











Understanding pregnant women's adherence-related beliefs about Nicotine Replacement Therapy for smoking cessation: A qualitative study

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Introduction. Reducing smoking during pregnancy is a public health priority. Nicotine replacement therapy (NRT) is offered routinely to pregnant women who smoke in the United Kingdom. However, evidence of treatment efficacy in this population is weak, most likely due to poor adherence. Guided by the Necessity-Concerns Framework, we conducted a qualitative study to better understand pregnant women's perceived needs and concerns regarding NRT use, with consideration of combination NRT.

Methods. Semi-structured interviews were conducted by telephone with 18 pregnant or recently pregnant women in England and Wales, purposively sampled for different NRT-related experiences. Participants were recruited online via Facebook adverts and through a Stop Smoking Service. A hybrid approach of deductive and inductive thematic coding was used for analysis.

Results. Findings were organized around three themes: 1) the role of motivation to stop smoking; 2) necessity beliefs about using NRT; and 3) concerns about NRT. Some women reported fluctuating motivation for stopping smoking which undermined their NRT use. Others used NRT to cut down the number of cigarettes they smoked. Reasons for low NRT necessity beliefs included a preference for quitting unassisted, low or unrealistic expectations of efficacy, and overconfidence in achieving cessation (necessity testing). Concerns included safety, particularly around increased nicotine exposure with combination NRT, addictiveness, side effects, and capability to use.

Conclusion. Pregnant women have multiple necessity beliefs and concerns that influence their use of NRT. Targeting these, alongside increasing and maintaining motivation to quit smoking, will likely help optimize NRT use in pregnancy and improve quit rates.

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Statement of contribution

What is already known on this subject?

- Smoking during pregnancy is the largest avoidable cause of negative health outcomes for mothers and babies. Nicotine replacement therapy (NRT) is an effective cessation aid in the general population. However, there is uncertainty about whether it helps pregnant women to quit. One likely reason for this is that pregnant women do not adhere to treatment, meaning they use too little NRT or stop earlier than recommended. Qualitative methods can enable deeper understanding of the factors that influence pregnant women's adherence to NRT.

What does the study add?

- A theoretically informed understanding of pregnant women's adherence-related beliefs and concerns about using NRT for smoking cessation.
- Insight into the complex concerns pregnant women have about using combination NRT.
- Support for the theoretical predictions of the Necessity-Concerns Framework in that necessity beliefs and concerns are important factors in adherence to NRT in pregnancy; this can be used to develop interventions that target these determinates more effectively.
- Highlights the importance of sustaining motivation to quit smoking in enabling better NRT adherence in pregnancy.

Background

Smoking in pregnancy is the leading modifiable cause of adverse pregnancy and perinatal outcomes (Cnattingius, 2004). Globally, large numbers of pregnant women smoke, with rates highest in Europe and the Americas (Lange, Probst, Rehm, & Popova, 2018). In England, it is estimated that around one in ten women smoke during pregnancy (NHS Digital, 2019). Many women quit smoking in the first few days after discovering they are pregnant (Heil *et al.*, 2014; Solomon & Quinn, 2004), with almost half 'spontaneously quitting' before their first antenatal appointment (Hotham, Ali, White & Robinson, 2008). However, those who continue to smoke are often more dependent on nicotine (Riaz, Lewis, Naughton, & Ussher, 2018) and so find it particularly hard to quit.

Nicotine replacement therapy (NRT) is recommended in the current National Institute for Clinical Excellence and Health (NICE) guidance for pregnant women in England who are unable to quit smoking unassisted (NICE, 2010). However, while there is high-quality evidence that NRT is an effective cessation treatment in the general population (Hartmann-Boyce, Chepkin, Ye, Bullen, & Lancaster, 2018), evidence for NRT efficacy in pregnancy is less strong (Claire *et al.*, 2020). In trials enrolling pregnant smokers, those with comparable data revealed that only 7% to 29% reported finishing prescribed NRT courses (Claire *et al.*, 2020). One explanation for this is poor treatment adherence, meaning that pregnant women do not use enough NRT, use it incorrectly, or stop treatment prematurely. Increased nicotine metabolism in pregnancy, which might make the dose of nicotine in NRT less effective at ameliorating cravings, may partly help explain this poor adherence (Bowker, Lewis, Coleman, & Cooper, 2015; Dempsey, Jacob, & Benowitz, 2002).

Expert opinion is that using NRT in pregnancy is much safer than continuing to smoke (Bar-Zeev, Lim, Bonevski, Gruppetta, & Gould, 2018; Claire *et al.*, 2020) and, in England, it is standard practice to offer combination NRT (i.e., a nicotine patch combined with a fast-acting NRT product, such as the nicotine gum, inhalator, or lozenges). A recent survey in England found that 86% of smoking cessation services offered combination NRT in

pregnancy (Cooper *et al.*, 2019). Evidence among non-pregnant smokers shows that using combination NRT has greater efficacy than a single NRT product (Lindson *et al.*, 2019). Combination NRT may be particularly helpful for pregnant women given their increased nicotine metabolism. One observational study has found that use of combination NRT in pregnancy can increase the chances of successfully stopping smoking (Brose, McEwen, & West, 2013); however, further evidence of the incremental benefit of using combination NRT in pregnancy from randomized trials is needed.

The reasons why pregnant women do not use NRT as instructed are not fully understood. Quantitative research primarily provides contextual data (Fish *et al.*, 2009; Hotham, Gilbert, & Atkinson, 2006; Ussher & West, 2003; Vaz *et al.*, 2016). The few qualitative studies which have explored women's perceptions and behaviour related to NRT have highlighted that expectations around the use of NRT, safety concerns, and the experience of side effects are all potential issues (Ashwin & Watts, 2010; Bowker *et al.*, 2016). Additionally, pregnant women often use NRT in ineffective ways based on their fears about nicotine (Bowker *et al.*, 2016). However, none of these studies characterize findings using theory to understand the likely process of behaviour change, which is considered an integral step in the development of complex interventions (Craig *et al.*, 2008). Nor do they consider women's concerns and beliefs about using combination NRT.

Theory-informed evidence is needed to advance our understanding of NRT use in pregnancy and to guide interventions aimed at improving adherence. The present study draws on the Necessity-Concerns Framework (NCF) (Horne *et al.*, 2013; Horne & Weinman, 1999; Phillips, Diefenbach, Kronish, Negron, & Horowitz, 2014) to understand pregnant women's NRT adherence-related beliefs, with consideration of combination NRT. This framework proposes that an individual's adherence to prescribed medication is dependent on the relationship between two dimensions: beliefs about need for treatment (necessity beliefs) and concerns about using the treatment. If perceived need to use the medication outweighs concerns, then adherence is more likely. We chose to focus on how individual-level factors (i.e., cognitions and perceptions) might affect adherence to NRT since they are typically modifiable and therefore are most suited to targeting in behaviour change interventions.

Methods

Design

The research forms part of a multi-phase programme to develop and test a behavioural intervention to encourage pregnant women's adherence to combination NRT for smoking cessation, to ultimately be used in UK NHS Stop Smoking Service (SSS) support (Thomson *et al.*, 2018). The present study involved semi-structured telephone interviews. Ethical approval was obtained from the National Health Service (NHS) Ethics Committee (12/EM/0388). The manuscript follows the Consolidated Criteria for Reporting Qualitative Research (COREQ) guidelines (Tong, Sainsbury, & Craig, 2007).

Sampling and recruitment

A purposive sampling frame was developed to ensure inclusion of four different NRT-related experiences: having been offered NRT but not accepted it; accepted NRT but discontinued use prematurely; accepted NRT but concurrently smoked, or relapsed to smoking; and used/using NRT successfully. These categories were chosen in order to

provide insight into pregnant women's decisions about whether or not to use NRT, along with influences on both continued and optimal use. We recruited participants through targeted Facebook adverts and a Stop Smoking Service. The Facebook adverts contained a brief study description with an emphasis on the study being NHS research (see Appendix S1). A maximum £15 daily advertising budget was set. When the advert was clicked, women were redirected to an online registration form. Those who registered interest in the study were sent a participant information sheet electronically or by post and then contacted by telephone to have the study explained further. The total cost of recruitment via Facebook was £377.00.

For the face-to-face recruitment, Stop Smoking Practitioners from a service in the East Midlands region of England gave pregnant clients a participant information sheet and explained the study. If the client was interested in taking part, their contact details were securely sent to the first author to contact them. To take part in the study, women had to be 1) over 16 years old, 2) pregnant or have given birth in the last 6 months, 3) tried to quit smoking while pregnant, 4) offered NRT to help them quit (even if they decided not to use it), and 5) an English speaker.

Eighteen participants were recruited from 66 women who had registered interest to take part (15 out of 62 from the Facebook adverts, and 3 out of 4 from the SSS). Reasons for non-participation were as follows: 1) not meeting eligibility criteria (11); 2) unable to contact using details provided (20); 3) participant not answering for scheduled interview or attempts to contact thereafter (9); and 4) reached data saturation for NRT-related experience category (8). We attempted to ensure that we recruited a diverse sample within each of the purposive categories and continued recruitment until we judged that we had achieved data saturation, that is, no new issues or themes emerged.

Participant characteristics

Out of the eighteen participants (mean age: 30 years), 14 reported accepting NRT in their most recent pregnancy: Eight were offered combination NRT, with five accepting it straight away and one accepting it after a week of using a single NRT product. The remaining six who accepted NRT but had not been offered combination NRT had typically accessed NRT through a GP or hospital midwife. All participants recruited via the SSS were using NRT successfully, which is perhaps reflected in their continued engagement with the service. Participants were White (17) or mixed ethnicity (1) and mostly from more deprived backgrounds (12). Full participant characteristics are shown in Table 1.

