45 (10.1)	53 (12.0)	98 (11.1)
Missing	1 (0.2)	0	1 (0.1)
NRT product used in past week:			
No	433 (97.3)	426 (96.6)	859 (97.0)
Yes	11 (2.5)	15 (3.4)	26 (2.9)
Missing	1 (0.2)	0	1 (0.1)

e-cigarette used to help stop smoking:			
No	283 (63.6)	265 (60.1)	548 (61.8)
Yes	161 (36.2)	176 (39.9)	337 (38.0)
Missing	1 (0.2)	0	1 (0.1)
e-cigarette used in past week:			
No	393 (88.3)	389 (88.2)	782 (88.3)
Yes	51 (11.5)	52 (11.8)	103 (11.6)
Missing	1 (0.2)	0	1 (0.1)
Heat-not-burn product used to help stop smoking:			
No	422 (94.8)	425 (96.4)	847 (95.5)
Yes	22 (4.9)	16 (3.6)	38 (4.3)
Missing	1 (0.2)	0	1 (0.1)
Heat-not-burn product used in past week:			
No	442 (99.3)	436 (98.9)	878 (99.1)
Yes	2 (0.5)	5 (1.1)	7 (0.8)
Missing	1 (0.2)	0	1 (0.1)
Professional help with stopping smoking:			
No	422 (94.8)	409 (92.7)	831 (93.8)
Yes, no longer receiving it	18 (4.0)	21 (4.8)	39 (4.4)
Yes, still receiving it	4 (0.9)	11 (2.5)	15 (1.7)
Missing	1 (0.2)	0	1 (0.1)
Currently use apps to help quit smoking or stay quit:			
No	422 (94.8)	427 (96.8)	849 (95.8)
Yes	22 (4.9)	14 (3.2)	36 (4.1)
Not answered	1 (0.2)	0	1 (0.1)
Mean (SD) EPDS score*	8.92 (4.84); n=444	8.71 (4.96); n=441	8.82 (4.90); n=885
Mean (SD) PSS-4 score†	4.71 (2.73); n=444	4.58 (2.85); n=441	4.64 (2.79); n=885
Mean (SD) IMD score:			
Least deprived four fifths‡	349 (78.4)	322 (73.0)	671 (75.7)
Most deprived fifth§	93 (20.9)	114 (25.9)	207 (23.4)
Missing	3 (0.7)	5 (1.1)	8 (0.9)
Study sites:			
London	82 (18.4)	80 (18.1)	162 (18.3)
Northeast of England	57 (12.8)	59 (13.4)	116 (13.1)
Norfolk	153 (34.4)	152 (34.5)	305 (34.4)
Remote delivery	102 (22.9)	100 (22.7)	202 (22.8)
Scotland	51 (11.5)	50 (11.3)	101 (11.4)

EPDS=Edinburgh Postnatal Depression Scale; IMD=index of multiple deprivation; NRT=nicotine replacement therapy; PSS-4=four item perceived stress scale; SD=standard deviation.

* Maximum score 30; scores >10 represent minor or major depression.20

† Maximum score 40; higher scores represent greater perceived stress.21

‡ Scores 3-10.

§ Scores 1 and 2.

The follow-up rate for self-report data collection was 86.2% (n=764) at six months and 84.8% (n=751) at 12 months. Follow-up rates were similar between the two study groups (fig 1).

Biochemically verified self-reported continuous abstinence at 12 months post partum was 54.9% (242/441) in the BabyBreathe group and 49.9% (222/445) in the usual care group (table 2). While the intervention appeared to have a small positive effect, the reported difference was not significant (adjusted odds ratio 1.23, 95% CI 0.94 to 1.60, fully adjusted, P=0.13, with a number needed to treat (NNT) of 21 (NNT to benefit 8.9 to ∞) and NNT to harm 59). The result was similar (odds ratio 1.23, CI 0.94 to 1.62, fully adjusted, P=0.13) after excluding 18 mothers who gave birth to infants with adverse birth outcomes.

Table 2 | Primary outcome: carbon monoxide validated smoking cessation at 12 months post partum. Values are number (percentage) unless stated otherwise

Analyses	Usual care (n=445)	BabyBreathe (n=441)	Minimally adjusted*			Fully adjusted†		
			Odds ratio (95% CI)	P value	Risk difference (% (95% CI))	Odds ratio (95% CI)	P value	Risk difference (% (95% CI))
Intention to treat	222 (49.9)	242 (54.9)	1.23 (0.94 to 1.60)	0.13	5.1 (-1.5 to 11.5)	1.23 (0.94 to 1.60)	0.13	4.8 (-1.7 to 11.2)
Compliance adjusted causal effect	-	-	1.30 (0.86 to 1.73)	-	6.5 (-1.8 to 14.8)	1.30 (0.86 to 1.74)	-	6.0 (-2.2 to 14.3)
Per protocol	222 (49.9)	200‡ (57.6)	1.36 (1.02 to 1.81)	0.03	7.4 (0.5 to 14.3)	1.36 (1.02 to 1.81)	0.04	7.2 (0.3 to 14.1)
Excluding mothers of babies with adverse birth outcomes	217 (50.1)	240 (55.2)	1.24 (0.94 to 1.62)	0.12	5.1 (-1.4 to 11.7)	1.23 (0.94 to 1.62)	0.13	4.9 (-1.7 to 11.4)

CI=confidence interval.

