ISRCTN70307341 https://doi.org/10.1186/ISRCTN70307341

A study to test a package of support to help women who have stopped smoking while pregnant to stay smoke-free after giving birth

Submission date 10/03/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 23/03/2021	**Overall study status** Completed	
Last Edited 30/12/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims
BabyBreathe aims to provide pre and postnatal support for women who have stopped smoking in pregnancy and wish to remain smoke free after giving birth. This support will come from health visitors, tailored experiences through online, app and text messages as well as support to use alternatives to smoking or e-cigarettes as ways to remain smoke free.

Who can participate?
Women who have recently quit smoking identified through their routine pregnancy appointments across four areas of the UK (Norfolk, London, Scotland, Newcastle)

What does the study involve?
Participants will be put into one of two groups, receiving the support of BabyBreathe, or usual care, with the same chance of being in either group. The researchers will measure how many women receiving the BabyBreathe support package are smoke-free at 12 months following the birth of their baby compared to those not receiving support. They will assess the value for money of the package of support. They will also look into which parts of the package are most used, 'liked' and appear most effective by talking in depth to women, partners and health visitors.

What are the possible benefits and risks of participating?
In the past the researchers have found that many people enjoy taking part in research. Participation in the study could also help others in the future if the researchers are able to show this supportive intervention is effective and can be used in future as part of usual care. Participants' views will directly help to shape the programme of research which may help many families in the future to stay smoke-free. At the end of the study (12 months after giving birth) participants will be able to keep any resources and are offered a £15 voucher for providing a CO reading and completing questionnaires, as a thank you for their time.

Where is the study run from?
University of East Anglia (UK)

When is the study starting and how long is it expected to run for?
October 2020 to June 2025

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Prof. Caitlin Notley (c.notley@uea.ac.uk)
Dr Gregory Howard (gregory.howard@uea.ac.uk)

Contact information

Type(s)
Scientific

Contact name
Prof Caitlin Notley

ORCID ID
https://orcid.org/0000-0003-0876-3304

Contact details
Chief Investigator
University of East Anglia
Norwich Medical School
University of East Anglia
Norwich Research Park
Norwich
United Kingdom
NR4 7TJ
+44 (0)1603591275
c.notley@uea.ac.uk

Type(s)
Scientific

Contact name
Dr Gregory Howard

ORCID ID
https://orcid.org/0000-0001-5749-0782

Contact details
Clinical Trials Manager
University of East Anglia
University of East Anglia
Norwich Medical School Room 2.17
NCTU
Norwich
United Kingdom

NR4 7TJ
+44 (0)1603591745
gregory.howard@uea.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
291746

Protocol serial number
CPMS 48117, IRAS 291746

Study information

Scientific Title
BabyBreathe Trial: a randomized controlled trial of a complex intervention to prevent return to smoking postpartum

Study objectives
To definitively test the real-world effectiveness of BabyBreatheTM in comparison with usual care, by comparing smoking abstinence rates at 12-month follow-up between trial groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/03/2021, North West – Preston Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Steet, Manchester M1 3DZ, UK; +44 (0)207 104 8206; preston.rec@hra.nhs.uk), ref: 21/NW/0017

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Pre and postnatal support for women who have stopped smoking in pregnancy

Interventions
Screening:
RAs at each site will engage with service gatekeepers regarding the trial and they will disseminate trial information to relevant staff (e.g. midwives, health visitors, sonographers, stop smoking service, GPs) on how to best identify potential participants. The screening process can

take place at any time during pregnancy though the target is to identify participants ahead of 26 weeks pregnancy. During this screening process potential participants will be asked by staff about their smoking and recent smoking status to determine eligibility. This may be confirmed by a negative baseline CO reading where this is in place as usual service provision at the time (all CO monitoring is currently suspended due to COVID infection risk).

The health professional will ask for verbal, email or text consent from potentially eligible participants to transfer their name, email and mobile number, due date and date of birth to a member of the site research team. The health professional will provide, or direct potential participants to a flyer outlining basic study information. The health professional or research team member will input participant data into the online database so the participant can be contacted from 26 weeks pregnancy with the link to the PIS, consent form and eligibility confirmation questionnaire. There will be posters, flyers and e-adverts (e.g. Facebook targeted advertising) providing trial details and contact information. We may also send a text message to all pregnant women in recruitment sites to ask for eligible women to contact the research team if interested in taking part. If a participant self-refers via poster, flyers, e-adverts, or by responding to a text message, they will contact the site RA using a site-specific email address. Their name, email and mobile number, due date and date of birth will be collected and entered into the database by the research team. The research team will provide, or direct potential participants to a flyer outlining basic study information. From 26 weeks they will receive the link to the PIS, consent form and eligibility confirmation questionnaire.

As the gap between initial contact about the trial and consent might be lengthy, the RAs may aim to contact participants ahead of consent where possible to discuss the trial. At 26 weeks pregnancy the database will automatically generate an SMS/email link for the participant to the PIS, consent form and eligibility questionnaire with one follow up reminder if the link is not clicked. If the link is still not clicked after the reminder the RA will then follow up to confirm interest or address any issues and remove participant data if requested to do so.