Procedure

The interviews were conducted between April and August 2018 by LM (PhD) – a female qualitative researcher who has undertaken formal training in interviewing skills and qualitative data analysis. A flexible interview schedule was developed by LM with support from the research team and our Public Involvement Advisory Panel (see Appendix S2). This was guided by the NCF and explored participants' smoking histories, their perceptions of smoking in pregnancy, their concerns and necessity beliefs about using NRT, any other issues influencing their engagement and adherence, and preferences for support with using NRT. Participants were encouraged to talk at length and to raise issues they felt were important. This resulted in new questions to elicit clarification and to pursue emergent ideas raised by the participants, therefore reflecting an increased

Table 1. Participant characteristics

	Recruited Online (n = 15) n (%)	Recruited from a Stop Smoking Service (n = 3) n (%)	All (n = 18) n (%)
NRT experience			
Offered – not accepted	4 (27)	0(0)	4 (22)
Accepted – accepted but discontinued	4 (27)	0(0)	4 (22)
Accepted – relapsed/restarted smoking	4 (27)	0(0)	4 (22)
Accepted – using/used successfully	3 (20)	3 (100)	6 (33)
Age			
Under 25 years	4 (27)	0(0)	4 (22)
26 – 35 years	6 (40)	100 (3)	9 (50)
Over 35 years	5 (33)	0(0)	5 (28)
Ethnicity			
White British	1 (7)	2 (67)	16 (89)
White others	-	1 (33)	1 (6)
Mixed/multiple ethnic groups	1 (7)	0(0)	1 (6)
Pregnancy number			
First pregnancy	4 (47)	1 (33)	8 (44)
Gestational age			
First trimester (<14 weeks)	1 (7)	0(0)	1 (6)
Second trimester (14–27 weeks)	8 (47)	3 (100)	11 (61)
Third trimester (>27 weeks)	5 (33)	0(0)	5 (28)
Post-partum (≤6 month)	1 (7)	0(0)	1 (6)
IMD rank^a			
Less than median IMD rank	10 (67)	2 (67)	12 (67)
Past NRT use			
Used NRT before (any time)	10 (67)	1 (33)	11 (61)
Used NRT in a previous pregnancy	3 (13)	-	3 (17)
Offered combination NRT in pregnancy	5 (33)	3 (100)	8 (44)
Used combination NRT in pregnancy	4 (27)	2 (67)	6 (33)

Note. ^aEnglish Indices of Multiple Deprivation 2019 (Ministry of Housing Communities & Local Government, 2019).

understanding of the problem. An example of this was teasing out differences in perceptions between single versus combination NRT.

We obtained verbal consent at the beginning of the telephone interview and a hard copy was sent to the women afterwards, along with a £20 high street shopping voucher as a thank you for taking part. Interviews lasted 28–67 minutes, and were digitally recorded and transcribed verbatim. A written summary and reflective notes were also produced.

Analysis

We analysed the interview transcripts using the principles of thematic analysis (TA); this is a method for identifying and analysing common patterns (themes) within data (Braun & Clarke, 2006) and is widely used in health research. To begin, reflective notes were reviewed and transcripts carefully read for familiarization by LM. A hybrid coding approach was then used to develop themes systematically: 1) theory-driven and prior research-driven (deductive) and 2) data-driven (inductive) (Fereday & Muir-Cochrane,

2006). Initial deductive codes were identified from the interview schedule and constructs from the NCF (e.g., beliefs about smoking in pregnancy, beliefs about need to use NRT, and concerns about taking NRT). This was accompanied by a more exploratory approach, whereby the interview transcripts were broadly coded for any data relevant to NRT adherence. The codes were then grouped into themes, and this formed the basis for the final thematic framework, which was refined and agreed through several iterations by LM in discussion with RT and FN.

NVivo 11 software was used to sort the data into themes and subthemes. Case classifications were assigned based on NRT-related experience to allow for comparison. To ensure quality and rigour in the analytical process, the coding was independently reviewed by RT (PhD) in order to establish consistency. We did not return transcripts to participants for review, but our Public Involvement Advisory Panel was involved in the interpretation of the data. This gave first-hand insight during this process and enabled us to check whether the data resonated with their experiences (Birt, Scott, Cavers, Campbell, & Walter, 2016). Constant comparison was used throughout the analysis and when interpreting the findings in relation to other studies and relevant theory to help ensure internal validity (Boeije, 2002). The analytical write-up was reviewed by all authors, who are specialists in smoking cessation and behaviour change.

Results

The data describe women's necessity beliefs and concerns in relation to using NRT for smoking cessation in pregnancy. Representative quotations have been selected to illustrate key findings and bring transparency to the qualitative analysis. The results are presented under three main themes: 1) the role of motivation to stop smoking; 2) necessity beliefs about using NRT; and 3) concerns about NRT – and 10 subthemes (see Table 2). Quotes from participants are identified in the following manner: Participant 1 (P1), age, and NRT-related experience.

The role of motivation to stop smoking

Helping women to quit smoking in pregnancy involves two processes: motivating them to quit and enabling them to stop once they try. We found that the consistency and drivers of women's motivation to stop smoking may influence their NRT use but, equally, NRT use can potentially strengthen women's desire to quit.

Table 2. Themes and subthemes

Theme	Subthemes
The role of motivation to stop smoking	Fluctuating motivation to stop smoking undermines NRT use NRT use strengthening motivation to stop smoking
Necessity beliefs about using NRT	Weighing up need for NRT Expectations of NRT efficacy Necessity testing
Concerns about NRT	Safety in pregnancy Combination NRT Side effects Dependency on NRT Capability to use

Fluctuating motivation to stop smoking undermines NRT use

The majority of interviewees tried to quit smoking once they found out they were pregnant; a few tried to stop entirely but most started by cutting down the number of cigarettes that they smoked. Some women had strong intrinsic motivation to quit, such as beliefs about NRT harming their baby or concerns for their own health, which led them to seek out cessation support proactively. Others were motivated by social influences and the stigma associated with smoking in pregnancy. Conflict about quitting was common and, despite recognizing that smoking in pregnancy was harmful and harbouring feelings of guilt, a number of the women talked openly about the enjoyment value. In this context, accepting NRT showed an initial motivation to stop smoking, but attitudinal ambivalence or a lack of intrinsic motivation could undermine pregnant women's NRT use and quit attempts. This suggests that not all women who accept NRT are motivated to quit smoking or convinced NRT will help them.

I've tried nicotine replacements and, at the minute, it's just not working at all. But then I'm not sure if that's because part of me wants to and part of me doesn't [. . .] If people are nagging me to give up or saying 'right, you need to give up, you need to do this', your mind's not fully into it because you don't want to give up there and then. P1, 28yrs, started NRT but discontinued

Among those women who opted to use NRT, a few continued to smoke daily or on occasion. Smoking was often triggered by life events and stressors, and it was apparent that some women saw quitting as temporary. When they were struggling to use NRT or not finding it effective, returning to smoking felt almost inevitable and this seemed to lead them to think there was no point trying to stop.

I think I'm at the point now where I'm like 'Oh well I might as well every now and then' [smoke]. Because I know I probably will just go back to smoking once I've had the baby. P18, 24yrs, started NRT but discontinued

NRT use strengthening motivation to stop smoking

The relationship between motivation and NRT use was occasionally two-way; once a woman had started using NRT, this could increase her motivation to want to quit.

Once I'd got the product I was quite eager to – I was a bit more enthusiastic and a bit more eager to give it a try. And then when I didn't like it, I thought well I'm going to go back for something else because, you know, I was more like I want to do this thing more now, let's try this. P6, 39yrs, started NRT but discontinued

Necessity beliefs about using NRT

Generally, NRT was viewed positively by the women, even among those who did not think it was right for them. Necessity beliefs to use NRT were closely aligned with motivation to stop smoking but also incorporated other dimensions, such as weighing up the need for NRT, expectations about the helpfulness of NRT, and overconfidence in achieving cessation without it (necessity testing).

Weighing up need for NRT

A number of the women had experienced difficulty quitting without NRT and described needing something to 'take the edge off' their nicotine cravings. These women showed strong necessity beliefs towards using NRT.

It was because I'd tried to cut down on my own and I was like crying and everything. I was finding I was getting stressed out and things and I just couldn't – I knew I needed something to help us stop and I just couldn't do it on my own. P12, 36yrs, using NRT relapsed/restarted (including smoked alongside)

Those who believed that the effectiveness of NRT could be improved by using more nicotine rather than less were more likely to be open to the idea of using combination NRT:

I just thought the more the better really, like, if it's going to stop me from smoking - I'll try it!
P15, 26yrs, using/used NRT successfully

Contrary to this, some women thought it was better to quit without NRT, instead preferring to use 'just determination'. Typically, these women believed that quitting unassisted was the most effective method, a perception which was often combined with negative views about NRT. Perhaps more implicit in some explanations was a reluctance to access help or wanting to take charge of quitting themselves without continuing nicotine dependence. Yet sometimes it took a long time to quit this way, especially if there were setbacks due to nicotine withdrawal.

From what I understand it's like the nicotine's harmful as well [...] It made me think that for me that if I just set a date it could be easier. And I tried to set a date a few times and then ended up not working, so I ended up slowly cutting down. P5, 17yrs, offered NRT but did not accept it

Expectations of NRT efficacy

Women who had successfully used NRT in the past were more likely to want to use NRT again, while reporting that NRT was helping with a current quit attempt helped to reinforce necessity beliefs and encourage continued use.