* Adjusted for randomisation arm, site, quit timing (before versus during pregnancy), and smoking status of partner (non-smoker/no partner versus smoker).

† Additionally adjusted for e-cigarette use in past week (yes or no).

‡ Out of 347 who received the intervention.

In total, 72.6% (320/441) of participants in the BabyBreathe group and 69.4% (309/445) in the usual care group self-reported smoking abstinence at six months (table 3). This finding was not significant (odds ratio 1.17, 0.87 to 1.57, fully adjusted, P=0.31). At 12 months, 67.1% (296/441) of participants in the BabyBreathe group and 61.8% (275/445) in the usual care group self-reported smoking abstinence. The result was not significant (odds ratio 1.27, 0.96 to 1.68, fully adjusted, P=0.10).

Table 3 | Secondary outcomes: smoking cessation at six and 12 months post partum. Values are number (percentage) unless stated otherwise

Outcomes	Usual care (n=445)	BabyBreathe (n=441)	Minimally adjusted*			Fully adjusted†		
			Effect estimate‡ (95% CI)	P value	Difference in risk (95% CI)	Effect estimate‡ (95% CI)	P value	Difference in risk (95% CI)
Abstinence:								
6 months	309 (69.4)	32 (72.6)	1.17 (0.87 to 1.57)	0.30	2.3 (-3.5 to 8.2)	1.17 (0.87 to 1.57)	0.31	2.1 (-3.8 to 7.9)
12 months	275 (61.8)	296 (67.1)	1.27 (0.96 to 1.68)	0.10	5.3 (-0.9 to 11.5)	1.27 (0.96 to 1.68)	0.10	5.3 (-0.8 to 11.5)
Non-smoking partner:								
6 months§	257/363 (70.8)	239/350 (68.3)	1.06 (0.70 to 1.63)	0.77	-0.4 (-5.0 to 4.5)	1.06 (0.70 to 1.62)	0.77	-0.3 (-0.5 to 4.6)
12 months§	238/325 (73.2)	232/333 (69.7)	1.19 (0.78 to 1.83)	0.42	1.0 (-3.5 to 5.5)¶	1.21 (0.79 to 1.85)	0.39	3.6 (-4.9 to 10.3)**
Median (IQR) time to relapse (days)	172 (96-247)	189 (126-294)	HR 0.75 (0.52 to 1.10)	0.14	-	HR 0.75 (0.52 to 1.09)	0.13	-
Breastfeeding:								
6 months	160/383 (41.8)	174/373 (46.7)	1.24 (0.92 to 1.66)	0.15	5.1 (-1.8 to 12.1)	1.23 (0.92 to 1.65)	0.16	5.0 (-1.9 to 12.0)
12 months	115/344 (33.4)	108/355 (30.4)	0.88 (0.64 to 1.21)	0.42	-2.8 (-9.7 to 4.1)	0.88 (0.64 to 1.21)	0.43	-2.7 (-9.6 to 4.2)
Very confident/extremely confident to stay abstinent:								
6 months	252/316 (79.8)	268/328 (81.7)	1.15 (0.78 to 1.71)	0.48	2.5 (-3.6 to 8.6)	1.15 (0.78 to 1.71)	0.48	2.5 (-3.6 to 8.6)
12 months	190/298 (63.8)	237/309 (76.7)	1.91 (1.33 to 2.75)	<0.001	11.6 (4.5 to 18.8)	1.90 (1.32 to 2.74)	0.001	12.7¶ (5.0 to 19.9)
Mean (SD) EPDS score:								
6 months	9.51 (5.56); n=382	9.00 (5.49); n=372	-0.33†† (-0.96 to 0.30)	0.30	-	-0.32†† (-0.95 to 0.31)	0.32	-
12 months	9.41 (5.56); n=343	8.76 (5.10); n=354	-0.37†† (-1.05 to 0.30)	0.27	-	-0.36†† (-1.03 to 0.31)	0.29	-
Behavioural support: received professional help:								
6 months	3/383 (0.8)	4/375 (1.1)	NA	0.72‡‡	-	-	-	-
12 months	1/344 (0.3)	2/355 (0.6)	NA	1.00‡‡	-	-	-	-
Mean (SD) PSS-4 score:								
6 months	4.98 (2.93); n=378	4.83 (2.92); n=369	-0.05†† (-0.42 to 0.32)	0.79	-	-0.05†† (-0.41 to 0.32)	0.81	-
12 months	5.14 (2.82); n=342	4.96 (2.85); n=350	-0.03†† (-0.41 to 0.34)	0.86	-	-0.04†† (-0.41 to 0.34)	0.85	-
e-cigarette use in past 6 months:								
6 months	152/383 (39.7)	146/375 (38.9)	0.97 (0.72 to 1.31)	0.84	0.0 (-6.7 to 6.7)	1.01 (0.74 to 1.40)	0.94	0.2 (-6.9 to 8.3)**
12 months	143/344 (41.6)	144/355 (40.6)	0.95 (0.70 to 1.29)	0.74	-1.2 (-8.3 to 6.0)	0.93 (0.67 to 1.28)	0.65	-1.1 (-7.9 to 5.6)
e-cigarette use in past 7 days:								
6 months	115/383 (30.0)	104/375 (27.7)	0.89 (0.64 to 1.23)	0.47	-1.7 (-7.8 to 4.4)	0.92 (0.64 to 1.31)	0.64	-0.2 (-5.8 to 5.4)
12 months	101/344 (29.4)	105/355 (29.6)	1.00 (0.72 to 1.39)	1.00	1.1 (-5.5 to 7.7)	0.98 (0.69 to 1.39)	0.90	0.1 (-6.0 to 6.4)
NRT product use:								
6 months	9/383 (2.4)	14/375 (3.7)	1.64 (0.69 to 3.88)	0.26	1.1¶ (-1.4 to 3.5)	1.67 (0.71 to 3.96)¶	0.24	1.5 (-0.7 to 6.5)**

12 months	9/344 (2.6)	27/355 (7.6)	3.14 (1.44 to 6.82)	0.004	5.6¶ (2.2 to 9.0)	3.11 (1.43 to 6.77)	0.004	5.2 (1.8 to 8.6)
NRT product use in past 7 days:								
6 months	3/383 (0.8)	7/375 (1.9)	2.43 (0.62 to 9.54)	0.20	1.0¶ (-1.5 to 3.7)	2.39 (0.61 to 9.43)	0.21	1.1 (-0.3 to 6.3)**
12 months	4/344 (1.2)	10/355 (2.8)	2.51 (0.77 to 8.17)	0.13	1.8 (-0.3 to 7.8)**	2.45 (0.75 to 8.00)	0.14	1.7 (-0.3 to 7.7)**
AUDIT-C score at 6 months:								
Mean (SD)	2.36 (2.26); n=377	2.11 (2.15); n=368	-		-	-	-	-
Median (IQR)	2 (0-4); n=377	2 (0-3.5); n=368	-	0.11§§	-	-	-	-
AUDIT-C score at 12 months:								
Mean (SD)	2.47 (2.19); n=342	2.05 (2.08); n=350	-		-	-	-	-
Median (IQR)	2 (1-4); n=342	2 (0-3); n=350	-	0.007§§	-	-	-	-

Smoking cessation was not validated using the individual carbon monoxide monitor.

AUDIT-C=Alcohol Use Disorders Test for Consumption; CI=confidence interval; EPDS=Edinburgh Postnatal Depression Scale; HR=hazard ratio; IQR=interquartile range; NA=not available; NRT=nicotine replacement therapy; PSS-4=four item perceived stress scale; SD=standard deviation.

* Adjusted for randomisation arm, site, quit timing (before versus during pregnancy) and smoking status of partner (non-smoker/no partner versus smoker)

† Additionally adjusted for e-cigarette use in previous week (yes or no)

‡ Odds ratio unless otherwise specified.

§ Women and people reporting no partner were included in this category.

¶ Result from adjusted model as previously specified but omitting site (inclusion of site yielded inadmissible mean estimates).

** Estimated assuming a risk in the BabyBreathe group of PUC×odds ratio/(1-PUC+OR×PUC), where PUC is the risk in the usual care group convergence not achieved with or without site.

†† Mean difference

‡‡ From Fisher's exact test.

§§ From Mann-Whitney test.

The fully adjusted hazard ratio for self-reported time until relapse was 0.75 and the failure curve was to the right of the control group, suggesting that even if individuals relapsed they did so later in the BabyBreathe group; however, this finding did not reach significance (P=0.13) (table 3 and fig 2).