If participant information is provided beyond 26 weeks the link to the PIS, consent form and eligibility questionnaire will be sent as soon as their data is input into the database.

Confirming eligibility after consent:
Once the participant has read the PIS and completed the electronic informed consent form they will be asked to self-report eligibility, and provide their address so that we can post a CO monitor in order to confirm eligibility using an expired carbon monoxide (CO) reading of less than 4ppm (this is the standard cut off used in pregnancy when metabolism is higher).

The participants will be asked to download the CO monitor's purpose-built app which can provide the database with the CO reading. If the participant has not provided a CO reading within a week of consenting and submitting their address, the RA will follow up to confirm receipt of the CO monitor and offer to take the reading virtually entering the reading manually into the database.

Baseline:
Once the participant has given informed consent and eligibility is confirmed through a CO reading, a link will be automatically generated through text/email to the participant to complete the baseline questionnaire. The baseline questionnaire will consist of demographics, smoking status, breastfeeding status, relapse predictors, self-efficacy related to long-term smoking abstinence, Edinburgh postnatal depression scale, behavioural support use, nicotine product use, perceived stress, AUDIT-C, HRQoL and the EQ-5D-5L. If participants do not respond to the link, they will be sent one follow-up reminder. If the link is still not clicked the RA will follow-up,

by email, telephone or text. If a participant is unable or unwilling to complete the baseline questionnaire electronically, RAs will contact potential participants by telephone, or post to complete the baseline questionnaire.

Randomisation:
The completion and submission of the baseline measures will trigger the database randomisation notifying the trial team and local lead health visitor of the patient's trial arm. For those allocated to the intervention arm, the database will automatically send a digital copy of the BabyBreathe leaflet and Partner leaflet.

Health Visit – Before Birth:
All participants would normally see a health visitor before birth as part of usual care. Due to COVID-19 these procedures may have been interrupted or adapted at sites. This will take place in the current standard way for the control arm participants. If the HV receives a notification that the participant was randomised to the intervention arm the participant will receive the BabyBreathe support in addition to usual care.

If the randomisation is delayed beyond the usual care HV visit, the HV would make an additional contact to provide the intervention at some point before birth.

Birth Notification:
The health visiting service will notify the research team to enter the baby's date of birth for all women participating in the trial into the trial database. As a backup, the trial database will automatically generate an email based on the estimated due date (gathered at baseline) to the research team, as a reminder to enquire about the date of birth if this has not occurred. If for any reason there is concern about the participant continuing in the trial due to issues surrounding the birth (e.g. stillbirth, physical or mental health of the mother) this will be flagged so that the mother can be sensitively approached about remaining in the trial. The health visitor service named lead is responsible for entering the date the mother gives birth into the database within 7 days of birth, or of notifying the site RA to enter the date of birth into the database.

For participants in the intervention arm, the birth notification will trigger the BabyBreathe box to be posted to the mother and the text message support system will commence.

Health Visitor – Postpartum 10-14 days:
All mothers will receive the current standard visit (whether face-to-face or remotely due to COVID-19) from the HV at approximately 10-14 days postpartum. Those in the intervention arm will receive the BabyBreathe package of support from the research health visitor at this visit.

All subsequent health visitor visits:
The mothers will continue to receive the standard visits from the HV beyond the initial postpartum visit. Those in the intervention arm will continue to be supported by the same intervention HV with the BabyBreathe intervention.

6-Month Postpartum Follow Up:
At 6 months postpartum, a link will be automatically generated by the database and sent by SMS /email to participants in both arms of the trial to complete the 6-month questionnaire. The questionnaire will consist of self-reported smoking abstinence, time to relapse, partner smoking status, relapse predictors, self-efficacy related to long-term abstinence, Edinburgh postnatal depression scale, behavioural support use, nicotine product use, perceived stress, AUDIT-C and quality of life (HRQoL/EQ-5D-5L). If participants do not respond to the link, they will be sent one follow-up reminder. If the link is still not clicked the RA will follow-up by email, telephone, or

text. If participants are unable or unwilling to complete the 6-month questionnaire electronically, research associates will contact participants by telephone or post to complete the 6-month questionnaire.

12-Month Postpartum Follow Up:
At 12 months postpartum, a link will be automatically generated by the database and sent by SMS/email to participants in both arms of the trial to complete the 12-month questionnaire. The questionnaire will consist of self-reported smoking abstinence, time to relapse, partner smoking status, relapse predictors, self-efficacy related to long-term abstinence, Edinburgh postnatal depression scale, behavioural support use, nicotine product use, perceived stress, AUDIT-C, and quality of life (HRQoL/EQ-5D-5L). If participants do not respond to the link, they will be sent one follow-up reminder. If the link is still not clicked the RA will follow-up by email, telephone, or text. If participants are unable or unwilling to complete the 12-month questionnaire electronically, research associates will contact participants by telephone or post to complete the 12- month questionnaire.

