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Original Investigation

Development of "Baby, Me, & NRT": A Behavioral Intervention to Improve the Effectiveness of Nicotine Replacement Therapy in Pregnancy

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Abstract

Background: The effectiveness of Nicotine Replacement Therapy (NRT) for smoking cessation in pregnancy is limited by inconsistent and incorrect use. This paper describes the development process for "Baby, Me, & NRT", a novel pregnancy-specific intervention aimed at enhancing adherence to NRT.

Methods: An integrated approach to intervention development was used, combining evidence, theory, stakeholders' feedback, and tailoring principles. The process involved six iterative steps: (1) synthesizing relevant published evidence and guidance, (2) collecting primary qualitative data on barriers and facilitators to NRT adherence along with potential intervention design features, (3) identifying relevant behavioral theories and mapping the evidence against these, (4) prioritizing behavioral determinants identified in steps 1 and 2, generating intervention objectives, and identifying behavior change techniques which target the prioritized determinants, (5) consulting with stakeholders on intervention components, key content and tailoring features, and (6) producing a prototype intervention along with implementation guidance.

Results: The prototype intervention comprises of a multi-component, 1-month cessation programme, which includes six enhanced behavioral support sessions delivered by a trained advisor, tailored text messages, a website, and an illustrated booklet. It promotes the uptake of high-dose and combination NRT, emphasizes the importance of adherence, addresses motivation to use NRT, proactively helps problem solve NRT use issues, and provides guidance on preventing and managing smoking lapses.

Conclusion: The development process generated an evidence- and theory-guided intervention, designed with stakeholder input, aimed at improving NRT effectiveness for smoking cessation in pregnancy. The prototype intervention has since been optimized and is being evaluated in a randomized controlled trial.

Implications

Clinical guidelines in the United Kingdom recommend the use of nicotine replacement therapy (NRT) in pregnancy, but it is not always used to the best effect. Improving adherence to NRT in pregnancy will likely increase its effectiveness and ultimately lead to higher levels of smoking cessation. Interventions which integrate the issue of NRT adherence into standard cessation support in pregnancy, such as "Baby, Me, & NRT", are needed to overcome barriers to use.

Introduction

Smoking is a leading modifiable risk factor for poor pregnancy, birth and child health outcomes.[1,2] Around the world, large numbers of people continue to smoke when pregnant. In high-income countries, the rates of smoking in pregnancy have been slowly declining.[3] However, this has not been consistent across socio-economic groups which is likely deepening health inequalities.[4,5] In low-to-middle income countries, the proportion of pregnant people smoking is increasing.[3] In the United Kingdom , around half of pregnant people who smoke want to quit,[6] but those who find it hardest are typically more nicotine dependent and live in circumstances that make it difficult.[7] Better ways to improve quit rates in pregnancy are therefore urgently needed.

Several countries offer Nicotine Replacement Therapy (NRT) to pregnant people as part of broader cessation strategies.[8–10] For example, in the United Kingdom, the National Health Service (NHS) provides a structured programme of behavioral cessation support delivered by a trained advisor and access to free NRT,[8,11] but NRT prescribing is generally low.[12] Even when NRT is used in pregnancy there is low certainty about whether it promotes

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cessation.[13] This is likely because pregnant people do not use NRT as instructed or take it for long enough to be effective. A large UK population-based study showed that NRT was prescribed for an average duration of just 2 weeks in pregnancy, even though a minimum of 8 weeks is recommended.[12] Similarly, a meta-analysis of five trials that enrolled pregnant people found that only 22% were adherent to NRT.[14] Low adherence to NRT in pregnancy has been linked to both perceptual and practical issues. For example, pregnant people can lack belief in the value of using NRT or have concerns about safety.[15,16] Problems when using NRT can also lead to inconsistent use and discontinuation (e.g. side effects, poor technique).[16] Additionally, a lack of support from health professionals, due to hesitation about NRT use in pregnancy, or gaps in knowledge and skills, can be a barrier to adherence.[16]

There is strong evidence that combination NRT (combining a patch with a fast-acting product) is more effective than using a single NRT product,[17,18] and in nonpregnant people, higher doses of NRT are associated with increased use.[19] Combination NRT may be particularly important in pregnancy because nicotine is metabolized faster and therefore a higher nicotine dose is likely needed to manage the cravings and withdrawal symptoms that can lead to nonadherence.[20] Yet, trials looking at the effectiveness of NRT for promoting smoking cessation in pregnancy have mostly tested a single NRT product, typically the lower dose 15 mg/16-h patch.[13] Increased nicotine metabolism together with low dosing and adherence therefore might explain why NRT appears to be less effective in pregnancy. This has led to calls for interventions that enhance adherence to NRT, using higher dose and combination NRT.[17]

A recent systematic review of adherence-promoting interventions for tobacco dependence medicines included seven studies which targeted NRT adherence.[21] These interventions were typically offered in addition to standard behavioral support and focused on addressing perceptions about taking NRT, the practicalities of using NRT or both. There was moderate certainty evidence that these interventions slightly improved adherence, but the studies were limited in number, quality, and estimates of effects, and none specifically focused on pregnant people. Therefore, it is currently unknown what strategies would best promote adherence to NRT in this population. Digital solutions could help as they are increasingly being used for the self-management of medication taking, but their use to improve NRT adherence has been limited.[22,23]

In this paper, we present our approach to the development of "Baby, Me & NRT," an individual-level behavioral intervention which aims to improve the effectiveness of NRT for smoking cessation in pregnancy though increased adherence. This work was undertaken as part of the Nicotine Replacement Effectiveness and Delivery in Pregnancy (N-READY) research programme. Baby, Me, & NRT has been designed to augment standard NHS cessation support in England with enhanced adherence counseling and digital tools. It is currently being evaluated in a randomized control trial (ISRCTN: 16830506). To ensure the quality and consistency of intervention development reporting, we have used the new Guidance for the Reporting of Intervention Development in Health Research (GUIDED)[24] (Supplementary Table 1).