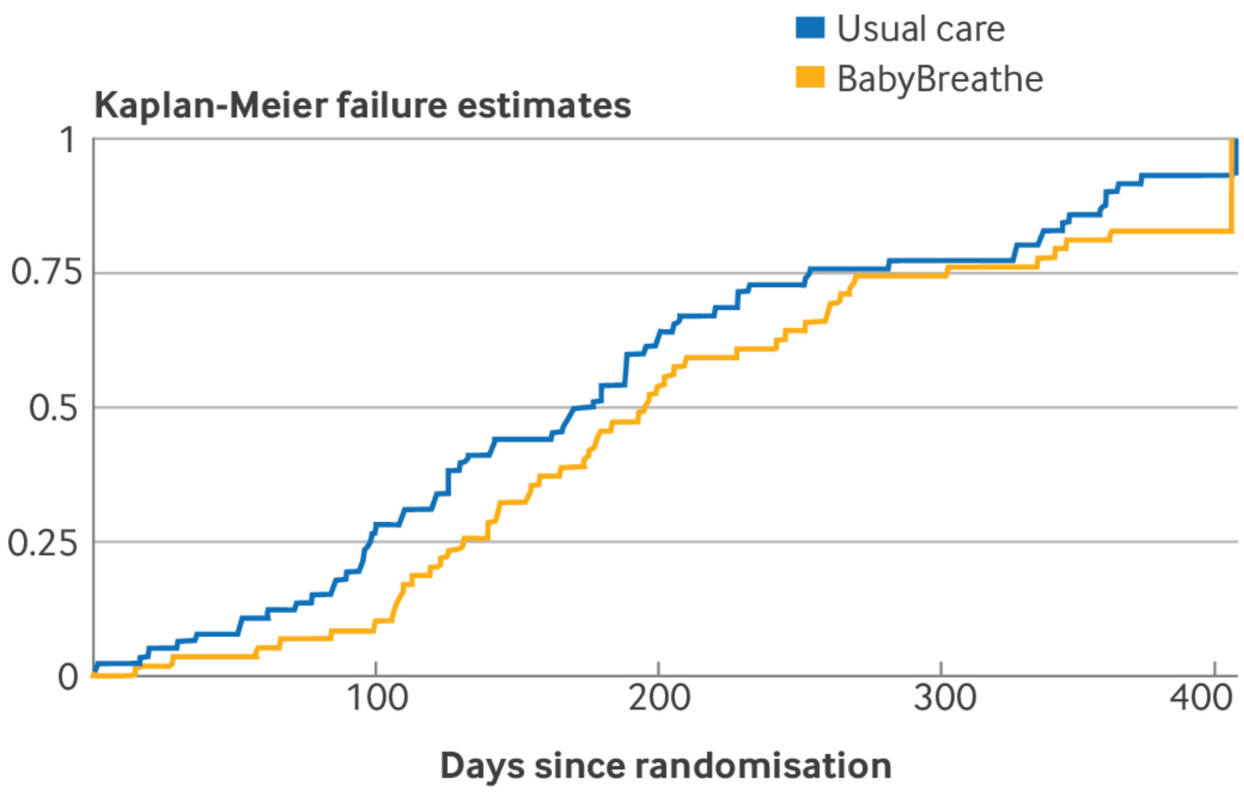


Fig 2 | Kaplan-Meier curve showing time to smoking relapse over 12 months post-randomisation. Individuals with date >365 days were truncated at day 393 (365 days+4 weeks)

At six and 12 months' follow-up, between group differences in smoking status for those who reported having a non-smoking partner at baseline were not statistically significant (table 3); nor were they for breastfeeding status. At six months there was no statistically significant difference between the two groups in self-efficacy to remain abstinent, but the between group difference in self-efficacy to remain abstinent at 12 months was significant, with 76.7% (237/309) of the BabyBreathe group very or extremely confident in remaining abstinent versus 63.8% (190/298) of the control group (P=0.001, odds ratio 1.90, 95% CI 1.32 to 2.74, fully adjusted) (table 3).

At six and 12 months' follow-up, between group differences for postnatal depression, behavioural support, perceived stress, and e-cigarette use were not statistically significant (table 3).

At 12 months, the BabyBreathe group showed significantly higher use of nicotine replacement therapy products compared with the control group (odds ratio 3.11, 95% CI 1.43 to 6.77, fully adjusted, P=0.004) (table 3), although there were no significant differences in use of nicotine replacement therapy products at six months, and no difference in reported use within the past seven days at either six or 12 months (table 3). There were no significant group differences in reported alcohol consumption at six months, but at 12 months the BabyBreathe group had significantly lower alcohol consumption compared with the control group (P=0.007) (table 3).

There were no statistically significant differences in health outcomes for infants between the intervention and usual care groups at 12 months (table 4).

Table 4 | Infant health outcomes at 12 months. Values are number (percentage) unless stated otherwise

Outcomes	ITT population		Minimally adjusted*			Fully adjusted†		
	Control (n=445)	Intervention (n=441)	Estimate (95% CI)	P value	Risk difference (% (95% CI))	Estimate (95% CI)	P value	Risk difference (% (95% CI))
≥1 hospital admissions	50 (14.7); n=341	50 (14.3); n=349	OR 0.97 (0.63 to 1.49	0.90	-	OR 0.97 (0.63 to 1.49)	0.90	-
No of visits to GP‡:								
Mean (SD)	2.42 (2.67); n=320	2.20 (3.16); n=333	-	-	-	-	-	-
Median (IQR)	2 (0-4); n=320	2 (0-3); n=333	IRR 0.91 (0.77 to 1.08)	0.27	-	IRR 0.91 (0.77 to 1.08)	0.26	-
Length of stay (days)§:								
Mean (SD)	2.85 (3.10); n=342	2.80 (3.70); n=350	NA	0.73¶	-	-	-	-
Median (IQR)	2 (1-4); n=342	2 (1-4); n=350	-	-	-	-	-	-
NICU admission	36 (10.6); n=340	38 (10.8); n=351	OR 1.04 (0.64 to 1.68)	0.88	0.3 (-4.3 to 4.9)	OR 1.04 (0.64 to 1.69)	0.89	0.2 (-4.0 to 4.8)

CI=confidence interval; GP=general practitioner; IQR=interquartile range; IRR=incidence rate ratio; ITT=intention to treat; NA=not applicable; NICU=neonatal intensive care unit; OR=odds ratio; SD=standard deviation.

* Only for stratification variables. Adjusted for randomisation arm, site, quit timing (before versus during pregnancy), and smoking status of partner (non-smoker/no partner versus smoker).

† Additionally adjusted for e-cigarette use in previous week (yes or no).