Participants reporting abstinence will be asked to provide another confirmatory CO reading at this time point using their CO monitors sent at the beginning of their involvement in the trial. If the monitors have been lost or damaged, they will be replaced for the purposes of providing this final CO reading. Once completing the 12-Month Follow-Up visit the participants will be reimbursed for their time with a £15 shopping voucher. Also, if the participant is asked and agrees to take part in a qualitative interview this will take place after completion of the final questionnaire and submission of the final CO reading and they will also be offered voucher reimbursement for completing the interview.

Following Study Participation:
Following study completion, the CRN or research midwives (in Scotland) will provide participant resource use and infant health outcomes data by accessing the hospital and GP records for all participants.

Retention:
To maximise retention and minimise loss to follow up, we will retain contact with study participants. There will be one text/email reminder sent if links to questionnaires/forms are not followed by participants. If participants have not followed the initial links or reminders, then the RAs will contact up to 5 times to offer support. Outcome data collection at 6 and 12 months flexibly includes electronic, phone, post and face-to-face options. Participants will also be offered reimbursement for their time (£15 shopping voucher) once completing their 12-month follow-up visit.

Intervention Type
Behavioural

Primary outcome(s)
Self-reported continuous postpartum smoking abstinence, biochemically validated by CO monitoring at 12-months postpartum

Key secondary outcome(s))
1. Postpartum self-reported abstinence measured using self-report questionnaire at 6 months postpartum
2. Self-reported time to relapse measured using time from randomisation to self-reported date first smoked at 6 and 12 months postpartum

3. Self-reported partner smoking status measured using self-report questionnaire at 6 and 12 months postpartum
4. Relapse predictors measured using self-reported past smoking behaviour at 6 and 12 months postpartum
5. Self-efficacy related to long-term smoking abstinence measured using self-reported self-efficacy to remain smoke free at 6 and 12 months postpartum
6. Postpartum depression measured using the Edinburgh postnatal depression scale at 6 and 12 months postpartum
7. Behavioural support use measured using self-report questionnaire at 6 and 12 months postpartum
8. Nicotine product use measured using self-report questionnaire at 6 and 12 months postpartum
9. Perceived stress measured using Cohen perceived stress scale at 6 and 12 months postpartum
10. Alcohol use measured using AUDIT-C at 6 and 12 months postpartum
11. Quality of life measured using EQ-5D-5L at 6 and 12 months postpartum
12. Participant resource use measured using data collection from patient notes and GP records at 12 months postpartum
13. Infant health outcomes measured using data collection from patient notes and GP records at 12 months postpartum

Completion date
30/06/2025

Eligibility

Key inclusion criteria
1. Pregnant women who have stopped smoking completely in the 12 months prior to pregnancy, or at any time during pregnancy
2. At 26 weeks gestation or any time up until birth, woman confirms having not smoked a single puff of a cigarette for at least 4 weeks.
3. Able to read and understand English
4. Willing and able to give informed consent for participation in the study
5. Smoking abstinence confirmed by expired carbon monoxide (CO) reading less than 4 ppm

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
Female

Total final enrolment

887

Key exclusion criteria
1. Under the age of 16 years

Date of first enrolment
01/04/2021

Date of final enrolment
31/08/2023

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
NHS Lothian
2 - 4 Waterloo Place
Edinburgh
United Kingdom
EH1 3EG

Study participating centre
St Thomas's Hospital
249 Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
St George’s Hospital
Blackshaw Road
London
United Kingdom
SW17 0QT

Study participating centre

King's College Hospital
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Central London Community Healthcare NHS Trust
Ground Floor
15 Marylebone Road
London
United Kingdom
NW1 5JD

Study participating centre
North Tyneside General Hospital
Rake lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
Queen Elizabeth Hospital
Gateshead Health NHS Foundation Trust
Sheriff Hill
Gateshead
United Kingdom
NE9 6SX

Study participating centre
Freeman Hospital
Newcastle Upon Tyne Hospital Trust
Freeman Road
High Heaton
Newcastle
United Kingdom
NE7 7DN

Study participating centre
Norfolk and Norwich University Hospital
Norfolk And Norwich University Hospitals NHS Foundation Trust

Colney Lane
Norwich
United Kingdom
NR4 7UY

Study participating centre
Cambridgeshire Community Services NHS Trust
Unit 7/8
Meadow Park
Meadow Lane
St. Ives
United Kingdom
PE27 4LG

Sponsor information

Organisation
University of East Anglia

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR129074

Results and Publications

Individual participant data (IPD) sharing plan
Data underlying the main trial results will be available in a public, open access repository immediately following publication of the major findings of the study. Details of the repository and a persistent URL will be provided on publication of the main results. Study protocol, statistical analysis plan, informed consent form, and other documents will also be available.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		04/09/2023	05/09/2023	Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes