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Smoking Relapse Prevention – Abstinence, Relapse, Current Practice and Effective Interventions

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Published works submitted to the University of Nottingham

for the degree of Doctor of Philosophy

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STATEMENT OF CONTRIBUTION TO PUBLISHED WORKS

I hereby certify that I was the main researcher and author on all five of the papers submitted, being responsible for leading each project, performing the majority of data extraction, analysis preparation of the manuscripts, submission and responding to reviewers' comments, and re-writing as appropriate.

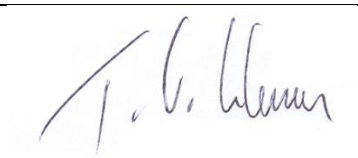
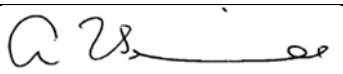
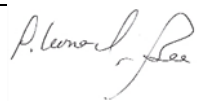
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- Turner JT wrote the first draft of paper 4
- Leonardi-Bee J provided statistical support on Papers 3 and 5
- McNeill A and Coleman T provided overall guidance and direction on all five submitted papers

Signed **Date 23/06/2016**



I hereby confirm that I agree with the above statement:

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Coleman T		16th September 2016
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Turner J		10th July 2016

Summary

Smoking remains a major cause of morbidity and mortality. In 2013/2014, 454,700 hospital admissions in the UK amongst persons 35 years and over were estimated to be attributable to smoking. This accounts for 4 per cent of all hospital admissions in this age group. In 2013, 17% (78,200) of all deaths in adults aged 35 and over were estimated to be caused by smoking[1]. Reducing smoking therefore, remains a major priority for governments and health systems like the UK National Health Service (NHS). Following the publication of the Government's White Paper, Smoking Kills[2] in 1998, a comprehensive tobacco control strategy was implemented. This strategy was aimed at reducing uptake of smoking and increasing quitting among existing smokers, and involved a combination of population tobacco control interventions (such as price rises, an advertising ban and smoke-free legislation) combined with treatment for dependent smokers through the NHS.

A Tobacco Control Plan for England was also produced in 2011 which explained the government's strategy to reduce smoking through the new public health system[3]. This plan outlined commitments to implement legislation to end display of tobacco in shops, to encourage smokers to quit and remaining quit by using effective forms of support and implementing a policy of using tax to maintain the high price of tobacco.

Effective forms of support may be behavioural, pharmacological or a combination of both[3]. In the UK, support is often delivered by stop smoking services (SSS), although smokers, who wish to, may obtain smoking cessation medication from their GP[4]. These SSS have been shown to be cost-effective, but the majority, 85% of smokers attending the services, have relapsed by one year.

The nature of nicotine addiction means that smoking is a chronic relapsing condition[5], with many smokers unable to sustain abstinence. Smoking relapse rates can be extremely high (up to 90% in the first 3 months)[6], and only 3%-5% of unsupported/untreated quitters maintain their quit attempt for 6 months or longer[7]. This high relapse rate reflects the addictive nature of cigarette smoking and underscores the importance of finding effective relapse prevention interventions for use in routine practice, which can be delivered alongside or after acute cessation has ended. There is no universally accepted definition of what interventions to prevent relapse to smoking (relapse prevention interventions - RPIs) should comprise; many smoking cessation programmes simply modify the content of existing, cessation-orientated support and deliver these as relapse prevention[8]. The paucity of information regarding provision of smoking relapse prevention is in contrast to the wide availability of evidence for the use of acute cessation treatments which has grown rapidly over recent decades. A variety of effective treatments now exist which can increase

the chances of stopping smoking up to fourfold compared with no support[9], but research suggests that relapse prevention interventions and treatments are not as widely known or even used.

At the time the research was conceived, there was very little information about the effectiveness of RPIs. A number of studies had investigated effectiveness of behavioural support, pharmacotherapies, and combination treatments, as forms of relapse prevention or maintenance treatment, and one Cochrane Review[8] found no evidence for the effectiveness of behavioural RPIs, but this may have been because the review combined smoking outcomes obtained at different follow-up time points after quitting and this may have obscured real effects of RPIs. The review found insufficient evidence for the effectiveness of extended treatment with bupropion and weak evidence for the effectiveness of nicotine replacement therapy for relapse prevention. There was, therefore, a need to examine current literature and synthesize data from a wide variety of studies, using a different approach from that used in the Cochrane Review to enhance interpretation of findings.

In addition to ascertaining whether or not RPIs are effective, there was also a need to explore feasibility of provision within local Smoking Cessation Services. No study had explored feasibility of provision of RPIs within Stop Smoking Services, and whether these interventions would be acceptable to smokers trying to quit, mainly because the use of relapse prevention interventions in a local smoking cessation service was not only relatively new and unproven, there was also no information regarding smokers' perceptions of relapse prevention interventions

Abstinence and relapse during a quit process is still poorly understood, especially relapse after the use of a smoking cessation aid. A few studies had investigated patterns of relapse and abstinence in smokers who quit smoking unaided and two reviews[7 10] found that the majority of relapse occurred in the first two weeks of starting a quit attempt. The majority of smokers who wish to quit smoking use some form of evidence-based treatment. It was therefore important to explore patterns of relapse in smokers who have attempted to quit smoking with the aid of a smoking cessation treatment.

The work presented here is for the degree of PhD by publication and is based upon five publications in high quality peer-reviewed journals between 2009 and 2015. I am the lead author on four of the included papers and the final and corresponding author on one paper. The research forms a coherent body of work informing the evidence base on smoking relapse prevention interventions (RPIs). This has contributed to the evidence base around four key aspects of smoking relapse prevention: knowledge, views and beliefs, effectiveness of smoking relapse prevention

interventions, feasibility of delivery of RPIs within UK Stop Smoking Services, and abstinence and relapse patterns amongst smokers who quit smoking with the aid of a pharmacological smoking cessation treatment. Systematic reviews, meta-analysis, quantitative research and qualitative research were used to generate the data which supported the exploration of the four themes outlined below.

Specifically, the published works have identified:

- Knowledge, Understanding, Views and Beliefs: there was no shared understanding of what relapse prevention meant to Stop Smoking Service professionals or the kinds of interventions that should be used for this, but a willingness to provide such treatments was apparent. *(Agboola SA, Coleman, T and McNeill, A. (2009). Relapse prevention in UK Stop Smoking Services: a qualitative study of health professionals' views and beliefs. BMC Health Services Research. **9**:67* and *Agboola SA, Coleman TJ, Leonardi-Bee J, McEwen A and McNeill A (2010). Provision of relapse prevention interventions in UK NHS Stop Smoking Services: a survey. BMC Health Services Research 1**0**:214)*

- Effectiveness of smoking relapse prevention interventions: A pooled analysis of randomized controlled trials of nicotine replacement therapy, bupropion and varenicline showed that these interventions are effective for relapse prevention. A meta-analysis of four studies of nicotine replacement therapy found that smokers who used NRT for relapse prevention were 1.56 times more likely to remain abstinent at six months follow-up compared to placebo (95% confidence interval 1.16 to 2.11). A pooled analysis of four studies of bupropion showed evidence for effectiveness at long-term follow-up (12 to 18 months) with an odds ratio of 1.49 (95% confidence interval 1.10 to 2.01). A single study of varenicline also demonstrated evidence for effectiveness for relapse prevention. *(Agboola S, McNeill A, Coleman T and Leonardi-Bee, J (2010). A systematic review of the effectiveness of smoking relapse prevention interventions for abstinent smokers. Addiction **105**, 1362–1380)* This was the first time that RPIs had been proven effective, and now that there appeared to be evidence of efficacy, it was appropriate to investigate feasibility of introducing these into routine clinical practice (next study).

- Feasibility of delivering relapse prevention: A study investigating the feasibility, uptake and acceptability of offering nicotine replacement therapy (NRT) as a relapse prevention

intervention (RPI) within UK Stop Smoking Services, showed that NRT can be added to existing treatment protocols, and that of 260 SSS clients who were eligible and offered this intervention, 44% (95% confidence interval 38% to 50%) accepted the offer. *(Turner JT, McNeill A, Coleman T, Leonardi-Bee J and Agboola S. (2013) Feasibility of offering nicotine replacement therapy as a relapse prevention treatment in routine smoking cessation services. BMC Health Services Research **13**:38)*

- Abstinence and relapse patterns: A pooled analysis of 19 trials of varenicline showed that varenicline recruits smokers into abstinence following the target quit date to a greater extent than placebo (point prevalence abstinence increased from 32% [95% confidence interval 25% to 40%] in week two to 54% [95% confidence interval 48% to 61%] in week 12). A higher immediate relapse rate following varenicline treatment discontinuation was also observed, which implied that there would be smokers who would benefit from a longer course of treatment. (*Agboola S, Coleman T, McNeill A and Leonardi-Bee J. (2015). Abstinence and relapse among smokers who use varenicline in a quit attempt—a pooled analysis of randomized controlled trials. Addiction **110**, 1182–1193)*

The five papers included in this submission have been widely cited (Appendix 1), reflecting a substantial contribution to the field, and have produced new knowledge in the form of a greater awareness of the types of smoking relapse prevention interventions that may be incorporated into existing treatment protocols. More importantly, this work has identified key lines of enquiry for future research and for policy makers.

The document contains eight chapters, structured as follows:

Chapter 1 presents an introduction, describes the author's role in the production and publication of the submitted papers, contextualizes the published works and reviews previous research in an extended abstract. This section also discusses methods used, analyses and main findings and relates these to previous and new research.

Chapter 2 discusses methodological considerations and provides a detailed critical analysis of the methods used and the information they provide.

Chapters 3 to 7 present each of the published papers as they appear in the journals in which they were printed and each paper includes results and analysis sections.

Chapter 8 summarises contributions to knowledge and highlights priorities for future research.

Chapter 1 Extended Abstract

1.1 Introduction

Models and Theories of smoking relapse/prevention

Several learning-based theories have been examined to account for the problem of smoking relapse, including conditioned withdrawal, conditioned compensatory responding, appetitive motivational models, and social learning theories[11]. This section will begin with a consideration of three models that underpin relapse; each emphasizing some unique features relevant to the study of smoking relapse, and will include a critical evaluation of the dominant model underpinning this thesis.

Three models of relapse that have been examined in relation to addictive disorders are the Cognitive/Behavioural model by Marlatt & Gordon[12], the Person-Situation Inter-actional model by Litman[13] and the Cognitive Appraisals model by Sanchez-Craig[14]. The models differ in the extent to which the focus is on the person, the situation, and/or their interaction[15].

The Person-Situational Inter-actional model by Litman[13] posits that relapse is a process that takes place within the individual and involves an interaction between: a perceived threatening (or high-risk) situation, the coping skills available to the individual, and the perceived effectiveness and appropriateness of these coping skills to the threatening situation. Relapse is most likely to occur in situations in which the individual feels that he/she lacks the coping skills with which to handle the situation. There is some overlap in the constructs between Marlatt's cognitive-behavioural and Littman's person-situational models in the sense that both approaches focus on the person and the situation. A combination of how an individual perceives his/her ability to cope with a risk situation and the individual's coping skills repertoire often determine the occurrence of relapse.

The second model (Cognitive Appraisals) is that proposed by Sanchez-Craig[14], which suggests that an individual's perception and interpretation of a situation are more influential in determining relapse than the situation itself. Individuals may appraise the situation as positive, negative or neutral, and respond accordingly. These appraisals are subject to change and are affected by the perceived availability of effective coping strategies to deal with the situation. This model is different from that proposed by Marlatt and Litman in that it is based primarily on the smoker's appraisal of the situation and ignores the reality that a smoker's interpretation of situations which lead to relapse may be flawed. The focus of this model on the individual's

perceptions of the high-risk situation also ignores the important role of critical situations and triggers that eventually lead to relapse.

The Cognitive-Behavioural model by Marlatt is one of the most frequently used models of relapse prevention and underpins the work presented in this thesis[16]. Although this model was developed over three decades ago, it produced key concepts which have continued to be used in the relapse prevention field today. Marlatt's relapse prevention model is an empirically-based, cognitive social learning theory explanation of the relapse process and incorporates both a conceptual model of relapse and a set of cognitive and behavioural strategies to prevent or limit relapse episodes. The model suggests that factors that precipitate relapse fall into two categories: immediate determinants (e.g. high-risk situations, coping skills, outcome expectancies, the abstinence violation effect) and covert antecedents (e.g., lifestyle factors and urges and cravings).

Immediate determinants

According to this model, high-risk situations frequently serve as the immediate precipitators of initial smoking after a period of abstinence[17]. A person who has initiated a behaviour change, such as smoking abstinence, should begin experiencing increased self-efficacy or mastery over his or her behaviour, which should grow as he or she continues to maintain the change. Certain situations or events, however, can pose a threat to the person's sense of control and, consequently, precipitate a relapse crisis. Situations that can play a role in relapse episodes include negative emotional states (such as anger, anxiety, depression, frustration), interpersonal high-risk situations (including conflict and social pressure) and positive emotional states.

An individual's coping behaviour in a high-risk situation is a particularly crucial determinant of the likely outcome, and people who have coped successfully with high-risk situations are assumed to experience a heightened sense of self-efficacy[18].

Outcome expectancies describe situations in which the smoker focuses primarily on the anticipation of immediate gratification, such as stress reduction, neglecting possible delayed negative consequences.

The abstinence violation effect influences the progression of a lapse to a relapse. This reaction focuses on a smoker's emotional response to an initial lapse and on the causes to which he or she attributes the lapse.

Covert antecedents

Covert antecedents include lifestyle factors, such as overall stress level, as well as cognitive factors that may serve to "set up" a relapse, such as rationalization, denial, and desire for immediate gratification[17]. Marlatt and Gordon[12] have proposed that the covert antecedent most strongly related to relapse risk involves the degree of balance in the person's life between perceived external demands and internally fulfilling or enjoyable activities. The RP model also proposes that both urges and cravings are precipitated by psychological or environmental stimuli, which may, in turn, erode the client's commitment to maintaining abstinence as his or her desire for immediate gratification increases. This process may lead to a relapse setup or increase the client's vulnerability to unanticipated high-risk situations.

Marlatt's model also incorporates numerous specific and global intervention strategies that allow therapist and smoker to address each step of the relapse process. Relapse prevention approaches based on the Marlatt's model begin with an assessment of the environmental and emotional characteristics of situations that are potentially associated with relapse (i.e. high-risk situations). This assessment is combined with an assessment of the smoker's response to these high-risk situations, and a strategy is devised to target weaknesses in the smoker's cognitive and behavioural repertoire and thereby reduce the risk of relapse.

Several studies have evaluated the reliability and predictive validity of Marlatt's model, and the efficacy of treatment techniques based on this model. Lowman et al[19] evaluated the reliability of raters' categorizations of high-risk situations using Marlatt's taxonomy, and assessed whether a prior situation could predict future lapse episodes. The findings from this study indicate that the original relapse taxonomy of the RP model has only moderate inter-rater reliability at the highest level of specificity, although reliability of the more general categories (e.g. negative affect and social pressure) was better. The model's predictive validity was also considered modest. Marlatt's model has also been criticized for the hierarchical classification of relapse factors[20], and newer psychological models of relapse/relapse prevention have been explored. Noteworthy is the approach by Witkiewitz and Marlatt[21] which allows for several configurations of distal and proximal relapse risks. Distal risks are defined as stable predispositions that increase an individual's vulnerability to lapse, whereas proximal risks are immediate precipitants that actualize the statistical probability of a lapse. This dynamic model of relapse acknowledges the complexity and unpredictable nature of substance use behaviour, and in this case, tobacco smoking addiction, following a commitment to abstinence, and allows clinicians and smoking cessation specialists the flexibility to design and tailor strategies to suit varying individual needs.

On the other hand, Miller et al found that Marlatt's model, applied to the manner in which people coped with high-risk situations, strongly predicted subsequent relapse or continued abstinence. The results of Miller and colleagues also support the role of the abstinence violation effect in predicting which participants would experience a full-blown relapse following an initial lapse. Another review of the literature on relapse precipitants also concluded that considerable support exists for the notion that an abstinence violation effect can precipitate a relapse[22]. Research findings[23-25] support both the overall model of the relapse process and the effectiveness of treatment strategies based on the model.

1.1.1 Process and predictors of smoking relapse

Smoking relapse after quitting is common[26], and frequent and multiple quit attempts are often needed before permanent abstinence is achieved[27]. Whilst the focus in smoking cessation is to assist the smoker to stop smoking in the first place, relapse prevention is directed more toward long-term maintenance of this change. Too often, these two aims are confused, because important distinctions between initial treatment and long-term maintenance of abstinence are not made[12]. Acute cessation treatments continue to be accompanied by high relapse rates, and such outcomes underscore the frequent recommendations that smoking researchers intensify their focus on interventions aimed at extending, rather than just producing abstinence[12].

Considerable variation remains in the operational definitions of smoking relapse and there is no universally accepted description. Piasecki[28] describes relapse as a period of several days or more of continuous smoking after a period of abstinence or an attempt at abstinence. The Russell Standard's definition of relapse is smoking more than five cigarettes after the quit attempt[29]. In randomized and non-randomized studies of smoking cessation and relapse prevention, relapse is often defined using either a dichotomous, point prevalence measure of whether a person has smoked at all (even one puff) in the past week, or a continuous abstinence criterion that requires that a quitter be totally abstinent from smoking from the target quit date until the follow-up end point to be counted as a treatment success[28].

Marlatt[12] describes relapse as a process rather than a discrete irreversible event. He distinguishes between initial post-cessation drug use, termed a "lapse," and full return to regular drug use, termed a "relapse." A lapse is likely to occur when an individual is in a high-risk situation, usually characterized by negative affect, interpersonal conflict, or social pressure. The probability of initial drug use should decrease if the individual is able to execute an effective

coping response. According to Marlatt, a person's cognitive/affective reaction to a lapse is a potent determinant of subsequent drug use.

The process of relapse is often determined by multiple factors that interact in a non-linear manner, leading to a relapse event[12]. Yong et al[30] found that relapse occurred sooner amongst younger smokers, those with many smoking colleagues, smokers with a history of schizophrenia and those who attended fewer smoking cessation programmes. There are also multiple psychological and treatment factors that influence the progression from lapse to full relapse[31]. Gokbayrak et al[32] examined static and dynamic variables to discern predictors of smoking relapse, and also found that participants aged 25-64 compared to those aged 18-24 were less likely to relapse. Not being in a treatment group or a cessation programme doubled the odds of relapsing at follow-up[32].

There is also evidence that relapsers tend to relapse not only due to smoking addiction severity, but also due to immediate precursor factors such as emotional distress[33]. Abstinence effects that play a central role in withdrawal from nicotine (anger, depression, craving, appetite, confusion and tension) have all been postulated to increase the risk of relapse following a quit attempt[34]. In particular, increases in anger, depressed mood, and craving following a quit attempt are significantly associated with a shorter time to relapse, and are significant predictors of a higher rate of relapse[34].

Other factors which have been shown to increase risk of relapse include lower educational level, higher baseline nicotine dependence, social smoking cues, recently failed quit attempt, cessation related sleep disturbance, anxiety and depression[35].

A cluster analysis of relapse situations describes an empirically derived multi-variate taxonomy of smoking relapse episodes[36]. The study categorizes the occurrence of relapse crises into four different situational clusters – Social situations, Relaxation, Work and Emotional upset. The researchers found that crises occurring in Social situations were significantly more likely to result in smoking relapse than those occurring in any other cluster, and Upset situations resulted in significantly more smoking relapse than crises in Relaxation situations.

The data on coping and relapse across the clusters suggest that Social situations may be particularly potent precipitants of relapse. Even when the effects of coping are controlled statistically, social situations are associated with significantly more smoking than the others. Subjects in each of the clusters were also compared on demographic and smoking history data. There were no differences among the clusters in sex, amount smoked, or number of years

smoked. There were no differences in cluster membership between subjects who had received formal treatment for smoking and those quitting on their own.

Smoking cessation medication use (NRT or bupropion) at the time a quit attempt is made is protective against relapse[37]. Use of other methods or smoking cessation/relapse prevention aids have also demonstrated a positive influence, including formal behaviour support programmes and social support[38].

Survival studies have identified that the highest relapse risk, on average, is in the first 2 weeks after a quit attempt. However, there is considerable between-individual and within-individual variability in risk-related symptom pattern[28]. Relapse prevention interventions may therefore be most effective if provided at the time of greatest relapse risk, given the multifaceted and individualised nature of withdrawal and environmentally induced relapse risks over time.

1.1.2 Smoking relapse prevention

Relapse Prevention (RP) may be described as a "self-control programme designed to teach individuals who are trying to change behaviour how to anticipate and cope with the problem of relapse", and may also include extended treatment with pharmacotherapy[12]. Smoking relapse prevention is considered to apply to interventions or programmes that explicitly seek to reduce relapse rates after an acute treatment phase is successfully completed, or at some time after the quit date of a self-quit attempt[3]. Some authors have argued that there is no clear definition of a relapse prevention intervention as distinct from an extended cessation treatment. This is because, in principle, resumption of smoking at any time after the quit date can count as relapse. The approach that is often adopted, therefore, is to consider as relapse prevention those interventions that are designated as such, or where there is extended treatment after what would be the normal treatment duration[8].

Frequently, treatment techniques are primarily geared toward producing cessation of smoking. What is often overlooked with this focus on initial cessation during the treatment phase is that relapse prevention or the maintenance of change, once it has been induced, may be governed by entirely different principles than those that are associated with initial cessation. Some of the principles that guide the relapse prevention approach include the need for motivated smokers to develop coping skills to manage high-risk situations, the recognition that lifestyle changes are essential, and the need to anticipate and prepare for lapses so that they do not lead to

relapse[39]. These principles have been derived from an examination of the theory of relapse prevention.

Relapse is by far the most likely outcome of any smoking cessation attempt, even those made with the benefit of intensive psychosocial treatment and pharmacotherapy. Several acute cessation aids, programmes and treatments have been delivered for extended periods in a bid to prevent relapse[8]. These programmes are often designed to address the triggers and situations that may lead to relapse, and teach motivated smokers ways by which such triggers and situations can be avoided or managed. There is evidence that some of these programmes and interventions prevent relapse and help the smoker to remain quit from smoking. Pharmacotherapies and some behavioural treatments have shown promise, but there is still scope for further research into definitive relapse prevention treatments.

1.1.3 Stop Smoking Services

One of the papers included in this submission reports findings from a feasibility study conducted within a Stop Smoking Service setting. This section therefore provides some background information.

In 1998 the UK government published a white paper entitled "Smoking Kills," outlining its plans to reduce the massive toll of death and disease in the country caused by smoking[2]. One innovative component of these plans was establishing a national network of Stop Smoking Services to ensure that every smoker in the country who wanted help with stopping would have access to evidence-based support[40]. Stop Smoking Services therefore represent a unique national initiative to provide support for smokers motivated to quit[40]. The service provision framework used by the smoking cessation clinics was originally based on an evidence-based approach to treating dependent smokers[41]. A recent systematic review examined the effectiveness of NHS Stop Smoking Services, and findings suggest that they provide effective support for smokers who want to quit[42]. The services have had an increasing impact in helping smokers to stop in their first 10 years of operation, and have successfully reached disadvantaged groups[43].

The Stop Smoking Services in England operate under local direction. Until 2013, this was through 151 primary care trusts; since April 2013, it has been through local authorities[43]. Each local area can configure its service as it sees fit, but is encouraged to follow national guidance[44]. Services

are expected to offer behavioural support and medication to all smokers in their community, and also to ensure that they are treating smokers proportionally to the demographics in their area. The services are free to users. A small prescription charge for medications is payable; people on low incomes, over 60 years of age, or pregnant/postpartum and patients with certain medical conditions are exempt[43].

From the outset, each local Stop Smoking Service has been required to submit quarterly data to the Department of Health on numbers of quit dates set (throughput), end of treatment abstinence rates (four weeks after the target quit date), characteristics of smokers using the services, and type of treatment provided[1]. These data provide a resource for evaluating the Stop Smoking Services and for examining trends over time. Whilst the services have so far been proven to be successful at achieving initial cessation, research from numerous randomized controlled trials and cohort studies show that 70% of people who access the service and are abstinent at four weeks will relapse by 12 months[45] and up to 35% of those remaining will relapse after that. There is currently very limited evidence on the impact of the services on smoking relapse prevention, but relapse prevention treatment may be an important development for Stop Smoking Services[46].

1.1.4 Published papers

This PhD submission is based upon five publications in peer-reviewed journals. The papers represent a coherent body of work and are derived mainly from a Health Technology Assessment funded research programme that was established to assess current practice, potential effectiveness and cost effectiveness of smoking RPIs. The papers emerging from the project are listed below, and my individual role in undertaking the research and writing is also described. Of the five papers included in this submission, I am first and corresponding author on four of these papers and last author and corresponding author on one of them. With respect to all five papers, a statement has been provided from each of the joint authors acknowledging my contribution (above).

Paper 1:

Shade A Agboola, Tim J Coleman and Ann D McNeill
Relapse prevention in UK Stop Smoking Services: a qualitative study of health professionals' views and beliefs. BMC Health Services Research 2009, 9:67

My role:

- Lead and corresponding author
- Contributed to the design of the interview guide
- Conducted all the interviews
- Transcribed all the interviews
- Conducted all the analysis with support from co-authors
- Wrote the first draft of the paper
- Responded to all requests for major and minor revisions from peer reviewers
- Re-wrote the final draft following revisions and comments from peer reviewers

Paper 2:

Shade A Agboola, Tim J Coleman, Jo A Leonardi-Bee, Andy McEwen and Ann D McNeill. Provision of relapse prevention interventions in UK NHS Stop Smoking Services: a survey
BMC Health Services Research 2010, 10:214 (Agboola 2010a)

My role:

- Lead and corresponding author
- Contributed to design of the survey questionnaire
- Administered the questionnaire using survey monkey (REF)
- Followed up non-responders
- Collated responses
- Analysed responses
- Wrote first draft of paper
- Responded to all requests for revisions from peer reviewers
- Re-wrote the final draft following revisions and comments from peer reviewers and co-authors

Paper 3:

Shade Agboola, Ann McNeill, Tim Coleman and Jo Leonardi Bee. A systematic review of the effectiveness of smoking relapse prevention interventions for abstinent smokers. Addiction 2010 105, 1362–1380 (Agboola 2010b)

My role:

- Lead and corresponding author
- Selected studies for inclusion or exclusion using pre-specified inclusion criteria
- Extracted data in conjunction with a second author
- Designed method of analysis and analysed study data
- Wrote first draft of paper
- Responded to all requests for revision from peer reviewers
- Re-wrote the final draft following revisions and comments from peer reviewers and co-authors

Paper 4:

Jessica Turner, Ann McNeill, Tim Coleman, Jo Leonardi Bee, **Shade Agboola.** Feasibility of offering nicotine replacement therapy as a relapse prevention treatment in routine smoking cessation services. BMC Health Services Research 2013, 13:38

My role:

- Designed the study, completed application for funding, sought and received ethical approval
- Designed the questionnaires and interview guides for the study
- Led research team, conducted half of the interviews
- Analysed responses
- Contributed to analysis and interpretation
- Last and corresponding author – responded to all requests for revisions from peer reviewers
- Re-wrote the final draft following revisions and comments from peer reviewers and co-authors

Paper 5:

Abstinence and relapse amongst smokers who use varenicline in a quit attempt – a pooled analysis of randomized controlled trials. **Shade Agboola**, Ann McNeill, Tim Coleman, Jo Leonardi-Bee Addiction (2015) 110: 1182–1193

My role:

- Lead and corresponding author
- Identified studies for inclusion in conjunction with co-author
- Completed data extraction and analysis
- Wrote the first draft of the paper
- Responded to all requests for revisions from peer reviewers
- Re-wrote the final draft following revisions and comments from peer reviewers and co-authors

1.1.5 Aims

The overall aim of the published papers presented in this thesis was to determine the nature of relapse, and current practice, effectiveness and feasibility of provision of relapse prevention interventions in the UK.

The more specific aims of each paper were as follows:

Papers 1 and 2 (Chapter 3 and 4)

Rationale: There had been no attempt to obtain the views of Stop Smoking Service professionals to fully understand and explore current provision and experiences of Stop Smoking Service advisors. We therefore surveyed SSS practitioners and obtained their views to achieve the following:

Aims:

i. To describe and categorize RPIs that are currently used within Smoking Cessation Services

ii. To explore knowledge and attitudes to the provision of relapse prevention

iii. To ascertain barriers to the trialling or introduction of RPIs within current clinical practice

Paper 3 (Chapter 5)

Rationale: A Cochrane Review published before this paper was produced did not find evidence for effectiveness of any RPI.

Aim: To update estimates of effectiveness in the Cochrane Review[8] on interventions for preventing relapse to smoking, altering analysis methods, as appropriate, to enhance interpretation of findings.

Paper 4 (Chapter 6)

Rationale: There had been no study prior to the publication of this paper that had explored feasibility of provision of RPIs within Stop Smoking Services

Aim: To determine the feasibility and acceptability of providing relapse prevention interventions in routine practice.

Paper 5 (Chapter 7)

Rationale: Abstinence and relapse patterns had previously been explored using systematic review methodology in smokers who had quit unaided[7].

Aim: To determine abstinence patterns and relapse curves in smokers who have used a specific smoking cessation treatment – varenicline.

1.2 Contextualization of Published Works

This section of the submission contextualizes the published works and highlights their original contribution to knowledge. It also includes descriptions and review and synthesis of previous research, where applicable. The five papers included in this submission are based on four distinct but linked themes within the overall submission, and these are presented in a logical and progressive manner. The first theme explores what was known at the time about smoking RPIs within current practice in the UK, and is based on two published papers[47 48]. The second theme explores the evidence for effectiveness of these interventions using systematic review methodology[49]. The third theme investigates the feasibility and acceptability of provision of an RPI identified as effective from the systematic review[50], and the final theme considers the nature of abstinence and relapse amongst smokers who have used evidence-based smoking cessation treatment[51]. The themes and relevant papers are considered in turn:

1.2.1 Research theme 1 - Knowledge, Understanding, Views and Beliefs of smoking cessation health professionals:

Objectives

1. Describe and categorise RPIs that are currently used within SSS
2. Explore knowledge and attitudes of Stop Smoking Service professionals to the provision of relapse prevention
3. Ascertain barriers to the trialling or introduction of RPIs within current clinical practice

Overview

This section of the document is based on two publications:

Submitted paper 1:

Shade A Agboola, Tim J Coleman and Ann D McNeill
Relapse prevention in UK Stop Smoking Services: a qualitative study of health professionals' views and beliefs. *BMC Health Services Research* 2009, 9:67

Submitted paper 2:

Shade A Agboola, Tim J Coleman, Jo A Leonardi-Bee, Andy McEwen and Ann D McNeill. Provision of relapse prevention interventions in UK NHS Stop Smoking Services: a survey
BMC Health Services Research 2010, 10:214 (Agboola 2010a)

The two studies examined current practice of relapse prevention provision in UK Stop Smoking Services. Agboola et al (2009)[48] explored the views, knowledge and understanding

of health professionals working in UK SSS, and also their experiences of providing RPIs in clinical practice. Agboola et al (2010a)[47] aimed to quantify the current provision of relapse prevention interventions within Stop Smoking Services in the UK and ascertain the feasibility of introducing them to services where they were not currently provided.

Both papers included in this section examined practice in the UK context only. In the UK, reducing smoking prevalence is a key local public health priority and a national focus. The tobacco control plan for England (2010-2015)[52] outlined three national ambitions to focus tobacco control work across the whole system, one of which was to "reduce smoking prevalence amongst adults in England from 21.2% in 2010 to 18.5% by the end of 2015". The plan recognized that, whilst NHS SSS are not the main driver for reducing smoking prevalence, they form part of wider action in reducing smoking prevalence and sit within an overall tobacco control programme.

NHS SSS were set up in 1999[45] to offer evidence-based treatment to smokers wanting to stop, in recognition of the fact that many smokers needed such support, and although these services have been shown to be effective and cost-effective[53], relapse is still the most common outcome for those using them. This may be because, presently, Stop Smoking Services operate an "abrupt quit" model where a smoker sets a quit date and is expected to have stopped smoking completely from that date onwards. Whilst this form of quitting may be effective in the short term, there is evidence that the majority of smokers need longer-term support and relapse prevention. Effective stop smoking commissioning considers the entire pathway that smokers follow, starting with service promotion and engagement, providing support to quit, and ongoing support and relapse prevention, and concluding with follow-up and re-engagement. The services offer flexible treatment, which usually involves the most effective combination of individual or group behavioural therapy, backed-up by the offer of smoking cessation medications, such as nicotine replacement therapy (NRT), bupropion and varenicline[9]. Services are required to offer, for at least 4 weeks after smokers' quit dates, these effective treatments, and are also encouraged to monitor longer-term success at one year, but many services find such monitoring difficult in practice[36]. The focus on delivering short-term quitters may deter services from offering relapse prevention treatments.

Services are encouraged to provide a treatment programme that includes, but is not limited to[54]:

- Building rapport and boosting motivation throughout
- Assessing and confirming current readiness and ability to quit
- Informing clients about the treatment programme
- Assessing current smoking behaviour
- Assessing past history of quit attempts
- Relapse prevention

Interventions may be delivered via one-to-one sessions, proactive telephone support, text-based support, open (rolling) groups, reactive telephone support, online and drop-in sessions[54]. It is recommended that all interventions are delivered by National Centre for Smoking Cessation and Training (NCSCT) certified practitioners. Practitioners are also expected to assess the smokers' level of nicotine dependence and measure smoking status at follow-up visits using carbon monoxide monitoring.

Whilst relapse prevention is listed in the National Centre for Smoking Cessation and Training's (NCSCT) service delivery guidance[54] as part of the core treatment offered to all smokers that access support, the guidance acknowledges that there is very little guidance on effective relapse prevention. What is starkly clear is that the recommended model of service delivery lacks detailed information and guidance about targeted relapse prevention. The high relapse rates observed after initial smoking cessation treatment ceases underscores the need for effective relapse prevention interventions.

Review of previous research

A number of studies have explored the views of smoking cessation professionals as they pertain to provision of support for specific groups. For example, the challenges of provision of acute cessation support in pregnant women[55], smokers with mental illnesses[56], minority ethnic groups[57] and young smokers have all been explored in depth. The studies included in this submission were the first of their kind to explore smoking cessation professionals' experiences and beliefs about providing RPIs for smokers. There is no previous research on this topic from the UK and internationally, and the World Health Organization report on the global tobacco epidemic[58] provides no information on the provision of relapse prevention interventions. At the time of publication, there were no studies which described the views of smoking cessation advisors or other healthcare professionals on the provision of relapse prevention interventions in routine clinical practice.

Methods used and findings

Health professionals working in UK Stop Smoking Services attending a UK smoking cessation conference in 2007 were asked to indicate their willingness to be interviewed at a later date on relapse prevention, and 23 professionals provided contact details. All 23 were emailed seven months after the conference, invited to re-confirm their willingness to take part and agree a convenient time to be interviewed. Non-respondents to the email were contacted via telephone two weeks later. A literature review identified issues of potential importance to RPIs and, using these, a semi-structured interview schedule, with prompts, was developed. Throughout interviews, open-ended questions were used to encourage participants to answer freely. I conducted these interviews via telephone in January and February 2008. Interviews covered the following subjects: knowledge and understanding of relapse prevention, types and duration of RPI provided, and barriers and challenges encountered. Each interview lasted 20–25 minutes and all were audio-taped and transcribed verbatim. Of the 23 individuals who had indicated their willingness to participate in the study, four could not be contacted, and three potential participants indicated that they no longer wished to participate, so a total of 16 interviews were conducted (12 with females). Fifteen interviewees were smoking cessation professionals who were also responsible for overseeing the day-to-day activities of their respective services or actively involved in managing one aspect of the service in which they worked, and one was a regional tobacco control lead.

The key finding from this qualitative study was that the sample of health professionals working in UK Stop Smoking Services did not appear to have a shared understanding of what interventions aimed at preventing relapse to smoking should encompass. Interviewees used their experiences to conceptualise relapse prevention, and their beliefs and understanding of this were often based on the kinds of support that services in which they worked offered as relapse prevention to clients. Interviewees believed that introducing relapse prevention support into NHS Stop Smoking Services would be hindered by current performance targets which are focussed on achieving short-term abstinence from smoking, following cessation treatment. There had been low uptake of RPIs in services which previously offered this, and interviewees were negative about introducing specific relapse prevention support (for example, additional, proactive telephone support counselling), but most were much more positive about the possibility of using pharmacotherapy for this purpose. The interviews also identified the pressure of meeting performance targets at the time, which required that SSS

services should treat at least 5% of their local population of smokers in the course of a year, with an expected success range of 35% – 70% at four weeks.

The survey of health professionals (Agboola 2010a) was completed in December 2008. An email with a flyer advertising the survey and a link to the survey homepage was sent out to a total of 185 managers. Non-respondents were followed up via a reminder email and telephone call inviting them to visit the survey homepage and complete the survey. Responses were anonymous and data were summarised descriptively using SPSS version 16.0 for Windows[59]. A total of 96 managers completed the survey (52% response rate). Fifty-four managers responded to the first survey email and completed the online questionnaire. A further 42 respondents completed the survey following the reminder email and telephone call.

More than half of respondents, 58.3% (n = 56) reported that their services currently provided relapse prevention interventions, with behavioural interventions being preferred over the pharmacotherapies (Table 1). Of those providing relapse prevention interventions, 60.7% (n = 34) stated that these were offered to abstinent smokers for as long as these clients perceived they required them, 25.0% (n = 14) for 3-6 months and one service (1.8%) did so for three months or less. Of the 40 services reporting that they did not currently provide relapse prevention interventions, 42.5% (n = 17) had provided such interventions in the past and cited the following reasons for no longer offering this kind of support: pressure to meet government targets, poor client attendance, inadequate funding, and a belief that relapse prevention interventions are not effective

What these studies added

The qualitative paper (Agboola 2009) showed that health professionals would be comfortable with the notion of delivering RPIs to abstinent smokers, but highlighted the need for a stronger evidence base for the effectiveness of RPIs. It also demonstrated that the introduction of RPIs into routine practice would be helped by the development of a clear definition on what relapse prevention is. Finally, it highlighted that, if relapse prevention support was to be provided by Stop Smoking Services, there would need to be a different approach to services performance management. Performance management targets were highlighted as a substantial barrier to the introduction of relapse prevention support in the UK National Health Service (NHS).

Stop Smoking Services are expected to use the four-week quit rate as a measure of successful quitting, and this may not be a good metric for supporting and facilitating relapse

prevention within local services. For example in October 2002, the English Department of Health (DH) stated an aim that 800,000 smokers would successfully quit following help from smoking cessation services by 2006[60] and this was subsequently translated into an aspiration that services should treat at least 5% of their local population of smokers in the course of a year, with an expected success range of 35% – 70% at four weeks[61]. For these targets, success involves smokers achieving a four-week period of abstinence, so there is considerable pressure on services to achieve a high throughput of smokers who manage to stop smoking for at least one month. The findings suggest that the provision of RPIs could not be a priority for services without a change in the targets against which they are measured.

The survey paper (Agboola 2010a) revealed that about half of the services surveyed reported providing relapse prevention interventions despite, at the time of the survey, there being only a weak evidence base for their effectiveness and no guidance as to whether or not this kind of support should be provided within the UK Stop Smoking Services. The relapse prevention interventions provided most frequently were telephone and individual behavioural counselling, although, at the time of the survey, there was no evidence for the effectiveness of these interventions. Many managers were positive about either offering relapse prevention interventions within the Stop Smoking Services or potentially introducing these in the future, and the most commonly cited reasons for not providing or wanting to provide these interventions were that: Stop Smoking Services' targets are focussed on achieving short periods of cessation by smokers and inadequate funding for relapse prevention support, rather than the relatively weak evidence base (at the time of survey completion) for the effectiveness of relapse prevention interventions.

Both studies demonstrated a lack of universally accepted descriptions of effective relapse prevention. It was clear that Stop Smoking Service professionals at the time did not have clear guidance on what constituted effective relapse prevention, and current practice was, at the time, unfortunately devoid of recommendations on relapse prevention delivery. Both studies underscored the need for clear guidance on RPIs and their provision within local SSS. The findings also emphasized the importance of developing a comprehensive and integrated approach to smoking cessation and relapse prevention that is underpinned by evidence and will result in maintenance of cessation (reductions in relapse rates)[62].

As mentioned above, there has been no study to date that has made a systematic attempt to identify knowledge, views and beliefs of health professionals as they relate to provision of

RPIs using qualitative and quantitative methodology. This research is the first to have contributed to this evidence base and has provided a foundation for subsequent research.

Both publications have been cited 13 times in the research literature, including in a systematic review and meta-analysis[63] and in two cost-effectiveness studies[64 65]. (Appendix 1)

1.2.2 Research theme 2 - Evidence for the effectiveness of RPIs

Objective

To carry out a systematic review of the effectiveness of relapse prevention interventions (RPIs) among abstinent smokers who had completed an initial course of treatment or who had abstained unassisted, pooling only outcome data from similar follow-up time points.

Overview

This section of the document is based on one publication:

> *Submitted paper 3*
>
> **Shade Agboola,** Ann McNeill, Tim Coleman and Jo Leonardi Bee Addiction 2010 (Agboola 2010b). A systematic review of the effectiveness of smoking relapse prevention interventions for abstinent smokers. Addiction **105**, 1362–1380 (Agboola 2010b)

Smoking relapse after quitting is common[26], and frequent and multiple quit attempts are needed before permanent abstinence is achieved[27]. Whilst the focus in smoking cessation is to assist the smoker to stop smoking in the first place, relapse prevention is directed more toward long-term maintenance of this change. Too often, these two aims are confused, because important distinctions between initial treatment and long-range maintenance are not made clear[12]. Acute cessation treatments continue to be plagued by high relapse rates, and such outcomes underscore the frequent recommendations that smoking researchers intensify their focus on interventions aimed at extending, rather than producing, abstinence[12].

Acute cessation treatment and relapse prevention are therefore two conceptually distinct processes. Attempting to design and evaluate strategies to prevent relapse and/or to provide assistance for those who do relapse is of crucial importance in reducing the overall prevalence of smoking in the population, and, as a consequence, reducing rates of disease, death and cost due to smoking[66].

Smoking relapse prevention is considered to apply to interventions or programmes that explicitly seek to reduce relapse rates after an acute treatment phase is successfully completed, or at some time after the quit date of a self-quit attempt[3]. Some authors have argued that there is no clear definition of a relapse prevention intervention as distinct from an extended cessation treatment. This is because, in principle, resumption of smoking at any time after the quit date can count as relapse. The approach that is often adopted, therefore, is to consider as relapse prevention those interventions that are designated as such, or where there is extended treatment after what would be the normal treatment duration[8].

Review of previous research

Individual trials and systematic reviews have explored the effectiveness of a wide range of interventions for relapse prevention. These are categorized as either behavioural or pharmacological interventions.

Behavioural interventions

Four commonly used behavioural interventions include minimal clinical intervention, such as brief advice from a healthcare worker[67], and more intensive interventions, including individual counselling, group counselling and telephone counselling. These four interventions have been investigated for their impact on relapse prevention with widely varying quit rates. For example, two trials[68 69] examined the efficacy of group and individual behavioural sessions and brief advice on smoking relapse rates, and found these interventions did not have any impact. On the other hand, three studies that looked at the effectiveness of computer generated advice letters for relapse prevention[70], the effectiveness of mails and telephone follow-up for relapse prevention[71], and the effectiveness of a minimal behavioural intervention to prevent relapse[72] all found no evidence for the impact of these interventions on relapse rates.

Pharmacological interventions

Nicotine replacement therapy[73], bupropion[74], varenicline[75], and rimonabant[76] are pharmacotherapies that have been investigated for their impact on relapse. Nearly all studies that have explored the effect of pharmacotherapies for relapse prevention report a positive intervention effect, with abstinence at six and 12 months significantly higher than placebo comparisons.

Combination treatments

Combined behavioural and pharmacological treatments have been investigated for their impact on relapse[77]. These therapies operate by different mechanisms, and therefore complementary and potentially additive effects may be expected. Three mechanisms have been suggested to account for improved efficacy observed with combined therapies[78]. These are: enhanced compliance with treatment interventions; independent effects on different outcome targets (pharmacological withdrawal relief versus behavioural coping skills training); and independent effects on different populations - some people benefit from pharmacotherapy and others from behaviour[79]. It is not clear, however, whether the lower relapse rates observed in smokers who have received a combination of pharmacotherapy and behavioural support is simply a carry-over from improved early treatment success. There is evidence, nonetheless, that smokers who received ongoing behavioural support in addition to pharmacotherapy after they had quit had slower rates of relapse compared to those who received no additional counselling[80].

A Cochrane Review, published in 2009[81], found no evidence for the effectiveness of any specific type of relapse prevention intervention, but also noted that there was only a small evidence base from which this conclusion was drawn. Most of the trials included in the review tested interventions which taught smokers the skills to identify situations that may increase their risk of relapsing, and provided them with cognitive and behavioural strategies for coping with these. More intensive RPIs were usually delivered face to face, and less intensive ones involved briefer, minimal contact or self-help versions of these 'skills-equipping' interventions. As included trials involved a variety of relapse prevention interventions delivered to smokers with varied characteristics both before and after quit attempts, a pooled estimate for the general effectiveness of these interventions was not available at the time, and instead review authors pooled analyses for trials in subgroups where comparisons were valid.

The method of combining outcome data in the Cochrane Review[8] could, potentially, have obscured real effects of RPIs. The review pooled smoking status at final follow-up, resulting in data collected at different times after randomization being aggregated, thus potentially yielding clinically heterogeneous comparisons.

Methods used and findings

The paper used a similar search strategy to the Cochrane Review, but extracted and synthesized data from similar follow-up time-points only. Randomized controlled trials in which the participants had either quit smoking on their own (unassisted abstainers), undergone enforced abstinence from smoking or had enrolled in smoking cessation treatment programmes (assisted abstainers) were included. Any interventions (pharmacotherapy or otherwise) which were reported by the investigator of the trial as intended to prevent relapse to smoking were included. Comparators were either no intervention, a comparable intervention given for a shorter period, or an intervention not orientated towards relapse prevention. All trials that reported at least six months follow-up from randomization to the last follow-up reported were included. The primary outcome for this review was either continuous or point prevalence abstinence from smoking. A meta-analysis was performed to calculate a weighted intervention effect across trials using a random effect (DerSimonian and Laird) model. The results were expressed as pooled odds ratios (OR) with 95% confidence intervals (CI). Numbers needed to treat (NNT) for additional beneficial outcomes were calculated using pooled baseline event rates, where significant comparisons were seen. Statistical heterogeneity was assessed using I^2[12]. The follow-up time closest to one month from randomization (permitted range 1–3 months) was used for short-term follow-up, closest to six months (range 6–9 months) was used for medium-term follow-up, and closest to 12 months (range 12–18 months) for long-term follow-up. In pregnant/postpartum women, abstinence was also reported at delivery or the last follow-up prior to delivery.

Thirty-six studies were deemed eligible and included in the review. Meta-analysis of four studies of nicotine replacement therapy found that smokers who used NRT for relapse prevention were 1.56 times more likely to remain abstinent at six months follow-up compared to placebo (95% confidence interval 1.16 to 2.11). A pooled analysis of four studies of bupropion showed evidence for effectiveness at long-term follow-up (12 to 18 months) with an odds ratio of 1.49 (95% confidence interval 1.10 to 2.01). A single study of varenicline also demonstrated evidence for effectiveness for relapse prevention. Self-help materials also showed promise and may also be effective for those smokers who have achieved abstinence without any support. Combinations of bupropion and NRT failed to show evidence of an effect.

What this study added

This research has significantly contributed to the knowledge base on the effectiveness of smoking relapse prevention interventions and the results need to be viewed in the context of both clinical and statistical significance. The review produced new knowledge on the effectiveness of RPIs at clearly defined follow-up points and demonstrates that pharmacotherapy relapse prevention interventions are effective in persons who have achieved initial abstinence. Indeed, the updated 2014 Service and Delivery Guidance for Local Stop Smoking Services[54] acknowledges that extended use of varenicline may be helpful. An older version of the same guidance[82] (published in 2011) had stated that there was at the time little evidence for the effectiveness of any relapse prevention. This demonstrates the impact this research has had on recommendations for Smoking Cessation Service practice.

I used a similar search strategy to the Cochrane Review, but synthesized data from similar follow-up time-points only. In addition, in contrast to the Cochrane Reviews, which investigated the impact of RPIs delivered to abstinent and non-abstinent smokers, I restricted analyses to studies involving RPIs delivered only to abstinent smokers to try to emulate how RPIs would be implemented in practice, such as by the NHS SSS.

The Cochrane Review was updated in 2013[8], and the authors used the same methods that they had used in the 2009 review, but included a greater number of trials. The findings were, again, less straightforward, and the length of abstinence prior to the start of RPI treatments appeared to influence their effectiveness. For example, the review included two large NRT trials, in which participants were abstinent for only 24 and 48 hours prior to starting RPIs, found NRT effective for relapse prevention, but two smaller ones with much longer abstinence prior to randomization did not. Meta-analyses of bupropion trials found that this did not work for relapse prevention, whereas the one trial which tested varenicline found it effective. The conflicting findings from both Cochrane Reviews underscored the need for a consistent approach to pooling data within meta-analyses.

The method of combining population groups and outcome data has produced findings which would not have been obvious had I replicated the methods used in the Cochrane Review, thereby reducing methodological heterogeneity which might otherwise have obscured the real effects of interventions. The Cochrane Review combined studies with outcomes between six months and 24 months. This may have contributed to a less statistically powerful meta-analysis in the Cochrane Review.

My review pooled outcome data at different follow-up points, based on the recognition that relapse at three months is quite different from relapse at one year. The findings have been cited in studies of smoking relapse in specific groups of smokers. For example, the study by Cather et al (2013)[83] cited this review and highlighted the applicability of its findings to the management of smoking relapse in smokers with schizophrenia.

Another study by Niaura et al (2012)[84] cited Agboola et al (2010b) in reference to effective interventions for smokers living with HIV/AIDS. In addition, this paper has been cited 91 times (Appendix 1), which further underscores the impact this published work has had in the field of smoking relapse prevention.

1.2.3 Research theme 3 - Feasibility and acceptability of provision of NRT as a relapse prevention intervention

Objective

To investigate the uptake, feasibility and acceptability of offering extended courses of NRT as a relapse prevention intervention to recently abstinent quitters

Overview

This section of the document is based on one publication:

> *Submitted paper 4*
>
> Jessica Turner, Ann McNeill, Tim Coleman, Jo Leonardi Bee and **Shade Agboola**
> Feasibility of offering nicotine replacement therapy as a relapse prevention treatment in routine smoking cessation services.
> *BMC Health Services Research 2013, 13:38*

The paper included in this section examined the feasibility and acceptability to smokers of relapse prevention interventions within a Stop Smoking Service context. Feasibility of provision was investigated at a time when two main reviews of effectiveness of smoking relapse prevention interventions had been published[8 49], one of which is included in this submission (Agboola et al 2010[49]). Both reviews found some evidence for the short-term effectiveness of relapse prevention. The aim of the feasibility study was therefore to identify the uptake and acceptability of longer courses of treatment identified as effective for relapse prevention within the UK SSS setting, especially as there was evidence from the survey of health professionals working in Stop Smoking Services that clients may not accept RPIs that involve using medications for prolonged periods.

The feasibility study investigated the uptake, feasibility and acceptability of offering extended courses of NRT as a relapse prevention intervention to recently abstinent quitters, who had been helped to achieve abstinence in Stop Smoking Services located across the city of Nottingham. The decision to explore the feasibility of only NRT was based on evidence for its effectiveness as a relapse prevention treatment as identified from a previous review[49].

Review of previous research

Previous research has explored the feasibility of introducing a behavioural RPI into routine care[85]. This study found that a text message based RPI was easy to implement within SSS by trained advisors, and 94% of eligible participants enrolled. The intervention was also well received by clients and staff of the SSS. Our study was the first to attempt to quantify the potential demand for a pharmacological relapse prevention treatment within routine Smoking Cessation Services. Very little was known at the time about smokers' attitudes to pharmacological relapse prevention and whether smokers would be willing to use these for relapse prevention.

Methods used and findings

Eligible clients were those who had used NRT for their acute cessation treatment and consented to receive extended NRT therapy for up to 12 weeks. Those enrolled completed a baseline questionnaire, which sought their views on using the additional NRT treatment. We also sought permission to conduct follow-up at six months for those clients who did not wish to receive extended NRT therapy; these participants were also given a short questionnaire asking about reasons for declining participation.

Individuals who agreed to receive an extended course of NRT were issued with a four-week supply of the same NRT product that they had used for acute cessation, and they were asked to return in one month for a further four-weeks' supply to be provided by a cessation adviser, contingent on their continued abstinence from smoking (defined as not having smoked more than five cigarettes in the last month, with five or fewer cigarettes being defined as lapses and an expired air carbon monoxide (CO) measurement of <8 ppm). At six-months follow-up, participants provided information on smoking status, and completed questionnaires asking about the difficulty and acceptability they perceived in using NRT for an extended period NRT, and any side effects experienced.

A selection of participants were also interviewed. Interviews explored smoking history, experience of using NRT, the effectiveness of treatment, concerns about taking treatment,

consideration of other treatments (specifically bupropion and varenicline) and the optimum way of accessing NRT for RPI.

Of 493 recent quitters seen in the study clinics, 260 were eligible for the offer of relapse prevention treatment, and 44% of this number who had achieved cessation using NRT and SSS support accepted an offer of extended treatment with NRT; of these 41% continued using NRT for 12 weeks, which suggested that there would be a reasonable demand for RPIs (at least among those using NRT for acute cessation) if they were to be routinely offered by NHS SSS. Interviews with a selection of clients indicated that participants were generally satisfied with the RPI that they had received, welcoming both the extension of NRT supplies and the continuing contact with the NHS SSS advisors, and there were few concerns about the extended use of NRT.

What this study added

This study demonstrates that, with the support of the NHS SSS staff, a RPI involving NRT can be added to existing treatment protocols, and that around half of eligible smokers are likely to request it. This contrasts with the reported perception of likely low demand for RPIs that has previously been articulated by some SSS staff[48], although these perceptions were largely based on the variable experiences of providing non-evidence based, largely non-pharmacological RPIs in SSS. The acceptance rate of the RPI offered in this study, in contrast to these negative views, suggests that using extended courses of NRT is acceptable to SSS clients.

The study also highlighted the importance of specialist Stop Smoking Service advisor support in delivering the RPI. The majority of interview participants perceived that the SSS advisor support was extremely important for practical advice and motivational support, both in the initial cessation period and in the prolonged relapse prevention stage. Participants also suggested that the support they received from these specialist advisors contributed positively to their willingness to take up the offer of relapse prevention. Subsequent research has shown that people who receive support to stop smoking from a specialist appear to be at lower risk of relapse than those receiving support from a non-specialist advisor[86].

The study also showed that individuals who accepted the offer of NRT for relapse prevention were significantly more likely to pay for prescriptions, which may suggest that these individuals were more motivated to quit as they were willing to invest in the quitting process. Payment for prescriptions is a marker of socio-economic status in the UK and

patients on low incomes are exempted from the prescription charge[87]. Whilst there have been inconsistent findings on whether motivation to engage with smoking cessation treatment differs by socio-economic status[88], our findings dispel the assumption that smokers will only engage with treatment services if they are completely free.

1.2.4 Research theme 4 - Abstinence and relapse amongst smokers who have used varenicline to quit

Objectives

- To explore differences in *abstinence* between one and 12 weeks (during treatment) after the target quit date in users of varenicline compared to placebo
- To explore differences in *relapse rates* after treatment completion (11 weeks after target quit date) and at 52 weeks in users of varenicline compared to placebo

Overview

This section of the document is based on one publication:

> *Submitted paper 5*
>
> **Shade A. Agboola,** Tim Coleman, Ann McNeill and Jo Leonardi Bee
> Abstinence and relapse among smokers who use varenicline in a quit attempt—a pooled analysis of randomized controlled trials.
> *Addiction, 2015; 110, 1182–1193*

The paper included in this section examined differences in abstinence and relapse during and following treatment with varenicline, a nicotine receptor partial agonist[89] licensed for smoking cessation. There is evidence that smoking cessation medication use at the time a quit attempt is made is protective against relapse[37]. Use of other methods or smoking cessation/relapse prevention aids have also demonstrated a positive influence, including formal behaviour support programmes and social support[38]. There is also evidence that relapse is less frequent in supported quit attempts, but very little knowledge about how smoking cessation treatments might exert effects on relapse. It has been suggested that there may be greater relapse to smoking after treatment completion in smokers who have achieved cessation using evidence-based treatments, even though long-term abstinence rates are higher than that observed in smokers who have quit unaided.

At the time of publication, there were no studies that had pooled using statistical techniques, data from varenicline cessation trials to develop insight into abstinence and

relapse during a cessation attempt. Agboola et al[51] therefore investigated abstinence and relapse patterns at specific follow-up points after receiving varenicline to determine the timing and occurrence of relapse.

Review of previous research

At the time of publication, only one literature review had explored these patterns in smokers who have stopped smoking unaided[7]. Individual trials had presented abstinence and/or relapse rates, but no systematic attempt had been made to locate and synthesise data from these diverse studies. The review[7] found that, in smokers who had stopped smoking without the aid of smoking cessation treatments, most relapse occurred early in the quit attempt – in the first eight days of the quit attempt. This finding is supported by that reported in a cohort study of 235 self-quitters[10]. This study found that the majority of relapse occurred in the early days and weeks after a quit attempt.

Two separate studies had investigated abstinence and relapse patterns after cessation had been achieved in smokers who had used evidence-based smoking cessation treatments. The first study is a systematic review that examined relapse to smoking after use of NRT, but did not adequately describe relapse patterns immediately after smokers' quit dates when relapse rates are highest[90]. The second study is a non-systematic review that used data from a small number of trials and qualitatively compared relapse patterns after cessation had been achieved with NRT and behavioural support[91]. The findings from this study suggested that most variation in relapse patterns or rates of relapse happened in the very early stages of quit attempts.

Methods used and findings

The purpose of analysis was to investigate abstinence patterns at specific follow-up points after receiving varenicline to determine the timing and occurrence of relapse. Randomized controlled trials of varenicline at any dose compared to placebo or other pharmacotherapies in which trial participants received behavioural support in addition to varenicline were included. Only trials that examined the effectiveness of varenicline for smoking cessation as identified by a Cochrane Review of nicotine receptor partial agonists[89] were included. Quasi-randomized trials and trials of combination drug treatments were excluded.

Abstinence patterns and Relapse curves

In smoking cessation trials, participants usually set a target quit date, and abstinence from smoking is recorded as either point prevalence or prolonged/continuous measure at set times after the quit date. Ideally, for constructing relapse curves, one

would use a continuous or prolonged measure of smoking abstinence, but such measures are not usually available, and the repeated measure of point prevalence abstinence at multiple follow-ups was more likely to be recorded. Many trials either provide line graphs connecting the percentage or number still abstinent at different time-points or data from which these can be drawn[92].

Studies of varenicline as identified by an up-to-date Cochrane Review of nicotine receptor partial agonists were identified and included in the analysis, if they reported abstinence as either point prevalence or continuous. Studies that reported point prevalence abstinence also had to report abstinence at three points or more in the first month following the quit date, because, as is the case in untreated smokers, we anticipated that most relapse would occur in the first month. Repeated point prevalence abstinence estimates were used to derive abstinence patterns, and continuous abstinence estimates were used to construct relapse curves. Placebo data was extracted from trial reports to ensure meaningful comparisons.

Nineteen studies that assessed the efficacy of varenicline compared with placebo and with at least one varenicline arm were deemed eligible and included in the analysis.

Data was extracted from each included trial on the numbers randomized, and abstinence data at three points in the first month after quit date (weeks 2, 3 and 4) and at 12, 24 and 52 weeks for the intervention group for all the studies reporting point prevalence abstinence. Numbers randomized to treatment at any time-point reported, up to 26 or 52 weeks for studies reporting continuous abstinence, were also extracted.

Meta-analyses was used to estimate pooled proportions of abstinence at six follow-up time-points in studies reporting point prevalence abstinence, and to estimate pooled proportions of abstinence at three continuous time-periods for studies reporting continuous abstinence.

The pooled analysis of 19 trials of varenicline showed that varenicline recruits smokers into abstinence following the target quit date to a greater extent than placebo (point prevalence abstinence increased from 32% [95% confidence interval 25% to 40%] in week two to 54% [95% confidence interval 48% to 61%] in week 12).

Analysis of pooled continuous abstinence data showed that in weeks 9–12 to week 52, relapse in varenicline treated smokers was similar to that observed in placebo treated participants (55% and 53% respectively). However, examination of the resultant curves showed a higher immediate relapse rate following end of treatment in varenicline treated smokers.

What this study added

This recently published paper was the first to document the nature of abstinence and relapse in smokers that have used varenicline to quit smoking. The study showed that the higher immediate relapse rate following varenicline treatment discontinuation, notwithstanding that this disappeared with longer-term follow-up, implied that there would be smokers who would benefit from a longer course of treatment. From a clinical perspective, the findings provide support for suggestions that smokers who use varenicline should be advised to continue with their quit attempt and to use the drug even after lapsing. The paper, although published late last year, has been cited by three articles. It has also been presented at the last UK National Smoking Cessation Conference as an oral presentation. The study also highlights future priorities for research, including the need to explore patterns of abstinence and relapse in users of nicotine replacement therapy and bupropion.

Chapter 2 Critical Analysis of Methodology

The five published articles included in this submission used several methodological approaches to achieve their aims and objectives. One typology of methodological approaches distinguishes between positivist/post-positivist and interpretivist/hermeneutic orientations[93].

The positivist approach, also known as scientific, has an interest in cause, effect and generalisability, uses the testing of hypotheses, seeks objectivity, is often quantitative, but may also include qualitative work. A positivist approach suggests that the researcher is independent of the research; studies with a positivist paradigm are based purely on facts and consider the world to be external and objective. The interpretivist approach centres on the way human beings make sense of their subjective reality and attach meaning to it – researchers with this world view believe that understanding human experiences is as important as focusing on explanation, prediction and control. The philosophical base of interpretive research is hermeneutics and phenomenology. Interpretive studies generally attempt to understand phenomena through the meanings that people assign to them. Interpretive research does not predefine dependent and independent variables, but focuses on the full complexity of human sense making as the situation emerges[94]. There is considerable disagreement as to whether these research "paradigms" or underlying epistemologies are necessarily opposed or can be accommodated within the one study[95].

The publications in this submission take a variety of approaches, including those from both “positivist” and “interpretivist” camps with a preponderance of the former.

Three of the published works in this submission are based mainly on positivist approaches - Agboola et al (2010a) presents data and findings from a survey, Agboola et al (2010b) presents findings from a systematic review and meta-analyses, Agboola et al (2015) summarises the outcomes from a pooled analysis of randomized controlled trials, whilst Agboola (2009) exemplifies an interpretivist approach and presents data from semi-structured interviews. Turner et al (2010) used methods based on both positivist and interpretivist approaches – data was collected using qualitative and quantitative methods.

The publications are aimed principally at Smoking Cessation Service professionals, policy makers and health care professionals and are designed to influence policy and practice. They are original in the sense that they “consist of the discovery of new facts or the critical examination of existing facts or ideas and in devising and conducting investigations into ideas supplied by others” (as defined in the University of Nottingham research degree regulations).

Throughout this submission, a range of methodological approaches have been used: systematic review and meta-analyses, quantitative approaches (online survey), and combined qualitative and quantitative approaches. There are strengths and limitations associated with different methodologies and the strengths and limitations of the methods used in each paper are considered in turn.

2.1 Paper 1

Shade A Agboola, *Tim J Coleman and Ann D McNeill (2009). Relapse prevention in UK Stop Smoking Services: a qualitative study of health professionals' views and beliefs.*
BMC Health Services Research ***9****:67*

The main strength of this paper lies in it being the first qualitative study to explore smoking cessation professionals' experiences of and beliefs about providing RPIs for smokers.

Qualitative research is characterized by its aims, which relate to understanding some aspect of social life, and its methods which (in general) generate words, rather than numbers, as data for analysis[96]. This paper used semi-structured interviews which are conducted on the basis of a loose structure (topic guide, see below) made up of open-ended questions defining the area to be explored[97]. The advantages of this approach are that it enables probing of complex issues, answers can be clarified and sensitive information can usually be obtained[98]. The research framework in qualitative research can be quickly revised as new information emerges, and the data that is obtained from qualitative research is based on human experience, which is often more powerful and sometimes more compelling than quantitative data[99]. In addition, subtleties and complexities about the research subjects and/or topic are discovered that are often missed by more positivistic enquiries. For example, a qualitative study which explored barriers and motivators to gaining access to Smoking Cessation Services amongst deprived smokers found that deprived smokers generally had low awareness of the services available to help them, and misconceptions about their availability and effectiveness[100]. This insight may not have been gained through the use of quantitative methods. The use of interviews and focus groups to explore perceptions of socio-economically deprived smokers allowed in-depth and frank explorations of issues that may otherwise have been masked, if quantitative approaches to data collection and interpretation had been used.

The main drawbacks are that data may be time consuming to collect and analyse, and there is greater opportunity for interviewer bias to intervene. On the other hand, the involvement of the interviewer aims to prompt greater depth, especially when rapport has been established between interviewer and interviewee[98]. I especially found this to be the case whilst conducting the interviews for this study, and some of the issues regarding targets and their impact on capacity to provide relapse prevention were amenable to more in-depth exploration. Small sample sizes may also limit the range, quality and generalizability of findings from qualitative research. However, the aim of qualitative research is not necessarily to produce findings that may be considered generalizable. It is possible that by interviewing a larger, more diverse group, I would have found other important factors relating to the use of RPIs, although similarities inherent in the accounts I obtained suggest that I was able to identify and synthesize most of the major issues.

Several qualitative studies[101-103] that have explored professionals' views as they relate to smoking cessation in specific groups have also been limited by small sample sizes. These studies have served as vital starting points for in-depth exploratory research. In addition, qualitative research scrutinizes the dynamic qualities of a situation (rather than elucidating the proportionate relationships among its constituents) such that the issue of sample size - as well as representativeness - has little bearing on the research's basic logic[104].

Research quality in qualitative research is heavily dependent on the individual skills of the researcher and more easily influenced by the researcher's personal biases and idiosyncrasies, and rigour is more difficult to maintain, assess, and demonstrate. In conducting this research, however, two additional authors reviewed a sample of interview transcripts to ensure consistency and objectivity.

As the interviewees all worked within the UK NHS Stop Smoking Services, and as these have a strong focus on cessation treatment, findings have highlighted relevant issues that could hinder or facilitate the introduction of RPIs into this environment.

2.2 Paper 2

***Shade A Agboola**, Tim J Coleman, Jo A Leonardi-Bee, Andy McEwen and Ann D McNeill (2010). Provision of relapse prevention interventions in UK NHS Stop Smoking Services: a survey.*
*BMC Health Services Research **10**:214 (Agboola 2010a)*

The main strength of this paper lies in it being the first of its kind in the UK and internationally to investigate the provision of relapse prevention interventions in UK Stop Smoking Services.

Surveys are a method of collecting information from a sample of the population of interest, by using interviews or questionnaires. This paper used a structured electronic questionnaire to assess provision of relapse prevention in UK Stop Smoking Services. Structured questionnaires involve the use of fixed questions, standardised questions or scales which are presented to respondents in the same way, with no variation in question wording[98]. The key strength of structured questionnaires is the ability to collect unambiguous and easy-to-count answers. The methods also lead to greater ease of data collection and analysis. The questionnaire used in this survey was designed to obtain information pertaining to current provision of treatment for smoking cessation, as well as current and future relapse prevention treatment provision. The questionnaire also asked about the feasibility of providing the most promising relapse prevention interventions in routine clinical practice. The answers recorded were unambiguous and were easily analysed using statistical software.

The main disadvantage of surveys using structured questionnaires is that pre-coded response choices may not be sufficiently comprehensive, and not all answers may be easily accommodated. Consequently, some respondents may be forced to choose inappropriate answers that may not be fully representative of their views[97]. It is therefore possible that some of the survey questions may have been worded in such a way that some managers may have been unwilling to reveal that they do not provide some form of relapse prevention intervention in their services. The closed-ended questions used in the questionnaire may have restricted the respondents to the choices provided, but we do not believe this is the case, because we provided respondents with an "other" option with space for free text which gave managers the opportunity to expand on their response, and greater freedom of expression.

Structured questionnaires also rest on the assumption that questions can be ordered in a way that can be understood by all respondents. This may not always be justified, because respondents may not share the same perspective. This may have been the case for some of the respondents to this survey; at the time of the survey, there was no universally accepted definition of relapse prevention. I tried to overcome this by providing a definition of relapse prevention, so that there was a shared understanding at the time of completion. I also distinguished relapse prevention interventions from interventions delivered to smokers who had briefly lapsed to smoking (i.e. were not abstinent), and which aimed to prevent a full relapse to smoking, and respondents were asked to indicate provision of any such lapse-orientated interventions/treatments.

An online survey software (Survey Monkey[105]) was used to administer the survey questionnaire. The use of electronic/online data collection methods has a number of advantages. Online data collection methods facilitate access to individuals in distant locations and enhance the ability to reach difficult-to-contact participants. Another advantage is the convenience of having automated data collection, which reduces researcher time and effort[106]. Compared to traditional mail surveys, online surveys are significantly faster and less costly[107]. Questions can be written with more complete descriptions because a computer survey is not space-constrained, as with a printed one. Electronic surveys have fewer missing responses and can be coded and presented in a more flexible manner[108].