You know cos I could literally feel myself not wanting nicotine, which was amazing - so that made a massive difference, rather than me seeming like I was constantly battling the cravings.
P7, 26yrs, using/used NRT successfully

However, when NRT had previously been ineffective or unpleasant, this could put women off using it or choosing that particular product again.

I said I was pregnant, 'do you smoke', 'yeah', 'do you want to give up', 'yes I really would like to' - however, previously to being pregnant I had tried the patch. That didn't work at all [...] it just didn't fulfil the craving. P3, 27yrs, offered NRT but did not accept it

The majority of women prioritized lay knowledge when evaluating whether or not to use NRT: If NRT had worked for family members or friends, even if they were not pregnant, this could persuade the women to give it try, whereas negative stories of failure

or unpleasant side effects had the opposite effect. The quote below highlights how such knowledge was often conflicting and how a woman may choose to listen to whatever best aligns with her quitting and NRT intentions at the time.

I mean, she smoked quite a bit and she had them [nicotine patches] on all day at work and she'd said that it sort of takes the edge off. So, yeah, that's why I tried them [. . .] but I didn't use them for a particularly long period of time. I think my problem is I hear things about things and then it puts me off, like I heard that they give you funny dreams. P4, 33yrs, started NRT but discontinued

A few women had unrealistic expectations of NRT and believed that it would make quitting easy or that it would simulate the feeling of smoking. When they discovered this was not the case, this could inhibit use.

I think I thought it would be quite easy, if you know what I mean? [. . .] like this magic thing that's just going to all of a sudden make me stop smoking. P6, 39yrs, started NRT but discontinued

Necessity testing

Necessity beliefs about NRT were often dynamic and could change over time. Some women stopped NRT prematurely because they had become overconfident and assumed it was no longer needed. Other women had accidentally gone without NRT, and when nicotine withdrawal or cravings appeared to be controlled, this would lead them to see whether they could avoid smoking without it. In both these scenarios, the women were testing their need for NRT – namely, 'necessity testing'. However, stopping NRT too soon could lead to relapse.

One day I forgot to put it on, but I didn't want a cigarette, so I thought 'oh I don't need this anymore' but I was wrong. P11, 23yrs, using NRT relapsed/restarted (including smoked alongside)

Concerns about NRT

Various concerns about using NRT in pregnancy were expressed, relating to safety, side effects, addictiveness, and capability to use. For some women, these concerns intensified in relation to using combination NRT.

Safety in pregnancy

Women who declined NRT, discontinued use prematurely, or minimized their NRT intake often had concerns about the effects of nicotine exposure during pregnancy. Some felt that using any form of nicotine might increase the risk of health problems for their developing baby, while a minority were uncertain about whether NRT could be used in pregnancy. For some women, the negative image of nicotine was very apparent: '*I guess nicotine is still nicotine whatever you're using*' (P3, 27yrs, offered NRT but did not accept it). The majority of women, however, believed that NRT was less harmful to their health than smoking, or at least no more, but this perception still meant it came with risks: for example, that the addictive nature of nicotine still made it 'harmful' (see Dependence on NRT).

Often the women weighed up the risks and benefits of using NRT; even if they did not consider NRT to be completely safe, provided that it helped with cessation, it was seen as preferable to smoking cigarettes.

I was a bit dubious to be honest to start with about using nicotine replacement, 'cause obviously, you're still putting a chemical in your body which is still going to be absorbed by your child. But I sort of weighed it up with my partner and we thought well it's better than the alternative. P7, 26yrs, using/used NRT successfully

Some women had been advised by a health professional or Stop Smoking Practitioner not to smoke and use NRT at the same time. This resulted in varied interpretations, such as them delaying using the nicotine patch in the morning or removing it temporarily in order to have a cigarette.

At the weekend, I tend to go 'I'll just have one on a morning and then I'll put my patch on.' P12, 36yrs, using NRT relapsed/restarted (including smoked alongside)

Two key aspects played a role in minimizing the women's safety concerns: 1) that NRT is prescribed on the NHS and has been for many years; and 2) evidence of safety and effectiveness provided by health care practitioners.

I guess with something that the NHS is offering you, you know that surely that stuff's been tested and researched and there's a lot more – you feel a lot more confidence I guess in that respect that it's safer. P4, 33yrs, started NRT discontinued

So like I was really worried that it was going to harm the baby that was my main concern but all their research they gave me and then my little bit of research helped prove that it doesn't affect the baby. P9, 30yrs, using/used NRT successfully

Combination NRT

Some women worried about receiving more nicotine from NRT than they would have done from cigarettes, while others expressed concerns about getting 'too much nicotine' from using two NRT products together and decided to only use one.