Materials and Methods

This paper draws on several published studies from the N-READY programme to describe the intervention development process.[15,16,25–27] Therefore, it is not the primary source for reporting the full methods of these individual studies. Ethical approval was granted by East Midlands - Nottingham 1 NHS Ethics Committee (Reference: 12/EM/0388) and all participants gave informed consent.

Public Involvement

Three members from our public involvement advisory panel were involved in the development of participant materials (e.g., topic guides for interviews and focus group, recruitment adverts, participant information sheets), reviewing qualitative findings, developing intervention messages, and assisting with the development of prototype intervention components.

Development Framework

There are several published approaches which offer guidance on how to develop complex interventions to improve health and healthcare.[28] For this study, we drew on three complementary approaches. Firstly, the UK Medical Research Council's (MRC) guidance[29] advocates the use of evidence and theory in the design of interventions. The rationale for using behavioral theory is that this can help identify under what circumstances certain behaviors occur and the processes involved in changing them.[30]

Secondly, the Person-Based Approach[31] offers a systematic way to understand and address the views, needs, and experiences of the people who will use and deliver an intervention. This enables developers to gain insights into what intervention components and features might be useful, and to make modifications based on user feedback. The Person-Based Approach can enhance theory- and evidence-based approaches to intervention development.[31]

The final approach, which features in many health behavior interventions, focuses on tailoring intervention content to different user needs. Tailoring behavioral support increases recipients' perceptions of this being personally relevant and, in turn, increases the likelihood that it will promote the desired behavior change.[32] For computer-automated intervention components, we followed the methodology used by Dijkstra and de Vries[33]: (1) Preparation (developing objectives based on determinants of behavior), (2) Tailoring (mapping objectives against message tailoring characteristics and developing adapted messages), and (3) Integration (integrating all the intervention messages and designing the overall message structure).

Stages of Development

Our intervention development process combined the aforementioned frameworks into an iterative six step approach (illustrated in Figure 1): (1) synthesizing relevant published evidence and guidance, (2) collecting primary qualitative data on barriers and facilitators to NRT adherence along with potential intervention design features, (3) identifying relevant behavioral theories and mapping the evidence against these, (4) prioritizing behavioral determinants identified in steps 1 and 2, generating intervention objectives, and identifying behavior change techniques which target the prioritized determinants, (5) consulting with stakeholders on intervention components,

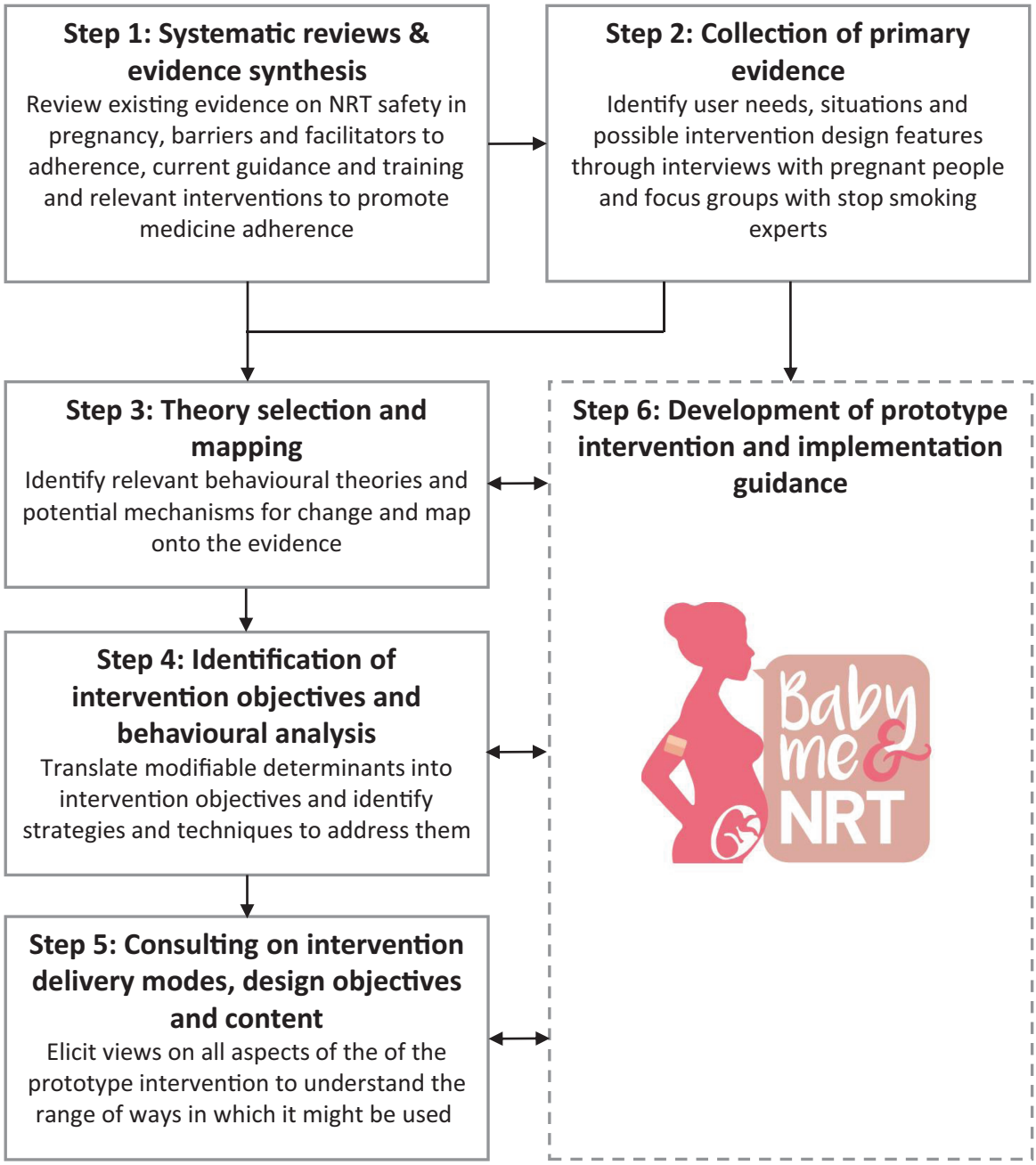

Figure 1. Six stage intervention development approach.

key content, and tailoring features, and (6) producing a prototype intervention along with implementation guidance.

Step 1: Systematic Reviews and Evidence Synthesis

Step 1 involved reviewing existing evidence to help better understand the problem of poor NRT adherence in pregnancy and its determinants, along with the safety of NRT use in pregnancy. Five systematic reviews were conducted focusing on: (1) comparing nicotine (cotinine) exposures from smoking and NRT use in pregnancy,[34] (2) effectiveness of pharmacological interventions for promoting smoking cessation in pregnancy,[13] (3) factors influencing the uptake and use of NRT,[16] (4) fetal safety from NRT exposure,[35] and (5) potential harms from nicotine administration to pregnant animals.[36] Alongside this, a broader literature search was carried out to explore other interventions aiming to improve adherence to NRT and to examine relevant guidance and training.

Step 2: Collection of Primary Evidence

We carried out primary qualitative research, which involved interviews with 18 pregnant people who had been offered NRT as part of a quit attempt[15] and focus groups with 19 stop smoking practitioners and other experts.[26] We used purposive sampling to ensure two-thirds of interview participants lived in disadvantaged communities, as these interviewees were expected to experience more barriers to quitting smoking and are overrepresented among pregnant people who smoke.[37] These activities sought to explore what makes it easier or harder for pregnant people to start and continue using NRT. Additionally, we asked experts about

potential implementation issues, for example, what might inhibit them from recommending higher doses of NRT or encouraging continued NRT use during brief smoking lapses during quit attempts.

Step 3: Theory Selection and Mapping

In this step, relevant behavioral theories were selected and mapped against the evidence. Literature was reviewed to identify which frameworks have previously had effective practical application to treatment adherence interventions and would most likely inform the pathway to behavior change in our intervention. From this, we decided to draw on multiple theories. Two integrative theoretical frameworks: the Capability Opportunity Motivation Behavior (COM-B Model),[38] which states that one or more of these dynamic factors need to be present for behavior change to occur, and the Theoretical Domains Framework (TDF; v.2),[39] which are designed to provide comprehensive theoretical coverage of behavior.

Additionally, we drew on two pragmatic theories which focus on the determinants of treatment adherence: the Perceptions and Practicalities Approach (PAPA),[40] which stipulates that adherence is a product of intentional (e.g. motivational beliefs and preferences) and unintentional (e.g. ability, opportunity, resources) factors, and the Necessities-Concerns Framework (NCF), which focuses on a person's beliefs about treatment.[41] It suggests that treatment adherence is influenced by perceptions about personal need for the treatment (necessity beliefs) and concerns about using it.

Each modifiable behavioral determinant of NRT adherence identified from relevant evidence from steps 1 and 2 was added to a matrix and then mapped against constructs in the selected behavior change frameworks and theories. Using an informal consensus approach, these were then rated for importance by the research team based on strength of evidence and potential for modification.

Step 4: Identification of Intervention Objectives and Behavioral Analysis

Modifiable determinants with potential solutions at an individual level were then translated into clear and measurable intervention objectives and potential behavioral change techniques (BCTs) from the Behaviour Change Techniques Taxonomy (BCTTv1)[42] were then selected. The selection of BCTs was based on relevant behavioral intervention literature (e.g. reviews of BCTs used to aid smoking cessation in pregnancy[43–45] and other NRT adherence interventions[22]), and those thought most promising to address each of the intervention objectives.

Step 5: Consulting on Intervention Delivery Modes, Design Objectives, and Content

Further qualitative research was carried out to help decide on intervention delivery modes, design objectives and content. First, we held an in-person expert advisory meeting[26,27] to build consensus and consolidate knowledge acquired from the formative research and mapping exercise. The research team then met to discuss potential delivery modes and which might work best for each of the intervention objectives. Next, 10 interviews with pregnant people who had declined NRT or struggled to quit smoking when using it and a focus group with six stop smoking experts were conducted.[25,27] The format between the two slightly differed, but both groups were presented with potential intervention content and were asked to share their thoughts on persuasiveness and acceptability. Participants were also asked for their views on how the intervention might be delivered and important design features for each of the delivery modes. Finally, we carried out an email consultation exercise within the research team, programme co-applicants and our public involvement advisory panel. This focused on identifying suitable phrasing for intervention content and how this content might be made more relevant through tailoring.

Step 6: Development of Prototype Intervention and Implementation Guidance

The final step was to specify and produce a protype intervention and implementation guidance. A research team meeting was held where key findings from the formative research stages were presented and discussed. An intervention structure, detailing how BCTs might be operationalized, delivery modes, and key content was agreed through informal consensus. From here onwards, regular meetings were held to evaluate progress and plan future work. An iterative process was followed, drafting content, seeking feedback from the research team, public involvement advisory panel and other expert advisors, resolving comments and then starting to develop each intervention component.

We also undertook additional consultation for specific components. For example, we worked with the National Centre for Smoking Cessation and Training (NCSCT) to ensure the enhanced behavioral support component complemented existing guidance. The text message component drew on previous text-based cessation support developed by the research team.[46] A collaborative exercise was also held with our public involvement advisory panel to determine the text message sending order and ensure a good mixture of different message types to address the intervention objectives. For the website and leaflet, we worked with a graphic designer to help improve visual engagement and communicate key messages.

Results

The Intervention Development Process (Steps 1 to 5)

Needs and Safety Evidence (Steps 1 and 2)

The specific findings from the systematic reviews[13,16,34–36] and qualitative data collection[15,25–27] are reported in detail elsewhere. This formative research confirmed that there are numerous modifiable determinants which contribute to poor NRT adherence in pregnancy, including motivation, concerns about using NRT, lack of perceived need, and practical issues. The results also strengthened the evidence-base to encourage high-dose and combination NRT use in pregnancy and counter safety concerns. For example, while many pregnant women have concerns about the safety of nicotine independent of smoking (i.e. delivered therapeutically and not by smoking), our systematic review of high quality studies found no evidence that suggests NRT might be harmful in pregnancy.[13]

Identification of Intervention Objectives and Behavioral Analysis (Step 3 and 4)

Determinants derived from evidence were mapped onto the identified theories and frameworks to systematically

identify the changes that needed to occur to improve NRT adherence. Formative research findings were mapped onto COM-B components and all 14 TDF domains, with five domains identified as the main influences on NRT adherence in pregnancy and targetable within an individual-level intervention: (1) Knowledge (e.g. NRT safety), (2) Skills (e.g. NRT technique), (3) Beliefs about consequences (e.g. side effect expectations), (4) Environmental context and resources (e.g. recommending and offering of combination NRT), (5) Behavioral regulation (e.g. proactive problem solving of NRT issues).

Following this, we mapped the findings to the NCF and PAPA to provide adherence-specific linkage with NRT-related beliefs in pregnancy and practical issues with NRT use. For example, using NCF, we identified that a person might weigh up "*How much do I need to use NRT to quit smoking?*" (necessity belief) against "*Will using NRT be safe for my baby?*") (concern). Where perceived need is high and concerns are low, then adherence is more likely, and vice versa. The PAPA model was used to draw out barriers that relate to unintentional nonadherence (e.g. recall of instructions, problems using NRT, forgetting to take NRT).

After prioritizing these, we created a list of 10 intervention objectives. Six objectives focus on NRT use only, including using sufficient NRT (Objective 1 and Objective 2 - O1, O2), perceptions about NRT safety (O3), problem solving difficult NRT-related issues (O4), and how to take and remember NRT (O5, O6). However, while the intervention was designed to work alongside standard treatment, it was recognized that the digital support would need to include some smoking cessation content as this is the key motivator for NRT use and would permit this component to function with or without interpersonal counseling. Therefore, four objectives focus on smoking cessation and NRT use, including motivation (O7), problem solving for trigger situations (O8), lapse management with NRT (O9), and social support (O10). The objectives, barriers and theoretical constructures they were mapped to are described in Table 1 (NRT only) and Table 2 (smoking cessation + NRT). These tables also show the BCTs selected for each objective to help change behavior.

Feedback on Intervention Delivery Modes, Design Objectives, and Content (Step 5)

Feedback from discussions with those who would use and deliver the intervention indicated a preference for a blended learning approach involving enhanced behavioral support and digital tools. This should target information specifically to pregnancy, tailor information based on the needs of the individual, and use personal narratives, expert opinion, and the latest evidence. A lack of educational materials for using NRT in pregnancy was highlighted. It also became apparent from this consultation exercise that the intervention would need to deliver both "enhanced" NRT content (i.e. new information and approaches to help overcome barriers to adherence to NRT in pregnancy), and reinforce "essential" NRT content (i.e. existing information on NRT within current guidance for smoking cessation in pregnancy that may not be consistently or well delivered). Examples of the intervention content are given in Supplementary Table 2.