The use of online data collection methods for smoking cessation research is not new. Saran et al[109] used Survey Monkey to explore the frequency of nurses' smoking cessation interventions. This approach ensured that the website link for the survey could be administered wherever the nurse had access to a computer connected to the internet (work, home, laptop, etc.) and at any convenient time. Lawrenson and Evans[110] also examined the content of smoking cessation advice delivered by eye care professionals in the UK. The survey was delivered entirely online and was hosted by Survey Monkey.

There are also limitations associated with the use of online surveys. Unreliability of the email address lists may mean that the email advertising the survey may not reach intended participants[111]. In conducting this survey, email addresses of the 96 smoking cessation service managers were retrieved from a national database, so it is unlikely that the lists contained inaccurate information.

It is also possible that by embedding survey questions within the email, rather than inclusion as an external link, response rates may have improved[112]. Survey links included as external links within emails often achieve response rates of between 25% to 30% without follow-up email and reinforcements[113]. Guidelines for maximising response rates to these types of survey include requesting participation from respondents in advance, giving respondents sufficient time to complete the survey, and sending reminders during the survey period[114]. The response rate accomplished in this survey was 52%. This was higher than the average response rates to electronic and online surveys[115], and was achieved through a reminder email and telephone contact of all non-respondents approximately two weeks after the initial email.

2.3 Paper 3

Shade Agboola, *Ann McNeill, Tim Coleman and Jo Leonardi Bee Addiction 2010 (Agboola 2010b). A systematic review of the effectiveness of smoking relapse prevention interventions for abstinent smokers.*
Addiction 105, 1362–1380 (Agboola 2010b)

This paper used systematic review and meta-analytic techniques to produce summary evidence on the effectiveness of smoking relapse prevention interventions. A systematic review uses a process to identify comprehensively all studies for a specific focused question (drawn from research and other sources), appraise the methods of the studies, summarize the results, present key findings, identify reasons for different results across studies, and cite limitations of current knowledge[116]. The results of a systematic review can be summarized as a narrative synthesis or mathematically combined (meta-analysis). A meta-analysis integrates the quantitative findings from separate but similar studies, and provides a numerical estimate of the overall effect of interest[117]. The main strength of mathematically combining data from a series of well-conducted primary studies is that it may provide a more precise estimate of the underlying "true effect" than any individual study[118], and meta-analysis of similar, well-conducted, randomized, controlled trials has been considered one of the highest levels of evidence[119]. However, the hallmark of a good review is in the approach used to combine data from eligible high quality studies, and our paper combined outcome data according to their delivery modality and by population and intervention group separately, which is a key strength. This is in contrast to the Cochrane Review[8] that combined trials testing a variety of different behavioural interventions. In addition, our review analysed trials which combined NRT and bupropion as one RPI separately from those that investigated bupropion alone. We believe that this approach yielded findings that may have been obscured had we combined and pooled data from both types of trials. Our superior approach to combining data has also been used in several reviews of pharmacotherapies for smoking cessation[120 121].

The review process inevitably identifies studies that are diverse in their design, methodologic quality, specific interventions used, and types of patients studied, and there may be some subjectivity when deciding how similar studies must be before pooling is appropriate. We reduced subjectivity by ensuring that study selection was completed by two authors, with disagreements resolved by a third.

Systematic reviews and meta-analyses also do not correct biases as a result of selective publication, whereby studies that report dramatic effects are more likely to be identified, summarized, and subsequently pooled in meta-analysis than studies that report smaller effect sizes (publication bias). More than three-quarters of meta-analyses do not report any empirical assessment of publication bias[122], but our paper used funnel plots to assess publication bias.

While it has been shown that it is common to combine studies of poor quality with those that were more rigorously conducted, which can lead to worse estimates of the underlying truth and high levels of statistical heterogeneity, several techniques have been developed to assess and determine the presence and extent of statistical heterogeneity. One of these is the I2 statistic[123], which we used in our study. Where extreme levels of heterogeneity were detected between the studies (I2 > 80%), the studies were summarized individually.

Our study used a comprehensive search strategy to identify relevant trials, and it is unlikely that any significant literature has been missed. All drug trials included in the review confirmed smoking status biochemically, so findings are likely to be valid and not prone to substantial bias in outcome ascertainment.

2.4 Paper 4

Jessica Turner, Ann McNeill, Tim Coleman, Jo Leonardi Bee and ***Shade Agboola*** *Feasibility of offering nicotine replacement therapy as a relapse prevention treatment in routine smoking cessation services.*
BMC Health Services Research 2013, 13:38

This paper used a combination of qualitative and qualitative approaches, in order to assess the feasibility and acceptability of provision of NRT for relapse prevention in a local Stop Smoking Service. A questionnaire survey was used to assess feasibility and acceptability, and semi-structured interviews were used to explore the perceptions of a selection of smokers, who agreed to the offer of extended NRT for relapse prevention.

The strengths and limitations of these methods have been explored and discussed above, under the papers 1 and 2. The feasibility study assessed smoking status at six-months follow-up, based on self-reported point prevalence smoking status at six months, rather than sustained abstinence over the six months, which might have been a better marker of smoking abstinence. Smokers who accepted the offer of NRT for relapse prevention may not have been truthful regarding their smoking status at six-months follow-up. A superior approach may have been to verify biochemically, self-reported smoking status, but the design of the study was such that it was not possible to determine the efficacy of the RPI treatments provided. This is because no control group (i.e. one not offered RPI) was included, and it was not possible to ascertain the numbers of extra smokers who remained abstinent at six months because of the RPI.

However, self-reported smoking status has been shown to correlate well with biochemical measurements. Murray et al (2002)[124] compared biochemical measures with self-report, and found that the size of the differences suggests that self-report bias does not appear to result in “seriously misleading findings in a smoking cessation study”.

2.5 Paper 5

***Shade A. Agboola**, Tim Coleman, Ann McNeill and Jo Leonardi Bee*
Abstinence and relapse among smokers who use varenicline in a quit attempt—a pooled analysis of randomized controlled trials.
Addiction, 2015; 110, 1182–1193

A meta-analysis integrates the quantitative findings from separate but similar studies, and provides a numerical estimate of the overall effect of interest. The effect of interest can be: an average of a continuous variable, a correlation between two variables, an odds ratio, risk ratio or risk difference, a proportion, the area under the ROC curve[125]. These effect sizes represent effects between treatment and control groups, such as group mean differences and odds ratios. This paper used proportion meta-analysis (STATS direct reference) to calculate an overall proportion from a set of proportions reported in randomized controlled trials of varenicline for smoking cessation.

A key strength of this approach is that calculating an overall proportion from a set of proportions using meta-analytic techniques improves statistical precision. On the other hand, validity of meta-analyses depends on the methodological quality of the included studies, the eligibility criteria used for the meta-analysis, and the various reporting biases. We therefore ensured validity by assessing the methodological quality of eligible trials independently using the Cochrane Collaboration's tool for assessing risk of bias[126], and by including only trials that have examined the effectiveness of varenicline for smoking cessation as identified by a Cochrane Review of nicotine receptor partial agonists[89]. We also used trial reports of varenicline which reported either continuous abstinence or repeated measures of point prevalence abstinence, but we pooled data separately and presented pooled proportions and curves for these separately. We believe this approach is appropriate because pooled point prevalence rates cannot be used to calculate relapse curves.

The use of only varenicline studies included in an up-to-date review of nicotine receptor partial agonists for smoking cessation means that some studies that met eligibility criteria may have been omitted. It was also difficult in this paper to conduct a subgroup analysis, mainly because individual patient data from the original studies would have been required for this. Individual patient data facilitates exploration of heterogeneity at the patient level and subgroup analyses of patient level data[127], but we did not have access to this information. In addition, many of the most important features of systematic reviews, including formal meta-analyses, are addressed by both individual patient data and aggregate patient data meta-analysis, and we believe these have been addressed in this review. Finally,

aggregate patient data meta-analyses continue to be the mainstay of systematic reviews utilized by the Cochrane Collaboration and many professional societies to support clinical practice guidelines[127].

Chapter 3 Relapse prevention in UK Stop Smoking Services: a qualitative study of health professionals' views and beliefs.
Shade A Agboola, Tim J Coleman and Ann D McNeill (2009).
BMC Health Services Research 9:67

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Relapse prevention in UK Stop Smoking Services: a qualitative study of health professionals' views and beliefs

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Abstract

Background: NHS Stop Smoking Services in the UK provide cost effective smoking cessation interventions, but approximately 75% of smokers who are abstinent at 4 weeks relapse to smoking by 12 months. This study aimed to explore health professionals' understanding of relapse prevention interventions (RPIs), the feasibility of offering such support and whether and how these are currently used in UK NHS Stop Smoking Services.

Methods: Sixteen health professionals working in UK NHS Stop Smoking Services, selected from those attending a national conference were interviewed and Framework Analysis was used to identify recurrent key themes and concepts in their perceptions and experiences of providing relapse prevention interventions (RPIs).

Results: Interviewees had diverse perceptions of relapse prevention as a concept. Whilst relapse prevention was largely seen as support to prevent abstinent smokers from relapsing to smoking, some interviewees stated that RPIs were being delivered to lapsed or relapsed smokers. Current provision of RPIs was most commonly described as behavioural counselling being offered predominantly after completed cessation treatment, often in the format of 'rolling groups' which the client was encouraged to attend. Commonly identified barriers to the introduction of RPIs were funding and government targets focussed on short term cessation, smokers' low uptake of offered RPIs and an uncertain evidence base for their effectiveness. Interviewees were positive about the potential use of pharmacotherapy for relapse prevention, but were negative about the possibility of introducing proactive telephone counselling for this purpose.

Conclusion: There is currently no shared understanding of the concept of relapse prevention amongst this sample of health professionals working in UK NHS Stop Smoking Services. For RPIs to be systematically delivered via these services, a commonly-held, widely-accepted and understood definition of relapse prevention would be needed. Other barriers towards introducing RPIs, such as their weak evidence and the short term cessation-focussed targets against which UK stop smoking services are measured, would also need addressing and interventions which are acceptable to abstinent smokers would need to be developed.

Background

NHS Stop Smoking Services were established from 1999 onwards across the UK to provide support for motivated smokers who wish to quit. The effectiveness of these services has been demonstrated: for example, more than half of English services' clients achieve validated abstinence from smoking for at least four weeks and around 15% do so for at least a year[1]. Services are also very cost-effective, achieving an average cost per life year saved, after allowance for future health care savings, of £438 [2], which is over 50 times below the English National Institute of Health and Clinical Excellence's benchmark cost-effectiveness figure of £30,000 [3]. Services' clients are offered pharmacotherapy and behavioural therapy in group or individual settings [4], but as the figures above suggest, quitters' rates of relapse to smoking are high, with around 75% of those abstinent at 4 weeks after their quit date restarting smoking by one year [1].

If stop smoking services provided abstinent smokers who are making quit attempts with effective treatments to reduce their rates of relapse to smoking (relapse prevention interventions, RPIs), then long term prolonged cessation rates could, potentially, be greatly improved. However, the evidence base for using RPIs is weak; a 2006 Cochrane review of pharmacotherapy, extended treatment interventions and interventions designed to provide smokers with skills to avoid relapse to smoking, found no evidence that any of these approaches worked for relapse prevention, although the evidence base was small [5]. As part of an investigation into the feasibility and potential effectiveness of introducing RPIs into the NHS, this evidence base is being updated and attitudes to the potential use of RPIs are being investigated. We report here the findings of a qualitative study which investigated the views, knowledge and understanding concerning RPIs of health professionals working in UK NHS Stop Smoking Services and also their experiences of providing RPIs in clinical practice. Factors which could hinder or encourage the efficient provision of RPIs in UK NHS Stop Smoking Services were also investigated.

Methods

Design

Health professionals working in UK Stop Smoking Services attending a UK smoking cessation conference in 2007 were asked to indicate their willingness to be interviewed at a later date on relapse prevention and 23 professionals provided contact details. All 23 were emailed seven months after the conference, invited to re-confirm their willingness to take part and agree a convenient time to be interviewed. Non-respondents to the email were contacted via telephone two weeks later. A literature review identified issues of potential importance to RPIs and, using these, a semi-structured interview schedule, with prompts (Appendix 1) was developed. Throughout interviews, open-ended questions were used to encourage participants to answer freely and these were conducted by SA via telephone in January and February 2008. Interviews covered the following subjects: knowledge and understanding of relapse prevention, types and duration of RPI provided and barriers and challenges encountered. Each interview lasted 20–25 minutes and all were audio-taped and transcribed verbatim.

Analysis

Table 1 summarises the process of data analysis. The interviews were analysed using the Framework Method [6]. The first stage of analysis involved identifying initial themes or concepts. The themes and categories on which the analysis is based were derived from the data, rather than being imposed by the researchers [7]. The definition of emergent themes and categories were checked against the data, and subsequently refined in an iterative process [8]. Themes and sub-themes were given unique codes and a manageable index was constructed. The index was subsequently applied to the raw data, and the references were noted in the margins of the transcripts. The next stage

Table 1: Process of data analysis

SA reads all transcripts in an iterative process to identify themes and sub-themes (variations in advisor experiences of providing relapse prevention treatments and variations in thinking within themes)
SA designs a framework (index) with themes and sub-themes and their working definitions
TC and AMc agree working definitions for the emerging themes and sub-themes
SA codes the transcripts for the themes. Data relating to each theme is assembled. TC and AMc independently read 10 randomly selected transcripts to see if they are being coded consistently
Working definitions for themes and sub-themes are refined. The framework (index) is re-structured to reflect the changes
SA re-codes the transcripts using the refined definitions. TC and AMc check reliability of the data and interpretation of the findings at each stage of the process

involved constructing charts with rows and columns for each of the main themes and sub-themes that emerged. This process of "charting" allows allocation of the main themes to each column on the chart, and each interview transcript is assigned to a particular row. It ensures that enough data and context are included in the charts such that the analyst is not required to go back to the transcribed data to understand the point being made [6]. Each interview stays in the same location on every chart. After charting all the interviews, interview text relating to the research aims and objectives was collated from the themes and sub-themes. Finally, AMc and TC read a sample of ten randomly selected transcripts and confirmed that the transcripts were coded consistently and they contained data that supported the key findings of the study. Any disagreements were resolved by discussion.

Results

Response

Of the 23 individuals who had indicated their willingness to participate in the study, four could not be contacted and three potential participants indicated that they no longer wished to participate, so a total of 16 interviews were conducted (12 with females). Fifteen interviewees were smoking cessation professionals who were also responsible for overseeing the day-to-day activities of their respective services or actively involved in managing one aspect of the service in which they worked and one was a regional tobacco control lead. We report our interpretation of health professionals' accounts below. Quotes from interviewees appear in Tables Three to Five and they are attributable to individual interviewees by code numbers.

The themes

Three broad themes emerged from interview data: beliefs, knowledge and understanding of relapse prevention; RPIs for abstinent/lapsed and relapsed smokers; and, barriers and challenges. A summary of the themes and sub-themes is shown in Table 2.

Beliefs, knowledge and understanding of relapse prevention

Interviewees had diverse perceptions of relapse prevention as a concept and shared no common definition of what this should entail (see Table 3). Their definitions of relapse prevention mostly appeared to be informed by the ways in which the cessation services for which they worked currently attempted to help abstinent smokers to remain stopped and achieve long term abstinence. Interviewees believed that relapse prevention should be mainly provided for abstinent smokers to help them remain smoke-free and **prevent lapses** by extending their acute treatment Some health professionals also believed that RPIs could be used for the **treatment of lapsed** (i.e. people who had smoked one or two cigarettes) or **relapsed smokers** (i.e. people who were now smoking regularly again).

Prevention of lapses

Most participants understood/thought that relapse prevention involved preventing lapses by providing treatment for longer than a 'usual' seven to eight week period, believing that, irrespective of the type of intervention used, offering acute cessation treatment for longer periods would ensure that more smokers remained abstinent.

Table 2: Index of themes and sub-themes

Beliefs, knowledge and understanding of relapse prevention
Prevention of lapses
Treatment of lapses
Treatment of relapsed smokers
Relapse prevention support for abstinent/lapsed and relapsed smokers
Support for abstinent/lapsed smokers
Content
Behavioural counselling & pharmacotherapy
Telephone follow up
Social Activities
Uptake
Support for relapsed smokers
Content
Rolling groups
Recycling – fresh quit attempt
Uptake
Barriers and challenges
Funding
Government targets
Paucity of information about effective relapse prevention interventions

Table 3: Beliefs, knowledge and understanding of relapse prevention

Prevention of lapses
"Relapse prevention is making sure that, to try and stop people lapsing back to smoking, that's what I understand relapse prevention would mean".
"It is some action, some clinical action that the practitioner takes in order to prevent the patient from in the first place lapsing that automatically implies that it would help prevent relapse". 12
"Relapse prevention to me is, we have an open clinic, we see them initially for at least seven weeks, but it doesn't finish at either at six or seven weeks, they can come for as long as they like". 13
Treatment of lapses
"Well it's for people who have tried to stop smoking and have lapsed, and they don't want to go back through the whole system again, they just need something to get them back on track again," 10
"I've always felt that it's enabling clients to remain quit in the long term.....so that at the point where they've had one lapse, they actually get support to prevent them from turning into one great big relapse". 2.
Treatment of relapsed smokers
"It's really about people who have relapsed to smoking, regularly, and have gone into full-blown relapse, where they are now smoking regularly, and they need help to actually stop". 1

Almost all participants stated that relapse to smoking was most frequent when smokers ran out of medication, which perhaps explains the strong belief that extending treatment would prevent lapses. The treatment was often either group or individual behavioural support, and was extended beyond the usual timeframe for which acute cessation treatment is provided.

Treatment of lapses

A small number of interviewees described relapse prevention as providing support for smokers who have already had a minor 'lapse' (i.e. smoked a few cigarettes during an otherwise abstinent period) to prevent subsequent complete relapse. Interviewees believed that a single lapse could be sufficient to precipitate a later, complete relapse and that managing these would substantially reduce the risk of smokers returning to regular smoking. Interviewees, again, provided a content-centred definition for relapse prevention as being the treatment of lapses citing the provision of behavioural support and pharmacotherapy as potentially effective for those who had smoked a few cigarettes during an otherwise abstinent period.

Treatment of relapsed smokers

Interviewees also described relapse prevention as providing treatment for smokers who have fully relapsed to smoking. They define this, again, in terms of the content of the relapse prevention intervention and reveal that this usually involved encouraging the client to begin a fresh quit attempt and begin acute cessation treatment again or attendance at 'rolling groups' (defined below).

Relapse prevention interventions for abstinent/lapsed and relapsed smokers

Interviewees described RPIs for abstinent/lapsed and relapsed smokers in terms of the types of support which could be provided and these differed for the two groups (see Table 4). They also reflect on the uptake of such support when offered within their services.

Support for abstinent/lapsed smokers

Content

Behavioural counselling & pharmacotherapy

Interviewees revealed that behavioural counselling was one of the most favoured forms of treatment used to help smokers who have quit or who have had one or two brief lapses remain smoke-free. The treatment is usually provided on an individual or group basis and these smokers are helped to identify situations and triggers that might lead to smoking lapses or relapse, taught strategies to help overcome the associated urge for a cigarette, and steps to take to prevent lapses, and the case of those who have had one or two lapses, steps to prevent full blown relapse. They are also helped to understand that relapse is a spontaneous, unplanned thought process or phenomenon which is often triggered by external factors such as holidays, bereavement, and unexpected personal or financial difficulties, and are equipped with strategies to deal with these. Few individuals spontaneously mentioned the use of pharmacotherapy to prevent relapse but all were asked to comment on the feasibility of using pharmacotherapies for relapse prevention (given emerging evidence on its effectiveness, see below) and most interviewees were positive about this. (Table 4).

Telephone follow up

Some interviewees reported that their services provide telephone follow up calls or text messaging to support abstinent clients who had completed acute cessation treatment. Advisors kept in touch with abstinent smokers via telephone to provide motivation and support, when needed, and to help them remain smoke-free with relatively short calls (< 10 minutes) made at times specified by clients as convenient. During the call, the advisor reit-

Table 4: Relapse prevention interventions for abstinent/lapsed and relapsed smokers

Support for abstinent/lapsed smokers
Content
Behavioural counselling & pharmacotherapy
"We run a group, so they can come in for a series of sessions which cover general healthy lifestyle, like healthy eating, getting advice, and stress reduction". 6.
"Well everything that is involved in behavioural support, going through every situation they may encounter, preparing themselves for that, looking at tactics to cope with situations....if they've got anything in particular they're worried about, we will approach it in a practical but relaxed manner". 2
"We work with people, whatever their issues/triggers are, we would deal with, it doesn't matter what it is, if its debt management, crisis resolution, if in quitting smoking they've got problems that need dealing with, we would deal with it". 5
"I would strongly recommend that (pharmacotherapy) because as I said, a lot of patients reported that they actually relapsed right after they are not provided with medications". 3
"I think it (pharmacotherapy) would be fantastic".5
Telephone follow up
"We do telephone follow-ups, say between six and twelve months, just to ask them how they are getting on, and to let them know they can access the service again and again, at any point they need". 18
"The problem you have there is if you are going to phone everybody, you have to have the manpower, the resources to do that, from a resource point of view, I wouldn't have time to phone everybody at the moment". 13
"It would be very hard for us to that, to phone everyone up would be ideal but impossible at the moment".15
Social activities
"We do use interventions such as diversion therapy, by getting people into community groups and community support....we don't send them home to continue sorting out themselves, we get them out in the community, get them busy and get them involved in things, they need to be busy and out there and feeling useful... we get them to go to care homes and just you know, do peoples' hair and make them cups of tea, its just engaging them with whatever involves them". 5
Uptake
"I think the picture is actually, people poorly attend relapse prevention. Because they feel once they've actually reached the quit, they don't need any help...a lot of smokers don't want you chasing them up, a lot of them are fed up if you do contact them". 6
"We used to, a couple of times a year, we'd put on like an open session, and invite everybody who'd been to the group in the last year, we'd put on a bit of food and make it a social event, and do some stuff about staying quit, but very few people attended, so it tended to be a waste of our time, so we didn't continue it". 16
Support for relapsed smokers
Content
Rolling groups
"We don't have any formal relapse groups, but there are no barriers to re-entry of the service, for example in my 12 week group, drop-in group, people can come along who have relapsed and re-join the group again". 12
"We have a rolling group that is open for anybody who wants to come back in at any time". 14
Recycling
"Yes, it's a new quit attempt isn't it? (For relapsed smokers). You would go over the reasons for relapse and then you need to go through the whole process of another quit attempt". 16
Uptake
"A lot of people would rather, even though you've built up a rapport, struggle than bother you, so they think, oh no, I've failed now, they may have had one, two cigarettes, they don't contact you, so that tends to be a problem.". 8
"I think, when you, from my experience as an ex-smoker, if you're trying to give up, and you've slipped up, and then somebody is ringing you, you think Oh God no, it's that woman again, and feel really bad". 13
"The trouble is when people do relapse there's sort of, they're embarrassed to come back". 15

erated the advantages of remaining smoke-free and reminded clients to contact the service once he/she experiences the urge to smoke a cigarette. Interviewees were quick, however, to point out that proactive telephone counselling for relapse prevention was logistically difficult and, as many clients found the calls intrusive, not a favoured intervention. They believed calls could be an unwelcome reminder for smokers that abstinence could be difficult to maintain (Table 4).

Social Activities

Interviewees talked about using 'diversion therapy' as a relapse prevention intervention for abstinent smokers. This was often reported to involve engaging clients in activities designed to take their minds off smoking, and provide them with feelings of well-being and importance, Activities were specially organised and could be conducted by the smoking cessation service or in community or leisure centres. Regular group activities could be lead by an abstinent smoker and those described included baking/cooking, community services and visiting hospices or nursing homes to lend support to residents.

Uptake

Interviewees revealed that where RPIs had been offered, most clients did not take advantage of them and it was difficult to keep providing them. They admit that an important focus in the management of smoking relapse should

be to help the smoker overcome such emotions. Interviewees' accounts suggest that making the client aware early on in the quit attempt of the possibility of relapse further down the quitting process may prepare the smoker for relapse and diminish the feelings of disappointment they may suffer.

Support for relapsed smokers

Content

Rolling groups

In some services, smokers who had already been treated but had relapsed to smoking were able to access 'rolling groups'. Health professionals described this as an 'open door' policy, with relapsed clients always free to return to the service and re-join support groups. 'Rolling groups' would not have fixed start or completion dates, so clients wishing to re-enter the service for help would be able to do so. Groups were perceived as able to provide clients the opportunity to mix with individuals who had received acute cessation treatment, relapsed, but had been able to become abstinent again. The groups are often led by a trained advisor and the sessions focus on, in addition to other issues, helping the smokers deal with circumstances that might lead to relapse.

Recycling – fresh quit attempt

In other services smokers who have suffered a full blown relapse were encouraged to re-enter the service as a fresh quit case. According to these health professionals' accounts, once a person has fully relapsed to smoking, relapse prevention is no longer appropriate and the individual is classified as a fresh quit attempt and begins the process of quitting smoking all over again.

Uptake

This process of re-cycling is often hampered by the unwillingness of the smoker to admit to relapse. Health professionals' accounts suggest that providing RPIs was made difficult by service users' profound feelings of failure and embarrassment after relapsing, plus reluctance to admit to relapse. Clients generally accessed services for cessation treatments and they might not view Stop Smoking Services as an appropriate place to seek help with lapses and brief relapses.

Barriers and challenges to using relapse prevention interventions

Funding and pressure to meet Government targets which are focussed on short term cessation and paucity of information as to the most effective relapse prevention interventions were repeatedly identified as challenges to the provision of RPIs (see Table 5).

Funding

Nearly all health professionals stated that drug budgets and funding constituted major obstacles to the introduction of RPIs for smokers. A number of interviewees revealed that they stopped providing RPIs due to a lack of funds for additional support beyond that provided during cessation treatment. Interviewees were positive about providing these interventions for motivated smokers if health authorities allocated adequate funding.

Government targets focussed on short term cessation

Interviewees' accounts suggested that the need to meet Government targets for NHS Stop Smoking Services exerts considerable pressure on them. Even for health professionals who were interested in and willing to provide RPIs, the pressure to achieve short term cessation for smokers (i.e. 4 week quits) often reduced the amount of time and resources that could be devoted to RPIs. Interviewees recognize this conflict and repeatedly identified this as a noteworthy barrier to the provision of RPIs within their services.

Table 5: Quotes relating to barriers and challenges

Funding
"We used to have a relapse prevention session, wherein we invite everyone that came to our service to attend these clinics, but we don't do that anymore because of financial pressures". 3
"I think most PCTs would be prepared to pay for a course of treatment, but not an extended course of treatment, that's why they cut down to stop methods unlikely to be funded locally". 4
Government targets
"If you've got very busy clinics and you have Department of Health Targets to meet, you know, there's always a bit of a squeeze, in terms of how much time you've got for people to see you beyond their successful four week quit". 7
"I think you know, the fact that we are so target driven, and the fact that reporting successes is at a month rather than if it was three months or something like that, you know the whole drive would be to see patients longer.....although I think targets are probably a good thing overall, because it does focus you on hitting the three pots and all the rest of it, but I think it can be a bit counter- productive". 14
Paucity of Information about effectiveness of RPIs
"I don't think we've got anything in black and white, to be honest". 1

Paucity of information about effective relapse prevention interventions

A lack of available evidence on the effectiveness of RPIs was perceived as a barrier to their use by some participants. It was believed that it would be easier to provide these interventions for motivated smokers if there was readily available and accessible information in the literature as to the most effective RPIs. Many indicated that they would be able to integrate RPIs into their mainstream service, but only if there was sufficient evidence regarding the effectiveness of these interventions.

Discussion

Summary of findings

This sample of health professionals working in UK NHS Stop Smoking Services do not appear to have a shared understanding of what interventions aimed at preventing relapse to smoking should encompass. Interviewees' used their experiences to conceptualise relapse prevention and their beliefs and understanding of this were often based on the kinds of support that services in which they worked offered as relapse prevention to clients. Interviewees believed that introducing relapse prevention support into NHS Stop Smoking Services would be hindered by current performance targets which are focussed on achieving short term abstinence from smoking, following cessation treatment. There had been low uptake of RPIs in services which previously offered this and interviewees were negative about introducing additional, proactive telephone support counselling as an RPI, but were much more positive about the possibility of using pharmacotherapy for this purpose.

Important emergent issues

Interviewees were generally positive about the potential for using RPIs for smokers accessing stop smoking services, but their varied descriptions of interventions indicated that they did not share a common definition of what these interventions should involve. Some believed relapse prevention should be aimed at lapsed smokers but, more commonly, it was perceived appropriate for preventing relapse among smokers who were still abstinent and attempting to quit. Often no distinction was made between relapse prevention treatments and routine cessation treatment. It is, perhaps, unsurprising to find differences of opinion about RPIs amongst health professionals, because the scientific literature on the subject describes studies which appear to conceptualise relapse prevention in different ways too. A Cochrane review described relapse prevention interventions as those which explicitly seek to reduce relapse rates after an acute treatment phase is successfully completed, or at some time after the date of the quit attempt [5]. However, studies in this review and which satisfied this definition include some which randomised abstainers and provided behavioural treatments [9,10] and/or drug treatments used for extended periods [11,12] and studies which randomised smokers and provided behavioural RPIs to help prevent relapse alongside standard cessation oriented therapy [13,14]. This latter approach is consistent with Marlatt and Gordon's model of relapse which predicts that relapse may occur when ex-smokers encounter high risk situations and employ inadequate coping responses to avoid smoking [15]. The behavioural counselling for relapse prevention provided would, therefore, focus on developing smokers' coping skills prior to, or early on within, a quit attempt.

Our findings suggest that health professionals would be comfortable with the notion of delivering RPIs to abstinent smokers, but the limited evidence base for the effectiveness of such interventions would need to be strengthened before this could occur. If this were to happen and RPIs were to be used in NHS Stop Smoking Services, interviewees believed that pharmacotherapy used as extended treatment for relapse prevention could be easily integrated into current routine practice, as long as costs were addressed. However, there was little or no enthusiasm for the use of proactive telephone counselling to help prevent relapse because it was considered that few abstinent smokers would welcome this type of contact and it would be logistically challenging for services to undertake.

Current performance management targets are a substantial barrier to the introduction of relapse prevention support in the UK National Health Service (NHS). For example in October 2002, the English Department of Health (DH) stated an aim that 800,000 smokers would successfully quit following help from smoking cessation services by 2006 [16] and this was subsequently translated into an aspiration that services should treat at least 5% of their local population of smokers in the course of a year, with an expected success range of 35% – 70% at four weeks [17]. For these targets, success involves smokers achieving a four week period of abstinence, so there is considerable pressure on services to achieve a high throughput of smokers who manage to stop smoking for at least one month. Interviewees' comments reflected this perceived pressure and indicated that the provision of RPIs could not be a priority for services without a change in the targets against which they are measured.

Interviewees were also concerned about the low uptake of RPIs which had often led to these being withdrawn after their introduction and was perceived as a major potential barrier to the successful introduction of RPIs into the NHS. Interviewees thought that relapsed smokers were embarrassed about their 'failure' and hence did not return for treatment. This view is consistent with the literature;

lapsed smokers often feel guilty [18] and experience negative affect and decreased confidence in their ability to quit [19].

Strengths and Limitations

This is, to our knowledge, the first qualitative study to explore smoking cessation professionals' experiences of and beliefs about providing RPIs for smokers. As interviewees all worked within the UK NHS Stop Smoking Services and as these have a strong focus on cessation treatment, findings have highlighted relevant issues that could hinder or facilitate the introduction of RPIs into this environment. Our sample was small and it is possible that by interviewing a larger, more diverse group, we would have found other important factors relating to the use of RPIs, however, similarities inherent in the accounts we obtained, suggest that we have identified most of the major issues. Also, as our sample were volunteers from those attending a smoking cessation conference, one might expect their views on relapse prevention interventions to be better informed than those of others working in smoking cessation.

Conclusion

Should effective RPIs be identified, it is clear that health professionals would be positively orientated towards delivering these via UK NHS Stop Smoking Services. However, this process would be helped by the development of a clear definition of what relapse prevention is and should involve and it seems very unlikely that RPIs could be successfully introduced without current targets for performance management being altered to reward longer term cessation. Potential RPIs should be piloted for their acceptability to smokers making quit attempts to ensure maximal uptake of those which are introduced and it would be unwise to ignore the views of those working in stop smoking services when deciding upon the logistics of intervention delivery.

Competing interests

Within the last five years Tim Coleman has undertaken consultancy work for Pierre Fabre Laboratories, France and also Johnson & Johnson. Both companies produce nicotine replacement therapy. The other authors declare that they have no competing interests.

Authors' contributions

All authors designed and contributed to the write up the study and read and approved the final manuscript. SA carried out the interviews as described in Box 1 and wrote the first draft of this article. SA is the guarantor for this manuscript.

Appendix 1

The interview schedule

1 What interventions are currently being used by your service to help smokers who wish to stop smoking?

2 In your experience, at what point do smokers who have quit smoking most often relapse to smoking?

3 What do you understand by smoking relapse prevention interventions?

Experiences of delivering Relapse Prevention Interventions within Stop Smoking Services

4 Do you routinely provide relapse prevention interventions to smokers in your service?

5 What types? (Content)

6 To whom, is it to those who have already relapsed or to all smokers after the four week quit date, regardless of smoking status at the time?

7 For how long is the relapse prevention intervention provided for? (Duration)

8 What percentage of smokers who relapse to smoking take advantage of relapse prevention treatments? (Uptake)

9 Are your staff trained to provide relapse prevention support?

10 Do you collect any data so as to monitor the effectiveness of relapse prevention support you provide?

Feasibility

11 What do you think about the effectiveness of.....? Varenicline (champix); bupropion (zyban); extended treatment with NRT; behavioural sessions after the four week quit date; extended telephone contact after the four week quit date; **(This question depends on the answer to questions 4 and 5)**

Challenges Experienced

12 Is it difficult to get smokers to attend any clinics or sessions after the four week quit date?

13 Are there any groups of smokers who pose a challenge in particular?

14 What other challenges do you face with respect to preventing relapse in smokers?

Service Provision

15 What is the nature and number of sessions offered?

16 What is the length and timing of these sessions?

17 What is the actual uptake of these treatment sessions by smokers?

18 What kind of staff are involved in providing these services for smokers who wish to quit?

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Chapter 4 Provision of relapse prevention interventions in UK NHS Stop Smoking Services: a survey

Shade A Agboola, Tim J Coleman, Jo A Leonardi-Bee, Andy McEwen and Ann D McNeill (2010)

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Provision of relapse prevention interventions in UK NHS Stop Smoking Services: a survey

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Abstract

Background: UK NHS Stop Smoking Services provide cost effective smoking cessation interventions but, as yet, there has been no assessment of their provision of relapse prevention interventions.