‡ Excludes 28 participants who responded "yes" to visiting a GP but did not provide number of visits.

§ Length of hospital stay after giving birth.

¶ From Mann-Whitney test.

Eighteen adverse incidents were reported during the trial: 12 in the control group (2.7%) and six in the intervention group (1.4%). None were deemed to be related to the trial. One participant (usual care) reported neonatal death. Two further participants (one in each group) were listed as lost to follow-up. The other participants indicated adverse health outcomes for the baby.

In preplanned subgroup analyses, there were no significant differences across all subgroups analysed; deprivation level (using index of multiple deprivation), timing of initial quit, e-cigarette use, partner smoking status, and those quitting during pregnancy (versus before pregnancy) (P>0.05, table 5 and fig 3).

Table 5 | Subgroup analyses of primary outcome

	12 Month abstinence (No (%))		Minimally adjusted*			Fully adjusted†		
	Usual care	BabyBreathe	Odds ratio (95% CI)	P value	P for interaction	Odds ratio (95% CI)	P value	P for interaction
Index of multiple deprivation score								
Most deprived fifth‡	42/93 (45.2)	63/114 (55.3)	1.55 (0.89 to 2.73)	0.12	0.40	1.54 (0.88 to 2.70)	0.13	0.44
Least deprived four fifths§	178/349 (51.0)	177/322 (55.0)	1.17 (0.86 to 1.58)	0.33		1.17 (0.86 to 1.59)	0.31	
Timing of quit								
Before pregnancy	83/142 (58.5)	86/143 (60.1)	1.08 (0.67 to 1.74)	0.76	0.52	1.06 (0.66 to 1.72)	0.81	0.47
During pregnancy	139/303 (45.9)	156/298 (52.4)	1.30 (0.94 to 1.80)	0.11		1.32 (0.95 to 1.82)	0.10†	
e-cigarette use¶								
Yes	30/48 (62.5)	31/48 (64.6)	1.05 (0.44 to 2.51)	0.91	0.84			
No	192/397 (48.4)	211/393 (53.7)	1.24 (0.93 to 1.64)	0.14				
Partner smoking status								
None/no partner	154/290 (53.1)	160/286 (55.9)	1.12 (0.81 to 1.57)	0.49	0.39	1.14 (0.82 to 1.59)	0.45	0.48
Smoker	68/155 (43.9)	82/155 (52.9)	1.44 (0.92 to 2.26)	0.12		1.39 (0.88 to 2.20)	0.16	

* Adjusted for randomisation arm, site, time of giving up smoking (before versus during pregnancy), and smoking status of partner (non-smoker/no partner versus smoker) except where the variable is the subgroup variable of interest.

† Additionally adjusted for e-cigarette use in previous week (yes or no).

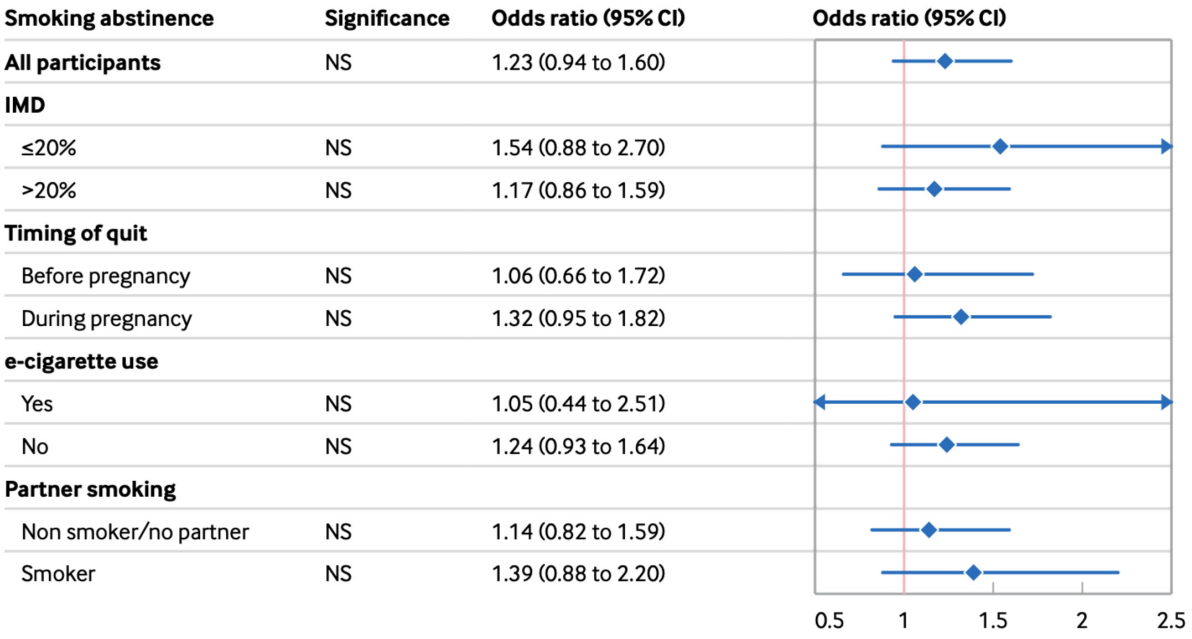
‡ Scores of 1 and 2.