As the aim was to test the intervention in a trial design, our approach had to balance the need to collect research data against the desired components for the intervention. One challenge was the need to capture detailed information relating to NRT adherence to measure the primary trial outcome, for which a separate application was developed as a research data collection tool (i.e. inputted data are not displayed to participants).[46] This limited some of the intervention design features, such as using digital self-monitoring tools to track NRT use, and to visually feedback this data, which we might have wished to incorporate if this was not the case. However, such features may be added in the future prior to implementation in a real-world setting.

The Prototype Baby, Me, & NRT Intervention (Step 6)

The prototype Baby, Me, & NRT intervention consists of a 1-month cessation programme which involves six enhanced behavioral support sessions delivered by a trained advisor, tailored text messages, a website, and an illustrated booklet (Figure 2 and Supplementary Table 3). Alongside this, implementation training and guidance has been developed for stop smoking advisors.

Enhanced Behavioral Support

The behavioral support component was designed to complement the current standard treatment model for smoking cessation in pregnancy in England.[11] Compared to standard care, the enhanced Baby, Me, & NRT support includes one additional counseling session on day 3, after the standard pre-quit consultation, where setting a quit date is encouraged. This is then followed by weekly sessions until 4 weeks after the quit date (pre-quit, days 3, 7, 14, 21, and 28) with referral to further local support on an as-needed basis, in line with standard care.

Baby, Me, & NRT behavioral support is front-loaded with additional NRT adherence-enhancing information and support. The pre-quit session includes a strong recommendation to use high-dose and combination NRT, information to enhance positive NRT beliefs and counter low necessity beliefs and concerns, emphasis on the importance of adherence, proactive problem solving, and guidance on preventing and managing smoking lapses. Participants are also encouraged to use the Baby, Me, & NRT written and digital resources (booklet, text messages, and website). All standard care elements, such as assessment of an individual's smoking circumstances, information on the benefits of quitting smoking in pregnancy, and preparations for quitting, continue to be delivered. The purpose of follow-up sessions is to review progress, plan future management strategies and provide further information or modifications to the NRT treatment plan if needed (e.g. right products for the individual, dose, usage techniques). See Supplementary Table 4 for a detailed description of session content.

The pre-quit consultation lasts around 45 minutes and was initially intended to be face-to-face, with the follow-up consultations by telephone. However, due to the COVID-19 restrictions, this was adapted to be compatible with a remote delivery model (video and/or telephone call).

Tailored Text Messages

The automated SMS text message component is a1-month programme of tailored support for enhancing NRT use in pregnancy. To help "futureproof" the design, optional features have been built in to extend the programme to 12 weeks and for it to be delivered alongside or without interpersonal counseling. Messages are divided into eight types: (1) quitting motivation,

Table 1. Matrix of links between intervention objectives, barriers, theory-based constructs, and behavior change techniques (NRT only)

Intervention objective	Barriers	Theory-based constructs (COM-B & TDF; N&CF & PAPA)	NRT BCTs to include in intervention
Objective 1: Sufficient NRT Strongly encourage high-dose, combination NRT use and ensure individual understands why this is important to support cessation in pregnancy	Lack of knowledge about increased nicotine metabolism during pregnancy (requiring higher dose/ combination NRT to reduce cravings and withdrawal symptoms), lack of understanding about combination NRT, offer/supply of combination NRT	Psychological capability (knowledge), physical opportunity (resources) Practical: information, supply	(9.1) Credible source, (11.1) Pharmacological support
Objective 2: Importance of NRT adherence Ensure that individual understands the importance of using NRT as recommended for quit success—the right amount, often enough and for long enough	Lack of understanding about the need to use NRT as instructed in pregnancy (regularly, high dose, long enough) to successfully quit, importance of adherence in first2 d for continued NRT use, perceiving NRT is no longer required (necessity-testing)	Psychological capability (knowledge) Practical: information Perceptual: necessity beliefs	(4.1) Behavioural instruction, (9.1) Credible source, (11.1) Pharmacological support
Objective 3: NRT Safety Ensure the perception is held that NRT for smoking cessation is considered safe to use in pregnancy	Unaware NRT can be used in pregnancy, belief NRT/nicotine is harmful in pregnancy (especially to the baby), concern about nicotine overdosing, belief that using two combined NRT products is more harmful than one, concern about getting more nicotine from NRT than previous smoking, belief NRT is addictive, belief switching one dependence for another, low awareness that NRT is approved in pregnancy, reliance on anecdotal evidence rather than scientific evidence	Psychological capability (knowledge), reflective motivation (beliefs about consequences) Practical: credible sources Perceptual: concerns	(1.2) Problem solving, (5.1) Information about health consequences, (9.1) Credible source, (9.2) Pros and cons, (11.1) Pharmacological support
Objective 4: Problem solving for potential NRT issues Ensure individuals are informed upfront about possible side effects and unpleasant sensations from using NRT and that they have the knowledge and self-efficacy to manage these	Lack of awareness of and/or anticipating side effects, concerns about consequences and meaning of side effects, low acceptability and limited endurance of side effects and unpleasant sensations, incorrect technique leading to side effects (see Objective 5), lack of awareness of how to manage NRT side effects and usage issues, low self-efficacy to use NRT, dislike of a particular product, limited access to alternative NRT products	Psychological capability (knowledge, skills, behavioral regulation), physical capability (skills), reflective motivation (beliefs about capabilities), physical opportunity (environmental context and resources) Practical: supply Perceptual: concerns	(1.2) Problem solving, (1.4) Action planning, (2.2) Feedback on behavior, (4.1) Behavioral instruction, (5.1) Information about health consequences, (6.1) Demonstration of behavior, (9.1) Credible source, (9.2) Pros and cons, (11.1) Pharmacological support, (15.1) Verbal persuasion about capability
Objective 5: Enhanced dosing and usage instructions Ensure individuals fully understand how the different forms of NRT work together (patch vs. fast-acting) and have the knowledge and technique for correct use and dosing	Inadequate process of NRT selection, lack of knowledge about using different NRT products together, limited knowledge and techniques to use NRT effectively, limited understanding of NRT dosing, incorrect technique leading to side effects, knowledge about level of dependence, poor control of withdrawal symptoms, low motivation to optimize NRT use, desire to "test" if absence maintained without NRT, lack of reinforcement of initial NRT usage advice, difficulty remembering NRT usage advice, changing dose without consulting health professional	Psychological capability (knowledge, skills), physical capability (skills), automatic motivation (reinforcement) Practical: information Perceptual: concerns, necessity beliefs, self-efficacy beliefs	(4.1) Behavioral instruction, (6.1) Demonstration of behavior, (11.1) Pharmacological support
Objective 6: Remembering to use NRT and never running out Ensure pregnant people are supported and aware of techniques to remember to use NRT, always have it with them, and to never run out	Forgetting to use NRT, forgetting usage advice, lack of NRT routine and habit formation, not having NRT available (with them/ on person when needed), poor monitoring and planning can lead to running out of NRT supply	Psychological capability (skills, behavioral regulation, memory attention and decision processes), physical capability (skills), automatic motivation (reinforcement), physical opportunity (environmental context and resources), Practical: reminding, planning, supply	(1.4) Action planning, (7.1) Prompts/ cues, (8.3) Habit formation, (11.1) Pharmacological support, (12.1) Restructuring the physical environment