Methods: Electronic questionnaire survey of 185 UK Stop Smoking Services Managers.

Results: Ninety six Stop Smoking Service managers returned completed questionnaires (52% response rate). Of these, 58.3% (n = 56) ran NHS Stop Smoking Services which provided relapse prevention interventions for clients with the most commonly provided interventions being behavioural support: telephone (77%), group (73%), and individual (54%). Just under half (48%, n = 27) offered nicotine replacement therapy (NRT), 21.4% (n = 12) bupropion; 19.6% (n = 11) varenicline. Over 80% of those providing relapse prevention interventions do so for over six months. Nearly two thirds of all respondents thought it was likely that they would either continue to provide or commence provision of relapse prevention interventions in their services. Of the remaining respondents, 66.7% (n = 22) believed that the government focus on four-week quit rates, and 42.9% (14 services) believed that inadequate funding for provision of relapse prevention interventions, were major barriers to introducing these interventions into routine care.

Conclusions: Just over half of UK managers of NHS Stop Smoking Services who responded to the questionnaire reported that, in their services, relapse prevention interventions were currently provided for clients, despite, at that time, there being a weak evidence base for their effectiveness. The most commonly provided relapse prevention interventions were those for which there was least evidence. If these interventions are found to be effective, barriers would need to be removed before they would become part of routine care.

Background

The effectiveness and cost-effectiveness of UK NHS Stop Smoking Services in providing support for smokers wishing to stop have been demonstrated, with more than half of English services' clients achieving self-reported abstinence from smoking for at least four weeks[1,2] However, quitters' rates of relapse to smoking are high, with around 75% of those abstinent at four weeks after their quit date re-starting smoking by one year[1]. The use of effective treatments to reduce rates of relapse to smoking (which we refer to here as relapse prevention interventions, could greatly improve long term cessation rates for the NHS Stop Smoking Services.

A Cochrane review found no clear evidence for behavioural relapse prevention interventions being effective and only relatively weak evidence that some medications, effective for smoking cessation, may also be effective as relapse prevention interventions when provided for extended periods to smokers who had achieved short-term abstinence[3]. We recently completed a review of the evidence base for relapse prevention interventions using a similar search strategy to the Cochrane review, but restricting included studies to those involving abstinent smokers only, and synthesising data from similar follow up time points only, rather than aggregating final follow up data collected at different times as the Cochrane review did[4]. We found that, amongst individuals who had stopped smoking without any cessation support, behavioural self help relapse prevention interventions were effective and varenicline, bupropion and nicotine replacement pharmacotherapy interventions also were effective for preventing relapse to smoking amongst smokers who had achieved abstinence using drug treatments.

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As little was known about either the current provision of relapse prevention interventions in UK NHS Stop Smoking Services or the feasibility of adding these to existing treatment options, we carried out a small qualitative study with a convenience sample of 16 Stop Smoking Service managers[5] to explore these factors. We found that managers had no shared understanding of either the concept of relapse prevention or the kinds of interventions that should be used to prevent relapse, but there was interest in relapse prevention interventions and a willingness to make these available to stop smoking services' clients and this was already happening in some areas. Consequently, in this study, we aimed to quantify the current provision of relapse prevention interventions within the Stop Smoking Services in the UK and ascertain the feasibility of introducing them to services where they were not currently provided. To overcome the lack of a shared understanding of relapse amongst NHS Stop Smoking Service staff, we defined relapse prevention interventions as behavioural or drug therapies delivered after acute smoking cessation treatment has ended and resulted in abstinence from smoking.

Methods

For the benefit of international readers, Additional file 1: Box 1, gives brief details regarding the characteristics of UK NHS Stop Smoking Services [6] and all service managers were asked to complete an electronic questionnaire. From the emergent findings of our systematic review[4] and qualitative research referred to above[4,5] issues of potential importance to the provision of relapse prevention interventions were identified and, from these, a structured questionnaire (Additional File 2), was developed (which was available online at http://www.smokingcessationmanagers.org). The questionnaire was designed to obtain information pertaining to current provision of treatment for smoking cessation as well as current and future relapse prevention treatment provision. The questionnaire also asked about the feasibility of providing the most promising relapse prevention interventions (identified from the reviews and qualitative research as NRT, bupropion, varenicline, group and individual behavioural counselling, and NRT combinations) in routine clinical practice. A clear definition of relapse prevention was given, namely "***Relapse Prevention Interventions (or Relapse Prevention Treatments) are behavioural or drug therapies delivered after acute smoking cessation treatment has ended and resulted in abstinence from smoking. Relapse Prevention Interventions therefore seek to reduce relapse to smoking among abstinent smokers***". We also distinguished relapse prevention interventions from interventions delivered to smokers who had briefly lapsed to smoking (i.e. were not abstinent) and which aimed to prevent a full relapse to smoking; respondents were asked to indicate provision of any such lapse-orientated interventions/ treatments. An email with a flyer advertising the survey and a link to the survey homepage was sent out to a total of 185 managers in December 2008. Non-respondents were followed up via a reminder email and telephone call inviting them to visit the survey homepage and complete the survey. Responses were anonymous and data were summarised descriptively using SPSS version 16.0 for Windows[7]. No hypotheses testing statistical analyses were performed, but some comparisons are presented for descriptive purposes.

Results

A total of 96 managers completed the survey (52% response rate). Fifty four managers responded to the first survey email and completed the online questionnaire. A further 42 respondents completed the survey following the reminder email and telephone call.

Current provision of smoking cessation and relapse prevention treatments

The vast majority of services provided both behavioural and pharmacotherapy interventions for initial cessation treatment. More than half of respondents, 58.3% (n = 56) reported that their services currently provided relapse prevention interventions with behavioural interventions being preferred over the pharmacotherapies (Table 1). Of those providing relapse prevention interventions, 60.7% (n = 34) stated that these were offered to abstinent smokers for as long as these clients perceived they required them, 25.0% (n = 14) for 3-6 months and one service (1.8%) did so for three months or less. Of the 40 services reporting that they did not currently provide relapse prevention interventions, 42.5% (n = 17) had provided such interventions in the past and cited the following reasons for no longer offering this kind of support: pressure to meet government targets, poor client attendance, inadequate funding, and a belief that relapse prevention interventions are ineffective (Table 2).

Managers that responded to the first survey email were compared to those that completed the survey after a reminder telephone call. There was no association between timing of responses and relapse prevention provision (Odds ratios (OR) 0.77; 95% confidence interval (CI) 0.34 to 1.75).

Current provision of treatment for brief lapses

A large percentage of UK NHS Stop Smoking Services, 77.1% (n = 74) also provided treatment for clients who had suffered a brief lapse to smoking. Of these, 72.9% of services (n = 70) indicated the types of support provided: one to one sessions (32.8%, n = 23); rolling groups and drop-in sessions (7.1%, n = 5); telephone support (8.5%; n

Table 1: Provision of acute cessation treatment and relapse prevention treatment in UK NHS Stop Smoking Services

	Type of Treatment % (n)					
	Individual behavioural counselling	Group behavioural counselling	Telephone counselling	Nicotine Replacement Therapy	Bupropion	Varenicline
Acute Cessation	99% (95)	87.5% (84)	81.2% (78)	97.9% (94)	86.5% (83)	92.7% (89)
Relapse Prevention	73.2%(41)	53.6% (30)	76.8% (43)	48.2% (27)	21.4% (12)	19.6% (11)

= 6); combinations of pharmacotherapy, telephone support, and one to one behavioural counselling (15.7%, n = 11); while 35.7% (n = 25) services continued acute cessation treatment. Although managers who provided relapse prevention interventions were also more likely to report providing treatment for brief lapses than those not providing relapse prevention interventions, this was not statistically significant (OR) 1.55; 95% CI 0. 59 to 4.04, P = 0.37).

Managers who responded to the first survey email did not differ from those that responded to the telephone reminder in terms of treatment of brief lapses (OR 1.92; 95% CI 0.70 to 5.26).

Feasibility of providing relapse prevention interventions

Respondents were asked to indicate the likelihood of future relapse prevention intervention provision within their service. Managers who had indicated that relapse prevention interventions were not currently provided were asked to indicate the likelihood of providing these in the future and those already providing relapse prevention interventions were asked about the likelihood of continuing this. Nearly two - thirds, 65.6% (n = 63) of managers thought it very likely or likely that they would continue to provide, or start to provide relapse prevention interventions in their services, while 34.4% (n = 33) of services were not sure or thought it unlikely that they would provide these interventions in the future. There was no association between managers who responded to the first survey email and those who responded to the second survey email in terms of likelihood of future relapse prevention provision (OR 1.05; 95% CI 0.45 to 2.46).

Table 2: Reasons for discontinuation of relapse prevention treatment

Reason	% (n)
Pressure to meet targets	64.7% (11)
Poor client attendance	70.6% (12)
Inadequate funding	29.4% (5)
Ineffectiveness of relapse prevention interventions	17.6% (3)

Managers who wished to discontinue or not to begin relapse prevention support cited the following reasons: cessation orientated targets focussed on four week quit rates (66.7%, n = 22); inadequate funding (42.9%, n = 14); and the fact that clients had usually relapsed before they re-contacted the cessation service (24%, n = 8).

These 33 respondents who indicated that they were not sure or thought it unlikely that their services would provide relapse prevention interventions in the future, were then asked to assume that barriers to provision of these interventions were removed, and to hypothesise, in this instance, which of these interventions they might encourage their NHS Stop Smoking Service to offer to abstinent quitters after smoking cessation treatment. Table 3 reports their responses.

Discussion

Summary of findings

About half of the services surveyed reported providing relapse prevention interventions despite, at the time of the survey, their being only a weak evidence base for their effectiveness and no guidance as to whether or not this kind of support should be provided within the UK Stop Smoking Services. The relapse prevention interventions provided most frequently were telephone and individual behavioural counselling although, at the time of the survey there was no evidence for the effectiveness of these interventions (i.e. from the Cochrane review) and this has not changed with our subsequent review. Many managers were positive about either offering relapse prevention interventions within the NHS or potentially introducing these in the future and the most commonly cited reasons for not providing or wanting to provide these interventions were that: NHS Stop Smoking Services' targets are focussed on achieving short periods of cessation by

Table 3: Likelihood of providing relapse prevention interventions in the absence of barriers

Intervention	Very Likely/Likely % (n)	Not sure/Unlikely/Definitely not % (n)
Individual Counselling	78.8% (26)	18.2% (6)
Group counselling	72.7% (24)	27.2% (9)
NRT	57.6% (19)	33.3% (11)
Bupropion	21.2% (7)	72.7% (24)
Varenicline	24.2% (8)	75.8% (25)
NRT combinations	54.5% (18)	39.4% (13)

smokers and inadequate funding for relapse prevention support, rather than the relatively weak current[3,8] evidence base for the effectiveness of relapse prevention interventions.

Strengths and Limitations

Approximately 50% of survey recipients did not respond and, consequently, the reported rates of interest in and provision of relapse prevention interventions may be overestimated as managers with little interest in providing relapse prevention interventions might have been less likely to respond. A greater response rate may have produced more varied results; non-responders to the survey may have different experiences of providing relapse prevention interventions in their services, although a comparison of the two waves of responses to the survey showed that there were no differences in variables relevant to the survey. Also amongst respondents, some managers may have been unwilling to reveal that they do not provide some form of relapse prevention intervention in their services. However, we believe that biases in the reporting amongst respondents are unlikely as, at the time of the survey, using such interventions was not standard stop smoking service practice and no official guidance recommended their use. The questionnaire used mainly closed ended questions as these are less time consuming to complete and help to optimise completion rates[9] but provided an "other" option for respondents to provide additional information where none of the available options fit the manager's response. Closed ended questions may restrict the respondents to the choices provided, but we do not believe this is the case, because we provided respondents with an "other" option with space for free text which gave managers the opportunity to expand on their response, and greater freedom of expression[10].

Despite these limitations, we believe that the survey is important; it is the first study to investigate the provision of relapse prevention interventions in UK NHS Stop Smoking Services and now that there is evidence that some of these interventions may be effective[4], findings can be used to facilitate the introduction of evidence based ones into the services.

There is no previous research on this topic from the UK and, we believe, internationally as the World Health Organization report on the global tobacco epidemic provides no information on the provision of relapse prevention interventions [11]. We could identify no similar studies internationally which described the provision of relapse prevention interventions in routine clinical practice, so it is difficult to make comparisons. The reasons why such a high proportion of managers reported offering relapse prevention interventions which had no proven evidence base are unknown and may be worth further exploration. For example, this could reflect a desire to do 'something' to remedy high relapse rates from acute cessation treatment, or their anecdotal experience of the effectiveness of relapse prevention interventions, or a perception that smokers appreciate being offered such treatment. As managers favoured behavioural over drug treatments, this suggests that, with smoking cessation services configured as they are currently, it may be difficult to encourage the use of pharmacological interventions for relapse without there being clear guidance on this. Almost 77% of respondents working in services that delivered relapse prevention interventions provided telephone counselling which could be explained by the finding that most services provided telephone support to aid cessation and this may have been relatively easy and inexpensive to extend. Clearly, integrating effective pharmacological interventions into routine clinical practice has cost implications and might be more challenging.

Conclusions

Current provision of acute cessation treatment largely reflected UK guidance (NICE, SCOTTISH NICE[12], DH Monitoring guidance[13]) and our survey suggests that similar evidence based guidance is needed to support managers wishing to provide relapse prevention interventions in order to ensure that, in the future, the most promising and effective interventions can be introduced into routine care. Further research is required to solidify current evidence on the effectiveness of relapse prevention interventions and then to explore further the feasibility and cost - effectiveness of introducing these in the NHS Stop Smoking Services. Should relapse prevention interventions be found to be cost - effective and acceptable for use by abstinent smokers in the NHS Stop Smoking Services the perceived barriers would need to be removed.

Additional material

Additional file 1 Box 1 - Characteristics of NHS Stop Smoking Services. The box provides a background, details of service provision and other characteristics of NHS Stop Smoking Services.

Additional file 2 Survey Questionnaire. This file contains the entire survey questionnaire.

Competing interests

Within the last five years Tim Coleman has undertaken consultancy work for Pierre Fabre Laboratories, France and also Johnson & Johnson. Both companies produce nicotine replacement therapy. Andy McEwen has received travel funding, honorariums and consultancy payments from manufacturers of smoking cessation products (Pfizer Ltd, Novartis and GSK Consumer Healthcare Ltd). He also receives payment for providing training to smoking cessation specialists and receives royalties from books on smoking cessation.
The other authors declare that they have no competing interests.

Authors' contributions

All authors contributed to design of the survey questionnaire. SA carried out the survey analysis and wrote the first draft of the paper. All authors read and approved the final manuscript.

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RESEARCH ARTICLE Open Access

Feasibility of offering nicotine replacement therapy as a relapse prevention treatment in routine smoking cessation services

Jessica Turner[1], Ann McNeill[2], Tim Coleman[3], Jo Leonardi Bee[2] and Shade Agboola[2*]

Abstract

Background: National Health Service stop smoking services (NHS SSS) in the UK offer cost- effective smoking cessation services. Despite high abstinence rates after acute cessation treatment, the majority of clients have relapsed by one year. Several interventions have been identified, from trial data, as effective in preventing relapse to smoking. This study investigated uptake, feasibility and acceptability of offering nicotine replacement therapy (NRT) as a relapse prevention intervention (RPI) in NHS SSS.

Methods: Eligible smokers who had successfully completed acute cessation treatment using NRT at Nottingham City NHS SSS between April 2010 and January 2011 were offered the RPI and the rate of uptake was monitored. Consenting individuals completed a baseline questionnaire, providing demographic and smoking behaviour data. The RPI consisted of using NRT for a further 12 weeks after initial cessation-orientated treatment had ended. At a six-month review, self-reported smoking status was assessed via telephone. Anonymised demographic data on NHS SSS users who did not agree to participate in the study were retrieved from NHS SSS records and used to determine the presence of any socio-demographic differences between individuals who agreed to participate in the study and those who did not. Semi-structured telephone interviews were conducted with a selection of participants; these were audio-recorded, transcribed and analysed to identify participants' views on the RPI.

Results: Of 493 stop smoking service clients who were assessed, 260 were eligible for and offered the RPI and 115 (44%, CI 38%- 50%) accepted. Individuals who accepted NRT were significantly more likely to be older ($p < 0.001$) and to pay for their prescriptions ($p < 0.001$). Quitters who had never worked or were unemployed were significantly less likely to accept the offer of relapse prevention compared to those in routine and manual occupations (55% reduction in odds, $p = 0.026$).
Interview findings revealed that clients who accepted extended NRT felt the longer duration of pharmacological and psychological support were both valuable in helping them to remain abstinent.

Conclusion: In routine smoking cessation service care, it is feasible to offer clients extended courses of NRT as a RPI. The RPI was acceptable to them as almost half of the eligible clients offered this treatment accepted it.

Keywords: Smoking relapse prevention, Nicotine replacement therapy, Feasibility study, Smoking cessation service

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Background

Smoking is a cause of significant preventable morbidity and mortality [1]; consequently, reduction in smoking prevalence is a priority for governments and health care systems across the world. The World Health Organisation's Framework Convention on Tobacco Control (FCTC), the world's first public health treaty, recommends a comprehensive strategy that participating countries can adopt to reduce tobacco use including advertising bans, the use of taxation and price increases, smoke-free policies, health promotion and mass media tobacco control campaigns, and cessation support. Many countries have smoking cessation services which offer advice and support for smokers to encourage them to quit successfully.