§ Scores of 3 to 10.

¶ Classified as "yes" if responded "yes" to both "did you use an e-cigarette to help you stop smoking" and "have you used an e-cigarette in the last week"?

Subgroup analyses for selected characteristics

Subgroup analyses of the odds of smoking abstinence at 12 months for selected characteristics



Article DOI: 10.1136/bmj-2026-100242. • Download data
CI=confidence interval; IMD=index of multiple deprivation; NS=not significant

Fig 3 | Subgroup analyses. An interactive version of this graphic is available at https://public.flourish.studio/visualisation/29737194/

Fidelity to the BabyBreathe intervention was variable. All intervention participants were sent the initial leaflets, and 98% of the intervention group were sent the BabyBreathe box. Seventy five per cent of participants were sent, and continued, SMS text message support for the full 12 months of the programme. The leaflets, BabyBreathe box, and SMS text messages were all passively received aspects of the intervention. Owing to pressures with health visiting services (eg, staff shortages, administrative errors in assigning participants) and participants missing appointments, 347 participants (79.0%) received the BabyBreathe intervention and 94 participants (21.0%) did not receive the intervention. In a post hoc compliance adjusted causal effect analysis, the difference increased, with a fully adjusted odds ratio of 1.30 (95% CI 0.86 to1.74) and risk difference of 6.0 (95% CI -2.2 to 14.3). In a post hoc per protocol analysis including only those who received the intervention (table 2), we found that participants in the BabyBreathe group were significantly more likely to remain free of smoking at the 12 month follow-up (BabyBreathe 200/347 (57.6%) *v* usual care 222/445 (49.9%); odds ratio 1.36 (1.02 to 1.81), P=0.04; risk difference 7.2 (0.3 to 14.1), fully adjusted), with a NNT of 13.9 (95% CI 7.1 to 333.3).

Overall, 60% of participants had an antenatal intervention contact and 70% had a postnatal contact. A subsample of 39 contacts with intervention participants were audio recorded and researcher coded for adherence, with a mean adherence score of 3.5 (range 2-5) out of 5. Engagement with the active elements of the intervention that were digital or remote was low. The website was accessed by 32% of intervention participants, and only 9% installed the BabyBreathe app (table 6). Overall, 42% (148/356) of participants in the BabyBreathe group and 21% (73/347) in the usual care group used the individual carbon monoxide monitors to self-monitor for motivational purposes (table 7).

Table 6 | Fidelity to interpersonal intervention (manualised). Values are number (percentage) unless stated otherwise

Variables	BabyBreathe group (n=441)	Notes
No intervention (antenatal or postnatal) received	94 (21)	Due to pressures with health visiting services, missed appointments by participants, and administrative errors.
Antenatal visit received	263 (60)	Based on at least ASK (asking about smoking) being delivered*
Postpartum visit received	307 (70)	One or more postpartum visits
Mean (SD) interpersonal intervention adherence score	3.9 (0.7)	39 subsample interpersonal intervention sessions were audio recorded and coded for adherence: from 1 for very low adherence to 5 for very high adherence
Link to leaflets provided (%)	100	Sent by email on randomisation
BabyBreathe website accessed at least once	140 (32)	User sent unique access code for log in
BabyBreathe app downloaded	39 (9)	Install rate
SMS messages	334/434 (77)	Received full text message programme for 12 months without opting out
BabyBreathe box dispatched	432 (98)	Sent in post at time of birth notification

* First step of the "3 As": Ask, Advise, and Act.

Table 7 | Self-reported use of individual carbon monoxide monitors

Use of monitor*	No (%) in usual care group (n=347†)	No (%) in Babybreathe group (n=356†)
No	274 (79)	208 (58)
Yes	73 (21)	148 (42)

Totals may not amount to 100% because of rounding.

* In additional to research recorded readings.

† Denominator represents respondents.

Discussion

An interpersonal intervention that could be delivered remotely, BabyBreathe, in addition to usual postpartum care, yielded 5% higher rates of sustained smoking abstinence at 12 months post partum, although this was not statistically significant. A compliance adjusted causal effect analysis showed that with better fidelity this may increase to 6% higher rates—less than the 10% difference used for the sample size calculation, suggesting that the clinical importance is uncertain. Consistent with the null finding, health outcomes for infants of participants did not differ between the study groups. Self-reported smoking outcomes were consistent with the carbon monoxide verified primary outcome. Between group differences for most of the secondary outcomes were not statistically significant, although the direction of effect consistently favoured BabyBreathe. Furthermore, a post hoc per protocol analysis showed a statistically significant effect of the intervention for those who received BabyBreathe, suggesting some concerns about fidelity, with intervention delivery impacting the primary outcome. At 12 months, the intervention group were statistically significantly more likely to be using nicotine replacement therapy products, as they had been encouraged to do as part of the intervention, had higher self-efficacy to remain abstinent, and reported statistically significant reductions in alcohol use compared with the usual care group. It is possible that use of nicotine replacement therapy increased abstinence rates in the BabyBreathe group, and such therapy should be further explored as an aid to maintaining postpartum smoking cessation. Reduced alcohol use may have been a behavioural effect of the intervention, or it may be that lower use of alcohol was protective against smoking relapse, since a strong association exists between alcohol use and tobacco smoking relapse.[16]

We found no strong evidence that intervention effectiveness varied across different subgroups. However, there was a (non-significant) tendency towards improved outcomes for BabyBreathe group participants from the lowest fifth of the index of multiple deprivation, those reporting quitting smoking during pregnancy (rather than before), those with no previous e-cigarette use, and among those living with a partner who smoked tobacco. That these factors are leading predictors of postpartum relapse,[16] suggest that relapse prevention intervention and support may be particularly beneficial for these subpopulations, although the current study did not provide definitive evidence of this benefit.

The trial did have some fidelity concerns with intervention delivery that may have affected outcomes. About a fifth of those randomised to the intervention group did not receive any interpersonal intervention with a trained BabyBreathe healthcare professional; due both to issues with provision of the intervention and participant factors such as cancelling a health visitor appointment and therefore potentially missing the most vulnerable people. Because of this fidelity issue, we ran an unplanned per protocol analysis. The analysis showed that for those who had at least one interpersonal contact, the intervention was effective for long term smoking cessation compared with usual care. Uptake of the app and website components of the intervention was low, and both intervention and control participants reported positive feelings of being part of a programme (qualitative data will be reported elsewhere). Finally, use of remote individual carbon monoxide monitors as a research tool across groups potentially had a motivating impact for control and intervention participants, since we noted instances of self-monitoring and positive feedback on use of the monitors by participants in both groups.

Comparison with other studies

Although we did not find a statistically significant effect of the BabyBreathe intervention on the primary outcome, we observed substantially higher than expected rates of sustained smoking abstinence across groups. Such high levels of abstinence in the usual care group at 12 months may have limited our ability to show an effect of the intervention. This trial reported much higher rates of sustained abstinence than the highly effective intervention of financial incentives, where a sustained abstinence rate of 40% was reported for the intervention group in a recent relapse prevention trial, with an abstinence rate of 27% for the control group,[13] compared with our control group abstinence rate of 50%. The higher reported rates of sustained abstinence reported across both groups in this trial may reflect the highly motivated, highly educated, and higher socioeconomic status population that we unintentionally recruited, perhaps due to including online recruitment methods and including people who quit in preparation for pregnancy. We also observed high levels of reported e-cigarette use both at baseline and at follow-up across groups, reflecting national trends in vaping level in an English population[25] and use of vapes by pregnant women and people,[26] which have increased since conception of the trial. Initially quitting smoking by vaping and then continuing to vape may have aided smoking cessation, although we did not find evidence of this during the study. This finding is in line with survey evidence suggesting that sustained regular vaping may promote cessation,[27] although studies directly examining this issue are needed.

A further explanation is the cultural change that has been observed in recent years in the UK. In England, population level smoking has continued to decline[28] and rates of smoking in pregnancy have sharply declined.[29] The UK government has invested substantially in an opt-out approach to smoking cessation during pregnancy, with support embedded throughout the maternity care pathway.[15] This approach appears to have been successful.[30] Increased focus on the harms of smoking, both generally and during pregnancy specifically, may be interpreted as a denormalisation of tobacco smoking that may be reflected in the trial population in terms of likelihood of sustained smoking abstinence status. Alternatively, or in addition, it may be that we observed a strong Hawthorne effect, as those randomised may have been more motivated to remain abstinent simply as an artefact of being in the trial.

Strengths and limitations of this study

This large study of smoking relapse prevention post partum tested a theory based co-designed intervention developed with input from pregnant and postpartum women and people, their partners, and healthcare professionals. The intervention enabled choice and provided multiple routes to support for maintenance of smoking cessation.

The trial was multicentre, recruiting to target across sites in England and Scotland and remotely across the UK. Multiple different approaches to standard care in terms of postnatal health support were involved, meaning that the trial was pragmatic and reflected real world practice. During covid-19 related restrictions, we adapted the trial to recruit and deliver the intervention remotely, in line with standard care provision. An authorised protocol amendment enabled flexibility and adaptiveness in both recruitment and intervention delivery. The trial achieved high follow-up rates and levels of carbon monoxide verification for those reporting smoking abstinence. Data quality, losses to follow-up, and missing data presented no concerns.

A limitation was that the initial sample size calculation was based on a much lower rate of sustained postpartum abstinence (25%) than was observed in the control arm. The high abstinence rates across both groups suggest that the trial may have been slightly underpowered to detect a difference. A further limitation was that not all participants received the intervention as intended, which may have affected the overall effectiveness of BabyBreathe. In addition, participants did not engage with some aspects of the intervention—for example, only 32% of participants visited the website and only 9% installed the app. Another limitation was that the recruited population comprised more highly educated people, with fewer participants in the lowest index of multiple deprivation fifth, compared with recent large UK trials of smoking cessation in pregnancy or post partum.[13 31] The skewed recruited population could be a limitation of the complex trial recruitment procedures, including remote online recruitment, that may have represented a barrier to engagement and potentially limits generalisability.

Policy implications

Further work is needed to assess the utility of BabyBreathe, particularly for less affluent populations, where our estimated fidelity was lower but the effect was larger; although outcomes still did not reach the threshold for statistical significance. Future approaches may consider delivery in combination with financial incentives, which have been shown to be effective at reducing postpartum relapse.[32]

Conclusions

BabyBreathe did not statistically significantly increase sustained smoking abstinence post partum for women and people who quit in pregnancy. Although 5% more participants receiving the intervention achieved validated, continuous smoking abstinence at 12 months post partum compared with usual postpartum care, this difference was not statistically significant. All secondary outcomes also showed a similar positive change, although not statistically significant. A per protocol analysis did, however, show statistical significance for those who received BabyBreathe. We conclude that, given the intervention fidelity achieved in this trial, BabyBreathe has not been shown to help pregnant women and people remain abstinent post partum beyond usual care.

What is already known on this topic

Postpartum smoking relapse is an important public health issue, with no routine support currently available

From pooled studies in a Cochrane systematic review, it was unclear whether interventions prevented smoking relapse among women who had stopped smoking spontaneously in early pregnancy, with a borderline effect at 6-11 months

A further Cochrane systematic review of relapse prevention interventions included postpartum relapse prevention trials as a subgroup; trials including postpartum follow-up found no statically significant benefit of interventions

What this study adds

A remote interpersonal intervention, BabyBreathe, in addition to usual postpartum care, yielded 5% higher rates of sustained smoking abstinence at 12 months post partum, although this was not statistically significant

A compliance adjusted causal effect analysis showed that with better fidelity this finding may increase to 6% higher rates

The 6% higher rate is less than the 10% difference used for the sample size calculation, suggesting that the clinical importance is uncertain

Contributors: CN, as chief investigator, took a lead role in conceptualisation, funding acquisition, investigation, methodology, project administration, resources, supervision, validation, visualisation, and writing the original draft and reviewing and editing the manuscript. CN takes responsibility for the overall content as guarantor. PB was the senior research associate, taking over from TB, being fully involved in investigation, methodology (leading oversight of data collection and process evaluation), formal analysis, project administration, validation, visualisation, and reviewing and editing the manuscript. LC was the senior clinical trials unit (CTU) trial manager, having oversight of data curation, investigation,

methodology, project administration, supervision of CTU staff, and reviewing and editing the manuscript. TB was the senior research associate before PB, being fully involved in conceptualisation, data curation, funding acquisition, investigation, methodology, project administration, and reviewing and editing the manuscript. LB was involved in conceptualisation, funding acquisition, methodology, and reviewing and editing the manuscript. AC was the senior statistician, being involved in conceptualisation and data curation, having oversight of formal analysis and methodology, using STATA statistical software, and being involved in reviewing and editing the manuscript. SD was involved in conceptualisation, funding acquisition, and reviewing and editing the manuscript. VG was involved in conceptualisation, funding acquisition, and reviewing and editing the manuscript. TH was involved in conceptualisation, funding acquisition, and reviewing and editing the manuscript. WH was involved in conceptualisation, funding acquisition, and reviewing and editing the manuscript. RH acted as a mentor for CN and was involved in conceptualisation, funding acquisition, and reviewing and editing the manuscript. GH was the CTU trial manager, being involved in data curation, investigation, methodology, project administration, supervision of CTU staff, and reviewing and editing the manuscript. FN was involved in conceptualisation, funding acquisition, and reviewing and editing the manuscript. KR was the computer science research associate, involved in formal analysis, use of software, methodology, validation, and reviewing and editing the manuscript. DS was the senior computer science lead, involved in conceptualisation, funding acquisition, and reviewing and editing the manuscript. SS was the CTU statistician, involved in data curation. formal analysis, investigation, use of stata software, and reviewing and editing the manuscript. DT was the health economist, involved in conceptualisation, data curation, formal analysis, funding acquisition, methodology, use of software, and reviewing and editing the manuscript. MU was involved in conceptualisation, funding acquisition, methodology, and reviewing and editing the manuscript. LC-T, KW, J McK, CW, IU, C O'D, and CS formed an author collaborator group. All were involved in data collection, project administration, validation, and reviewing and editing the manuscript. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Transparency: The lead author (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Dissemination to participants and related patient and public communities: The results of the study are made available to all research participants through the study website. Results were disseminated to relevant patient and public representatives at the BabyBreathe public dissemination event. A lay summary of the findings will be shared on the open science framework when available.

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An independent data monitoring committee reviewed data collection, planned analyses, and analysis.

Trial oversight: The trial was managed by the UK Clinical Research Collaboration registered Norwich Clinical Trials Unit (CRCUK 51), with weekly trial management meetings involving the chief investigator and named researchers. The trial steering committee, which included a chair and five independent members, provided independent oversight. The data monitoring committee met before each trial steering committee meeting and included three independent experts.

Ethical approval: This study was approved by the North West-Preston research ethics committee (21/NW/0017). All participants gave written informed consent before participation.

Data sharing: The code used to analyse the data in the paper can be found in the supplemental files. The data underlying the findings in this paper are openly and publicly available at osf.io/xyeuz. If you encounter problems accessing the data, please contact the corresponding author.

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