Table 2. Matrix of links between intervention objectives, barriers, theory-based constructs, and behavior change techniques (smoking cessation + NRT)

Intervention Objective	Barriers	Theory-based constructs (COM-B & TDF; N&CF & PAPA)	Smoking cessation BCTs to include in the intervention (digital support only)	NRT BCTs to include in intervention
Objective 7: Enhance motivation Ensure that individuals are aware of smoking harms and are motivated to start and continue with an NRT assisted quit attempt; and to get back on track after a lapse or relapse	Unwilling to start or continue with NRT unless motivated to quit smoking, doubts about need to use NRT to quit smoking, low or unrealistic NRT effectiveness expectations, previous NRT use impacts on current motivation, ambivalence or lack of perceived self-efficacy towards quitting smoking, cutting down smoking seen as sufficient, quitting smoking for pregnancy seen as temporary, lack of personal concerns about smoking harms, poor understanding of mechanisms of harm	Psychological capability (knowledge), reflective motivation (beliefs about capabilities, beliefs about consequences, intentions, goals), automatic motivation (optimism) Perceptual: necessity beliefs, self-efficacy beliefs	(1.2) Problem solving, (4.2) Information about antecedents, (5.1) Information about health consequences, (5.3) Information about social and environmental consequences, (5.6) Information about the emotional consequences, (10.9) Self reward, (13.5) Identify associated with behavior change, (15.1) Verbal persuasion about capability, (16.2) Imaginary reward	(1.2) Problem solving, (2.2) Feedback on behavior, (5.1) Information about health consequences, (5.6) Information about emotional consequences, (7.1) Prompts/cues, (9.1) Credible source, (9.2) Pros and cons, (10.4) Social reward, (11.1) Pharmacological support, (11.2) Reduce negative emotions, (15.1) Verbal persuasion about capability
Objective 8: Problem solving for trigger situations Ensure pregnant people are aware of trigger situations and have a plan for how to avoid these or manage them with fast-acting NRT	Emotional and situational triggers result in lapses to smoking, lack of routine and habit formation, insufficient dose of NRT leading to increased withdrawal and cravings, not using fast-acting NRT to top up in these situations	Psychological capability (knowledge, Skills, behavioral regulation), automatic motivation (emotion) N&CF & PAPA Practical: information	(1.2) Problem solving, (1.4) Action planning, (4.2) Information about antecedents, (5.3) Information about emotional consequences, (7.3) Reduce prompts/cues), (7.4) Remove access to the reward, (8.2) Behavioral substitution, (11.2) Reduce negative emotions, (12.1) Restructure the physical environment, (12.3) Avoidance/ reducing exposure to cues for behavior, (12.4) Distraction	(1.2) Problem solving, (1.4) Action planning, (4.1) Behavioral instruction, (4.2) Information about antecedents, (5.1) Information about health consequences, (8.2) Behavior substitution, (9.2) Pros and cons, (11.1) Pharmacological support, (12.1) Restructuring physical environment, (15.1) Verbal persuasion about capability
Objective 9: Lapse management with NRT Ensure pregnant people are aware of the need for continued NRT use during a lapse	Uncertainty about whether to continue with NRT after a lapse, concerns about using NRT and smoking at the same time	Psychological capability (knowledge), reflective motivation (beliefs about consequences) Practical: information Perceptual: concerns, necessity beliefs	(1.2) Problem solving, (6.2) Social comparison, (15.1) Persuasion about capability	(1.2) Problem solving, (5.1) Information about health consequences, (9.1) Credible source, (11.1) Pharmacological support
Objective 10: Social support Promote and provide social support for NRT use	Lack of support from others to stop smoking and use NRT, lack of role models/ NRT success stories from other pregnant people, negative relationship with stop smoking advisor, perceived social disapproval of NRT pregnancy	Social opportunity (social influences) Practical: information, social support	(3.1) Social support (unspecified), (3.2) Social support (practical), 3.3 Social support (emotional), (7.3) Reduce prompts/cues, (12.2) Restructuring the social environment, (12.3) Avoidance/ reducing exposure to cues for behavior, (12.4) Distraction	(3.1) Social support (unspecified), (3.2) Social support (practical), (11.1) Pharmacological support