I don't think I'd use both at the same time because it would be too much wouldn't it? [...] You don't know what's going to happen with too much nicotine. P10, 43yrs, using NRT relapsed/restarted (including smoked alongside)

A few women were more positive about using two products, especially if this helped to reduce cigarette cravings and increase the likelihood of them quitting.

I was OK about that because I thought I'm going to be getting – she explained that I'd be getting a constant feed with the patch so that would help with my cravings, but then if I had an urge to have a cigarette, rather than have a cigarette have a [nicotine] mint, which has really helped. P14, 31yrs, using/used NRT successfully

Side effects

Many of the women described a range of issues and side effects that they had experienced and/or heard about from others. Not only did the women feel this could discourage others from starting NRT, but it was also a common reason for not using NRT as instructed or

discontinuing use. Some women appeared to confuse NRT side effects with nicotine withdrawal or pregnancy-related symptoms, which led them to use less NRT or stop altogether. One participant described how useful it had been to have this explained by her Stop Smoking Practitioner.

Yeah, the only thing I find in pregnancy, which was a bit tricky, is a lot of the NRT symptoms are pregnancy symptoms, so I was a bit like is this a symptom from the pregnancy or from the patch? So I think if that was explained to people as well, like, don't panic, it might not necessarily be the patch or your NRT, it could just be your pregnancy. And that was nice to know because it was a bit reassuring. . . P14, 31yrs, using/used NRT successfully

Dependence on NRT

Some women expressed concerns about becoming addicted to NRT, in that they did not see NRT use as 'quitting' but rather substituting one source of nicotine for another and believed that they might be more likely to return to smoking post-partum.

Well I think, I feel like for me going from like cigarettes to nicotine replacement therapy would just mean that I was still addicted to cigarettes, I was just finding another way to get them. And then I feel like I'd be more inclined then to start cigarettes again. P5, 17yrs, offered NRT but did not accept it

With combination NRT, a few women minimized use of their fast-acting product because they did not want to become dependent on it or increase their nicotine dependence.

I don't want to become reliant on it [gum], you know, like I would use it only in an emergency. P8, 29yrs, using NRT relapsed/restarted (including smoked alongside)

Capability to use

The majority of women in this study recalled being given clear instructions on how to use NRT, particularly those who had accessed NRT through a Stop Smoking Service. However, some women were concerned about NRT dosage or the duration of treatment and so did not use it properly. A few women experienced practical issues using NRT which resulted in them not using NRT regularly; for example, forgetting to put a patch on in the morning or not having a short-acting product with them at all times.

I'm quite forgetful so I would just forget and kind of go back to smoking some days without even thinking and then I'd be like 'Oh I haven't even used something today'. P18, 24yrs, started NRT but discontinued

Setting up routines or reminders was one strategy used to overcome this. Concerns about access to NRT to ensure an adequate supply, compared with the ease of access to cigarettes, were also concerns for some women.

Discussion

This study highlights how women's beliefs about needing NRT to quit smoking in pregnancy and their concerns about using it might influence NRT adherence. The qualitative research design has generated new insights into the types of necessity beliefs

(quitting preferences, expectations of efficacy, and necessity testing) and concerns (safety, addictiveness, side effects, and capability to use) which are particularly relevant to pregnant women. These beliefs and attitudes seemed to intensify for combination NRT. The findings also revealed that NRT use is at least in part explained by women's motivation to quit smoking.

To our knowledge, no other study has used the Necessity-Concerns Framework in the context of smoking cessation in pregnancy. It has successfully been used to predict medication non-adherence for a number of chronic diseases (Horne *et al.*, 2013), whereby people who are persuaded of the necessity of their medication and have their concerns allayed are more likely to use their medication as directed. These cognitions are open to influence, and any change in these beliefs can in turn lead to changes in adherence (Schüz *et al.*, 2011). Unlike many diseases or conditions, however, smoking is a behaviour which provides physical and psychological rewards despite its harmful consequences. Moreover, people can be physically or emotionally dependent on cigarettes and many link smoking with certain activities, making the habit hard to break. Consistent motivation to stop smoking has therefore been suggested as a key variable in driving and sustaining attempts to quit (Perski, Herd, Brown, & West, 2018). Our findings highlight that this is likely connected with NRT adherence too; even when the pregnant women accepted NRT and appeared generally motivated to quit, sometimes their motivation was in flux, which could undermine NRT use. This was particularly apparent for women who appeared to accept NRT because of the pressure to stop smoking (i.e., extrinsic motivation) rather than the decision coming from within themselves (i.e., intrinsic motivation); this issue is particularly relevant for pregnant women. This finding supports research on the importance of intrinsic motivation for smoking cessation in pregnancy (Curry, McBride, Grothaus, Lando, & Pirie, 2001) and suggests that continued emphasis on the benefits of smoking cessation could indirectly facilitate adherence to NRT.

The fact that some pregnant women continued to smoke while using NRT points to the fact that knowledge of the smoking health risks alone is rarely enough to contribute to behaviour change. In a previous study, Bowker *et al.* reported that many women used NRT to cut down the number of cigarettes they smoked rather than to stop smoking (Bowker *et al.*, 2016). We similarly found that some women were not ready to give up smoking, while others had planned to quit but found NRT did not sufficiently ameliorate cigarette cravings or lacked the necessary willpower to quit smoking. Most notably, there were women who had been advised not to smoke and use NRT at the same time, resulting in them delaying use or temporarily stopping NRT in order to smoke. This is perhaps an example of where precautionary or inconsistent approaches by health care professionals could be compromising the effectiveness of a treatment.

This study identified a number of modifiable beliefs and concerns that could be targeted at an individual level to promote better use of NRT in pregnancy. For example, increasing confidence in NRT as a quitting aid or alleviating concerns about NRT addiction could facilitate women's initiation and continued use of NRT. In an effort to make sense of what can often be conflicting advice about how best to quit smoking in pregnancy (Herberts & Sykes, 2012), the women often made their own common-sense judgements, seemingly giving preference to personal observation over professional or evidence-based knowledge when it came to usage and efficacy. This concept is known as 'lay epidemiology' (Davison, Smith, & Frankel, 1991) and has previously been used as a way to explain why some initiatives designed to reduce smoking fail (Lawlor, Frankel, Shaw, Ebrahim, & Smith, 2003). Efforts to improve adherence to NRT in pregnancy may require further consideration of appropriate sources for different information, making evidence-

based information readily available and perhaps involving real-life testimonies or peer support to promote cessation as a way to engage with these lay knowledge values.

We also found that some women were keen to try stopping NRT prematurely if they thought they might no longer need it (necessity testing). Although not expressed explicitly, it seems likely that necessity testing might be intensified by a desire to minimize medication use in pregnancy. This mimics women's cessation of other prescription drugs during pregnancy without consulting health care professionals, for example asthma inhalers (Enriquez *et al.*, 2006) and antiepileptic drugs (Williams *et al.*, 2002). Health care practitioners should encourage women to use NRT for the recommended 8-12 weeks minimum, regardless of whether they feel like they need to use it. Establishing realistic expectations of what NRT can and cannot do might also reduce any frustrations or disappointment that can lead to its early discontinuation.

Many of the concerns raised about using NRT are similar to those found in previous studies, which have suggested some women believe that NRT might cause harm to their baby or increase their nicotine intake and dependence (Ashwin & Watts, 2010; Bowker *et al.*, 2016). Importantly, we found that some women reported heightened harm concerns when it came to using combination NRT in relation to getting 'too much nicotine' or more nicotine than they would otherwise have got from cigarettes. Such beliefs often endured despite knowledge that nicotine was not the harmful substance in cigarettes, arguably because of fears about increasing nicotine dependence or greater doses of nicotine being delivered to their unborn baby. However, NRT delivers a lower nicotine dose than smoking (Hickson *et al.*, 2019); RCTs have shown no demonstrable harm from NRT (Claire *et al.*, 2020) and the only RCT of NRT in pregnancy to report infant outcomes found better infant development at two years of age in those whose mothers used active NRT in pregnancy compared to a placebo (Cooper *et al.*, 2014). Interventions aimed at increasing adherence to NRT in pregnancy must recognize that women have specific concerns about using combination NRT and that these concerns are often multifaceted.

The findings showed that some women had practical concerns, such as remembering to use NRT, that could lead to unintentional non-adherence, while women's confidence in their knowledge of how to use NRT could also impact on its use. Research looking at NRT adherence in the general population found that a lack of procedural knowledge about NRT was likely to result in avoidable side effects and reduced effectiveness (Herbec, Tombor, Shahab, & West, 2018). Given that side effects or other product issues were reported to make it difficult to continue NRT use, it is important to help women manage these issues and be able to distinguish between NRT side effects and nicotine withdrawal symptoms as the latter may signal that more NRT is needed.

Recognizing the challenges in supporting pregnant women to stop smoking, the UK National Centre for Smoking Cessation and Training (NCSCCT) recently updated its 'Standard Treatment Programme for Pregnant Women' which now encourages Stop Smoking Practitioners to address misunderstandings about the safety of NRT and its importance in helping pregnant women to quit. However, there are still a number of opportunities to optimize NRT support, including specific messages to address women's common concerns and suboptimal usage.

Implications for future intervention development

The study identified a range of opportunities to enhance adherence to NRT in pregnancy which could be addressed as part of an intervention. These are summarized in Box 1.

Box 1 Implications of findings for future intervention development

- Even when women accept NRT and appear motivated to quit, ambivalence and uncertainties about stopping smoking can undermine NRT use. Continued focus on the negative health effects of smoking and enabling women to relate these to their personal situations therefore need to accompany NRT-specific support. Moreover, provision of NRT should be accompanied by an exploration about women's motivation, beliefs, and concerns irrespective of how readily they accept it.
 - Women often smoke alongside using NRT, but advice about this is currently inconsistent and confusing. Education around the dangers of smoking any amount during pregnancy is needed, along with clear and consistent advice about how NRT should be used during a smoking slip or longer lapse.
 - Some women had low expectations of the benefit of NRT, either because of personal experience or word of mouth. Discussing the reasons why NRT might not have been effective previously or for others (e.g., increased nicotine metabolism in pregnancy and the importance of following the recommended regime), along with promoting positive real-life testimonies, might encourage women to start and continue with NRT. Women should be strongly advised to use combination NRT from the start and explained why.
 - Anxieties about NRT safety and nicotine exposure can inhibit use, especially in the case of combination NRT. A number of steps can be taken to address these concerns: 1) reinforce that NRT is licensed for use in pregnancy and prescribed by the NHS, 2) explore and give women opportunity to discuss any concerns they might have, and 3) ensure that health professionals provide women with consistent, evidence-based information on the safety and effectiveness of NRT.
 - Some women felt that NRT was another potentially addictive substance or that they might increase their nicotine dependence by taking higher NRT doses or combination NRT. This is unlikely, given that the nicotine in NRT is delivered to the brain much more slowly than when smoking. The fact that NRT very rarely leads to dependence needs to be reinforced when NRT is provided.
 - Remembering to use NRT regularly was an issue for some women. Encouraging women to set up routines and reminders, along with providing extra supplies of short-acting products so that they can have it with them at all times, might help to address this unintentional non-adherence.
 - Equipping pregnant women with the right knowledge about their recommended NRT regime, especially combination NRT, is essential; otherwise, they may use it incorrectly and not get the maximum benefit. Moreover, women should be told upfront to use NRT for a minimum of 8-12 weeks but also that it can be used throughout pregnancy if needed.
 - Side effects and other issues were a key reason for NRT discontinuation. Managing expectations about side effects, providing tips for dealing with them, and helping women to distinguish between nicotine withdrawal, pregnancy-related symptoms, and NRT side effects could help women to continue using NRT.
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Strengths and limitations

A key strength is that this was a theory-informed qualitative study using the NCF, which can support health care professionals in targeting beliefs that form the basis of patients' attitudes about their medication and decisions on whether or not to take it. Both deductive and inductive coding were used for the analysis. This enabled us to examine the relevance of existing theory but also to identify new ideas emerging from the data. The recruitment method both ensured good representation from low socio-economic groups who are less likely to take part in research, and also reached women who might be disengaged from SSS (i.e., those who had not accepted NRT and those who had stopped using it). Indeed, compared to women recruited via Facebook, those recruited via the SSS all had ongoing engagement with the service which suggests that they were motivated towards quitting smoking and using NRT.

The main limitation of this study is that it only reports on individual-level barriers to adherence, and it is well recognized that some of the barriers to medication adherence are external to the patient, such as social support and health care system factors (Osterberg & Blaschke, 2005). There was also a reliance on telephone, rather than face-to-face interviews. This latter is a feature of the fact that pregnant women who smoke are hard to reach in terms of research and we wanted to recruit from across England and Wales. While it is more challenging to develop rapport with participants over the phone, this approach was found to be a good method when discussing topics of a potentially sensitive nature (Sturges & Hanrahan, 2004). Participants were primarily from a White British background, and because the sampling frame was designed to reflect different NRT-related experiences, there were small numbers within each group. Therefore, generalizations from this study should be made with caution. Moreover, while it appeared that the women received mixed support this was not directly observable by the researcher.

Conclusions

This study found that even when women are willing to accept NRT, their motivation to quit smoking may be in flux, which can undermine its use. Pregnant women have multiple necessity beliefs and concerns that can positively or negatively influence use of NRT. These beliefs and concerns often intensify for combination NRT, which is offered as standard in England. Interventions to support optimal adherence to NRT in pregnant women are likely to be more effective if they help to overcome these attitudinal and informational barriers to NRT use, while amplifying positive beliefs about NRT. Further research is required to identify optimal modalities for delivering support messages that enhance pregnant women's adherence to NRT.

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Author contribution

T.C., F.N., S.C., and L.B. conceived the study and acquired funding. T.C., F.N., S.C., L.M., and R.T. contributed to the methodology. L.M. and R.T. participated in the investigation, performed formal analysis, administered the project, and wrote the original draft of the manuscript. L.M., R.T., J.E., F.N., T.C, S.C., L.B., and L.P. wrote, reviewed, and edited the manuscript. T.C., F.N., and S.C. supervised the study.

Conflicts of interest

The authors declare no conflict of interest.

Data availability statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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Supporting Information

The following supporting information may be found in the online edition of the article:

Appendix S1. Facebook advert.

Appendix S2. Interview topic guide.