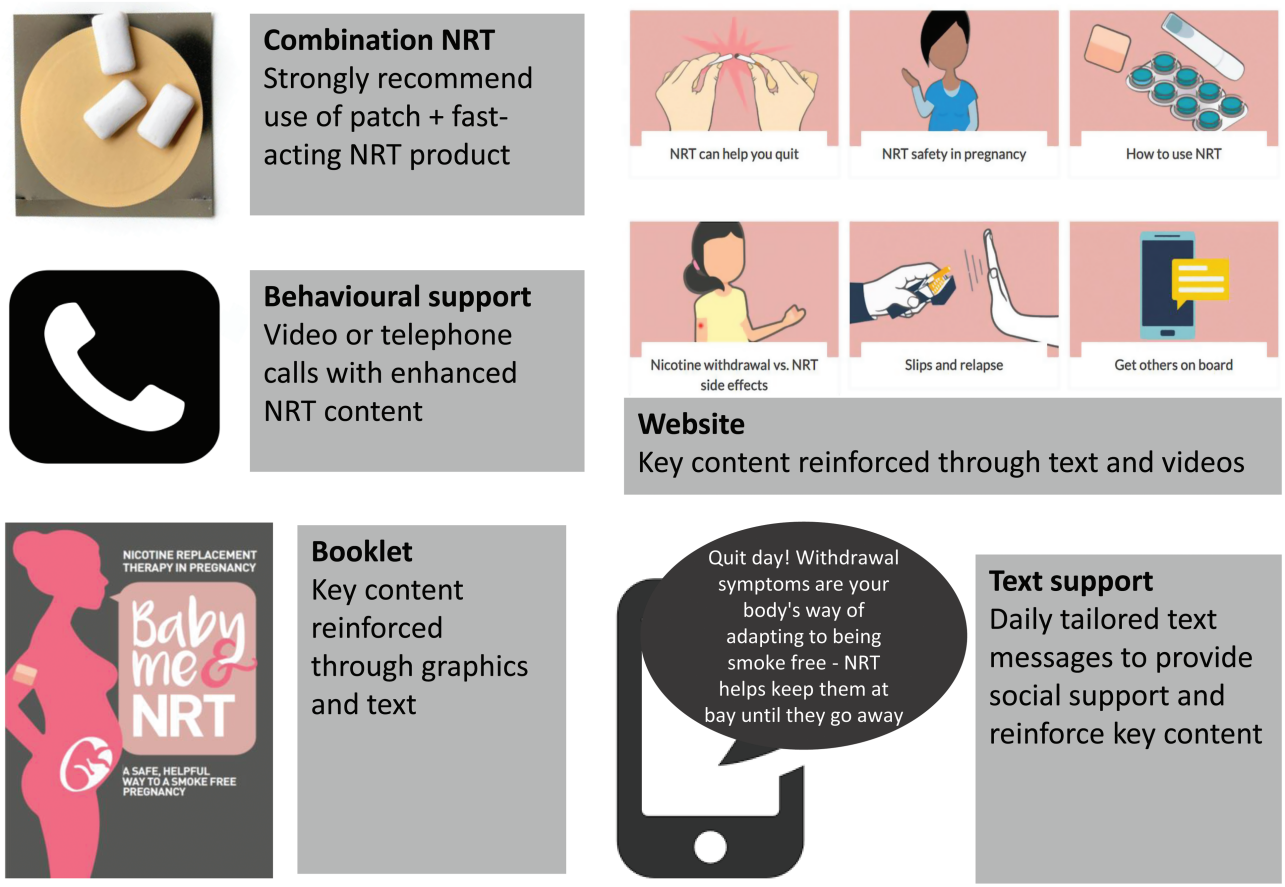

Figure 2. Components of the Baby, Me, & NRT intervention.

(2) NRT motivation, (3) intentional nonadherence (INA), (4) unintentional nonadherence (NINA), (5) NRT know how, (6) relapse prevention, (7) general support, and (8) programme information. A description of each message type and example messages are presented in Supplementary Table 5.

Text messages are tailored by the participant's chosen quit date, scheduled to begin 2 days prior, and are personalized using their preferred name. Other baseline tailoring characteristics include the participant's gestation, previous NRT products used, nicotine dependence, NRT product(s) given at the pre-quit consultation, and two items from a questionnaire designed to assess participants' necessity beliefs and concerns about NRT in pregnancy (relating to wanting to minimize NRT use in pregnancy and nicotine being harmful to the baby). Texts are also tailored by participants' ongoing NRT adherence behaviour (self-reported). This last tailoring variable is a particularly novel feature of the support, as it uses continuous data collected from an NRT adherence reporting app called "NicUse."[47] Additionally, users can request an on-demand quiz to distract themselves from cravings and withdrawal symptoms. The consensus among pregnant people was that a maximum of 2 to 3 messages per day should be sent, with the option to receive fewer messages or to stop them.

Illustrated Booklet

The booklet comprises a mixture of graphics and text. It is divided into six sections: (1) explaining what NRT is and how it works, (2) addressing common misconceptions about NRT, (3) instructions on how to use NRT and why it is important to use it correctly, (4) how to identify and manage side effects, (5) top tips, such as how to get the most out of NRT and relapse prevention, and (6) where to go for further information. Efforts were made to ensure the booklet was written in plain English. The final page includes the Baby, Me, & NRT website link. Two different sizes were printed (A5 and A6) to be tested during optimization.

Website

The website aims to reinforce and expand on key information. It consists of six sections (1) NRT can help you quit, (2) NRT safety in pregnancy, (3) How to use NRT, (4) Nicotine withdrawal versus nicotine side effects, (5) Slips and relapses, and (6) Getting others on board. A mix of text, images, expert videos, and animations were used to enhance engagement.

Implementation Guidance

The behavioral counseling component was designed to be delivered by trained stop smoking advisors. A training package was developed consisting of an implementation manual, a remote tutorial session, and videos to enable advisors to deliver Baby, Me, & NRT content. Additionally, a delivery checklist of key intervention messages was developed.

Discussion

This paper has described how we combined complementary intervention development frameworks to design and develop

a novel intervention to enhance NRT use for smoking cessation in pregnancy. Our six-step iterative approach brought together the latest research evidence, with behavioral theory and stakeholder perspectives, to help tailor the intervention to the unique needs of pregnant people. It is widely recognized that complex health problems, such as smoking in pregnancy, can be difficult to address, and behavioral change often requires complex interventions.[48] Our prototype Baby, Me, & NRT intervention consists of four components to help target 10 intervention objectives. It is specified by 18 NRT focused BCTs, such as problem solving, behavioral instruction, information about health consequences, and pharmacological support. A further 22 smoking cessation focused BCTs feature in the digital support.

Behavioral support has successfully been shown to increase smoking cessation rates in pregnancy[49] and is a key component of the UK standard treatment programme.[11] In the general population, interventions which provide enhanced behavioral support by focusing on changing perceptions about NRT and the practicalities of using it, can improve adherence.[21] Therefore, integrating elements of NRT adherence within behavioral support has the potential to be effective if specifically targeted to pregnancy. Baby, Me, & NRT builds on these strategies, but also aims to increase effectiveness using digital tools. For example, text messaging has been shown to be effective for smoking cessation in pregnancy[45] and the growing availability of mobile phones together with the effectiveness of text messaging in promoting adherence in other areas,[50] makes this a promising component for a pregnancy-specific NRT adherence intervention. Not only can text messaging provide prompts, tips and reminders, but it can also facilitate use of other intervention components.

Since its development, we have completed three sequential cohort studies to optimize the prototype intervention and research procedures. We are currently running a two-arm randomized controlled trial (ISRCTN: 16830506) to test whether the intervention helps to enhance adherence to NRT at 1 month follow up, compared to standard behavioral support for smoking cessation in pregnancy. If successful, we will then conduct a further trial to establish the effectiveness of the intervention for smoking cessation in pregnancy.

Strengths and Limitations

A significant strength of the design and development process was user involvement. Using the Person-Based Approach,[31] which focuses on user perspectives and context, and working closely with our public involvement advisory panel, ensured that the priorities of pregnant people, stop smoking experts, and other key stakeholders were the focus of the intervention. Moreover, it allowed us to consider implementation issues from the outset, especially in terms of how the intervention would be delivered. Developing a shared understanding of the issues with people who will deliver and receive the intervention, and agreeing on key intervention content and components, helped to increase confidence in the decisions that were made about the intervention design.

However, a limitation in the intervention design was the tension between research needs and implementation in a real-world setting. This meant that a desired BCT (self-monitoring) was excluded from the intervention to minimize data collection bias in the subsequent trial to determine whether Baby, Me, & NRT is effective. Furthermore, reporting on the intervention development process prior to feasibility and optimization testing may mean, in practice, that some of the aspects might need modification. However, the involvement of users throughout the design process to improve acceptability and engagement should minimize this. Finally, the scope of this paper limits the generalisability of the findings to the immediate context of delivery within the larger study. However, it is hoped that the systematic and transparent reporting can help others who are developing complex interventions.

Conclusion

The development process generated a unique evidence- and theory-guided intervention, designed with pregnant people's and stop smoking experts' input, aimed at improving NRT adherence for smoking cessation in pregnancy. The prototype intervention comprised of adherence-enhancing behavioral support, plus tailored text messages, a website, and booklet. The intervention has since been optimized and feasibility tested through sequential cohort studies and is currently being tested in a randomized control trial.

Supplementary Material

A Contributorship Form detailing each author's specific involvement with this content, as well as any supplementary data, are available online at https://academic.oup.com/ntr

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Declaration of Interest

The authors declare no conflict of interest.

Data Availability

The anonymised data that support the findings of this study are available on request from the corresponding author, LM. The data are not publicly available due to ethics restrictions. Examples of intervention content are provided in the supplementary materials.

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