The United Kingdom has implemented a comprehensive tobacco control strategy over recent years [2] including a national network of smoking cessation services, largely provided by the National Health Service (NHS); these services are referred to as the NHS stop smoking services (NHS SSS) (Table 1). NHS SSS commonly provide eight-12 weeks smoking cessation support incorporating pharmacological and psychological therapies to clients who are motivated to quit. Nicotine replacement therapy (NRT), buproprion and varenicline have been proven to be cost- effective with 15% of clients smoke-free at one year [3]. Recent data show 48% of NHS SSS clients have stopped smoking four weeks after setting a quit date [4], however, the majority (85%) have relapsed to smoking by one year, reflecting the addictive nature of cigarette smoking [5]. High relapse rates are common in other similar services offered elsewhere [6]. Effective relapse prevention interventions (RPIs) offered at the end of current treatment could therefore increase long term success rates. Systematic reviews have concluded that RPIs in the form of extended use of NRT, buproprion or varenicline are probably effective when used to prevent relapse amongst smokers who have recently become abstinent [7,8] and economic modelling suggests that this use of extended treatment is likely to be highly cost effective [9]. However, most trial data are from countries without the cessation infrastructure seen in the UK and hence their applicability to routine health care settings such as the NHS is unclear. There is also evidence that smokers trying to stop often use short and incomplete courses of NRT [10,11] and hence identifying the uptake and acceptability of longer courses of treatment is of importance to inform both NHS and similar services internationally. A recent study has identified that, despite there being no evidence to support this view, some providers of NHS SSS are concerned that clients will not accept RPIs that involve using medications for prolonged periods [12]. In this study we therefore investigated the uptake, feasibility and acceptability of offering extended courses of NRT as a relapse prevention intervention to recently abstinent quitters who had been helped to achieve abstinence in a routine health care setting, NHS SSS located across the city of Nottingham.

Table 1 Characteristics of stop smoking services

Background	Established in 1999 in the most disadvantaged areas in England
	Rolled out across the UK from 2000
	Represent a unique national initiative to provide support for smokers motivated to quit [1]
Service provision	Service provision framework is based on an evidenced based approach to treating dependent smokers [2]
	Usually involves regular meetings (one to one or in groups) with a trained adviser, using structured withdrawal-oriented behavioural support combined with smoking cessation medications [1]
	Smoking cessation medications are usually offered on the basis of an abstinent-contingent treatment programme involving an initial course of two to four weeks, followed by further prescriptions if the quit attempt is continuing [3]
	If a smokers' attempt to quit is unsuccessful, advisers can use discretion and professional judgement when considering whether a client is immediately ready to receive support to attempt to stop smoking again [4]
Training	Smoking cessation staff come from a wide variety of backgrounds
	They are trained in the provision of treatments to help with stopping smoking
	This training is currently being standardised in England through a newly established National Centre for Smoking Cessation and Training
Targets	For the first ten years, targets were set within England for the numbers of smokers attending the services who set a quit date and who quit smoking four weeks after the start of treatment
	Smoking cessation services are currently expected in the course of a year to treat 5% of their local population, in line with best practice recommendations contained within National Institute for Health and Clinical Excellence programme guidance for smoking cessation [3]

Methods

Design

Ten NHS SSS clinics were selected from clinics offering specialist intensive smoking cessation support across Nottingham to include a range of sociodemographic catchment areas. The clinics were located within Nottingham City at GP surgeries, Community Centres and Children's Centres. All clients at these settings who had completed acute cessation treatment eight weeks after their quit dates, and for whom self-reported abstinence was validated with an expired air carbon monoxide (CO) measurement of <8 ppm. were offered study enrolment by their smoking cessation advisor.

Sample

Eligible clients were those who had used NRT for their acute cessation treatment, were between 18 and 65 years of age and had been regular smokers for 12 months prior to their cessation treatment, and these were offered RPI in the form of extended courses of NRT. Relapse prevention treatment was not offered to those who were pregnant or breastfeeding, individuals with known hypersensitivity to NRT, individuals with unstable cardiovascular disease, unstable cerebrovascular disease including transient ishchaemic attacks, chronic generalised skin disorders or major psychiatric disorders. These individuals were excluded on the basis of information contained within the Nottingham New Leaf Clinical Guidance, (April 2010) which states that clients in these categories are "special precaution groups". Individuals who used other tobacco products including cigars, pipe tobacco, snuff and chewing tobacco were also excluded. Participants consented to receive extended NRT therapy for up to 12 weeks, to potentially be interviewed about this and to be followed up at six months. Those enrolled completed a baseline questionnaire, which sought their views on using the additional NRT treatment. We also sought permission to conduct follow up at six months for those clients who did not wish to receive extended NRT therapy; these participants were also given a short questionnaire asking about reasons for declining participation.

Relapse prevention intervention

Individuals who agreed to receive an extended course of NRT were issued with a four week supply of the same NRT product that they had used for acute cessation and they were asked to return in one month for a further four weeks' supply to be provided by a cessation adviser, contingent on their continued abstinence from smoking (defined as not having smoked more than five cigarettes in the last month, with five or fewer cigarettes being defined as lapses and an expired air carbon monoxide (CO) measurement of <8 ppm). Individuals who reported that they had smoked more than five cigarettes in the month prior to the visit, and with a CO level greater than 8 ppm were not issued additional NRT and were withdrawn from the study.

The following forms of NRT were available for relapse prevention: 24 hour patch, 16 hour patch, 2 mg gum, 4 mg gum, 1 mg lozenge, 2 mg lozenge, 4 mg lozenge, nasal spray and inhalator and 2 mg microtabs. A final month's NRT was supplied at a third appointment after identical procedures had been followed. Brief counselling support was offered and CO measured at each appointment. Additionally, at each appointment, participants provided information on smoking status, and completed questionnaires asking about the difficulty and acceptability they perceived in using NRT for an extended period NRT, and any side effects experienced.

At six months, an attempt was made to contact all participants who had agreed to telephone follow up regarding self-reported smoking status with three attempts at calling made; when this was successful, self-reported abstinence (i.e. no cigarettes smoked over the last month) was recorded. The stages involved in the study are described in Figure 1.

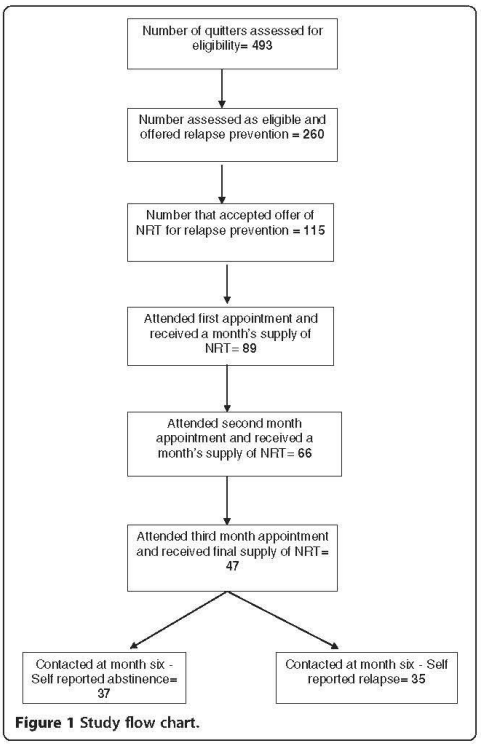


Figure 1 Study flow chart.

Data access and analysis

Anonymised demographic data on NHS SSS users who did not agree to participate in the study and who did not wish to be contacted at six month follow-up were retrieved from the NHS SSS records and used to determine the presence of any socio-demographic differences between individuals who agreed to participate in the study and those who did not. Data on individuals who refused to participate but agreed to be contacted at six months were also included. These data included age, gender, ethnicity, payment for prescriptions and occupation. Data were retrieved between the months of July 2010 and February 2011.

Data were analysed using STATA statistical software [13]. Summary statistics were performed to estimate the proportion of individuals who accepted the offer of an extended course of NRT (the primary outcome), based on responses to the questionnaire items. Bivariate analyses using chi-squared tests and t-tests were performed to assess any differences in age, gender, ethnicity, occupation and payment for prescriptions between those who accepted the offer of extended treatment and those who did not.

Qualitative research

Participants who consented to be interviewed were selected purposively to give a range of socio-demographic backgrounds and were then contacted via telephone. Attempts were made to include individuals who were still abstinent, individuals who had relapsed and individuals who had experienced a lapse. Interviews took place over the telephone from May 2010 to April 2011 at between one and four months after they had entered the study. Two different semi-structured interview guides were used; one for clients who had relapsed to smoking and another for those who were abstinent at the time of interview. Guides asked about smoking history, experience of using NRT, the effectiveness of treatment, concerns about taking treatment, consideration of other treatments (specifically bupropion and varenicline), the optimum way of accessing NRT for RPI and circumstances of any lapses to smoking. All who participated in the interviews were offered £10 shopping vouchers.

JT (an author) conducted interviews which were digitally audio-recorded and transcribed verbatim. Transcripts were open coded and a thematic framework was developed, in the context of the study aims, after consideration of themes emerging from the data [14]. Transcripts and the framework were then distributed to all other researchers for review; themes were validated and refined and then re-coded where required. Mapping was then used to look for associations and exceptions. Qualitative data analysis software was not used in the analysis Quotations in the results section are identified by sex, age and occupational status [retired, unemployed/sick, routine and manual, intermediate]/ professional].

Ethical approval

The study was approved by the Derbyshire Research Ethics Committee, REC reference number 09/H0401/87. The study also received organizational approval from the research and development department of Nottinghamshire County Teaching PCT.

Results

Of 493 recent quitters seen in the study clinics, 260 were eligible for the offer of relapse prevention treatment and 115 (44%, 95% confidence interval, CI 38%-50%) accepted the offer. Reasons for declining the offer of relapse prevention were given as follows: satisfied with eight weeks' NRT (n = 66, 46%); inability to attend monthly follow-ups (n = 29, 20%); concern about long-term use of NRT (n = 10, 7%); and 'other' (n = 40, 28%). The following explanations were given for those in the 'other category: "taking champix", "health problems", "no longer using NRT", "special circumstances", "taking zyban", and "declined without providing reasons". The mean age of participants was 43 years, (SD, 11.9 years), most were White British (76%), slightly over half of the participants were female (54%) and around two thirds were exempt from prescription payments (64%).

Table 2 presents participants' socio-demographic details and Table 3 compares socio-demographic characteristics of those accepting the offer of the RPI with those who did not. Those who accepted NRT were significantly more likely to be older ($p < 0.001$) and to pay for their NRT prescriptions ($p < 0.001$). Quitters who had never worked or were unemployed were significantly less likely to accept the offer of relapse prevention compared to those in routine and manual occupations (55% reduction in odds, $p = 0.026$).

Of those who agreed to use the extended courses of NRT, 77% (n = 89) attended the one month follow-up and were issued with a second month's supply of NRT; 57% (n = 66) attended the two month follow-up and were issued with a third month supply of NRT; 41% (n = 47) attended the three month follow-up. At each clinic visit, there was 100% agreement between a participant's self-reported smoking status and CO measurements, as recorded by the stop smoking advisor (clients are told about CO testing and know to expect it). At the six month telephone follow up, 63% (n = 72) of participants were contacted.

Ease of usage, acceptability and side effects

Of those followed up in the first month, 98% of individuals reported that they found it "very easy" or "easy" to use the NRT products, this remained at 97% and 98% of individuals finding NRT use "very easy" or "easy" at months two and three respectively. Ninety seven percent of individuals

Table 2 Sociodemographics of individuals accepting and declining the RPI

Variable	Individuals accepting RPI (n = 115) (As percentage of variable.)	Individuals declining RPI (n = 145) (As percentage of variable.)	Total offered RPI (n = 260) (As percentage of variable.)
Age:			
18-25	1 (0.9%)	15 (10.3%)	16 (6.2%)
26-33	11 (9.6%)	23 (15.9%)	34 (13.1%)
34-41	25 (21.7%)	40 (27.6%)	65 (25%)
42-49	30 (26.1%)	27 (18.6%)	57 (21.9%)
50-57	23 (20%)	21 (14.5%)	44 (16.9%)
58-65	25 (21.7%)	19 (13.1%)	44 (16.9%)
Gender:			
female	66 (57.4%)	75 (51.7%)	141 (54.2%)
male	49 (42.6%)	70 (48.3%)	119 (45.8%)
Payment for prescriptions:			
Paid	41 (35.7%)	23 (15.9%)	64 (24.6%)
Exempt	64 (55.6%)	102 (70.3%)	166 (63.9%)
Unknown	10 (8.7%)	20 (13.8%)	30 (11.5%)
Ethnicity:			
White	103 (89.6%)	113 (77.9%)	216 (83%)
Other	11 (9.6%)	15 (10.3%)	26 (10%)
Not recorded	1 (0.8%)	17 (11.8%)	18 (7%)
Occupation:			
Full time student	5 (4.3%)	6 (4.1%)	11 (4.2%)
Home carer	9 (7.8%)	13 (9.0%)	22 (8.4%)
Intermediate	6 (5.2%)	10 (6.8%)	16 (6.2%)
Managerial/ professional	3 (2.6%)	5 (3.4%)	8 (3.1%)
Never worked/ unemployed	19 (16.5%)	35 (24.1%)	54 (20.8%)
Retired	13 (11.3%)	4 (2.8%)	17 (6.5%)
Sick/disabled/unable to work	9 (7.8%)	13 (9.0%)	22 (8.5%)
Unable to code	1 (0.9%)	18 (12.4%)	19 (7.3%)
Unknown	3 (2.6%)	2 (1.4%)	5 (1.9%)
Routine and manual	47 (41%)	39 (27%)	86 (33.1%)

reported that they were "very pleased" or "pleased" with the experience of using NRT at one month; this satisfaction was maintained, with 97% and 96% of those followed up in the second and third month stating they were "pleased" or "very pleased" with the NRT.

A total of 27 (30%) participants reported that they experienced side effects to NRT in the first month, 14 (21%) in the second month and 10 (21%) participants in the third month. The most commonly reported side effects were skin rash from the patches, indigestion and insomnia.

Abstinence at six month follow-up

Of the 115 participants who took part in the study, 37 (32%, 95% CI 24%-41%) self -reported being abstinent at six month follow-up, 35 (30%, 95% CI 22%-39%) individuals had relapsed and 43 (37%) individuals were lost to follow-up. Only two of the eleven non-participants who consented to be followed up were contactable at six month follow up and both had relapsed to smoking.

Interview findings

Nineteen interviews were performed. After 16 interviews no new themes were identified and a further three interviews were conducted to confirm data saturation. Participant demographics and relapse/ abstinence status are outlined in Table 4.

In general, the interviewees felt that the RPI was very helpful and they reflected on it positively. The principal themes identified were reasons for continuing quit success, the concept of and reasons for relapse, choice of

Table 3 Comparison of individuals who accepted and declined the offer of relapse prevention treatment (univariate analysis)

Variable	Odds ratio	95% CI	P-values
Age:			0.001
Per year	1.04	1.02-1.06	
Gender:			0.363
female	1.26	0.77-2.06	
male	Reference group		
Payment for prescriptions:			0.001
Paid	2.84	1.56-5.17	
Exempt	Reference group		
Ethnicity:			0.604
White	1.24	0.55-2.83	
Other	Reference group		
Occupation:			0.024
Full time student	0.69	0.20-2.44	
Home carer	0.57	0.22-1.49	
Intermediate	0.50	0.17-1.49	
Managerial/ professional	0.50	0.11-2.22	
Never worked/ unemployed	0.45	0.22-0.91	
Retired	2.70	0.81-8.94	
Sick/disabled/unable to work	0.57	0.22-1.49	
Unable to code	0.05	0.01-0.36	
Unknown	1.25	0.20-7.83	
Routine and manual	Reference group		

Table 4 Socio-demographic breakdown of qualitative research interviews

	Number of participants
Gender	
Male	5
Female	14
Age	
18-25	1
26-33	1
34-41	2
42-49	4
50-57	8
58-65	3
Smoking status at interview	
Relapsed	4
Lapse(s)	1
Abstinent	14
Payment for NRT prescriptions	
Exempt from prescription charges	11
Pay for prescriptions	8
Occupation	
Unemployed/ sick disabled	4
Routine and Manual	7
Professional/ intermediate	3
Retired	5
Used NHS SSS during previous quit attempts.	7
Total number of previous quit attempts	
None	2
1or 2	7
3 or more	10
Number of years smoking	
<10	1
11-20	3
21-30	2
31-40	7
41+	6

service, and concerns about prolonged treatment; findings from those themes which relate to the new RPI being evaluated are described in more detail below.

Reasons for quit success

Participants outlined several factors relating to the extended treatment that they felt had helped them remain abstinent.

The majority of participants perceived that the NHS SSS advisor support was important for practical advice and motivational support, both in the initial cessation period and in the prolonged relapse prevention stage. The use of a carbon monoxide detector was identified as a deterrent to relapse but also as an indicator of physical improvement in the initial cessation stage (Table 5).

NRT was seen as crucial to reducing cravings and physical dependence. Interviewees had several theories as to why prolonged therapy with NRT may have improved their ability to quit and remain stopped. These included the concept that the level of physical addiction was related to the extent of smoking history and that those who had been smoking for longer might need longer to be weaned off smoking. Another concept was that changing ingrained, habitual behaviour is a lengthy process and the longer period of support provided a more appropriate timeframe for this. Other interviewees felt the extended support and treatment was a 'back-up' or 'fail safe' (Table 5). However, all participants identified that, once a quit attempt had started, NRT alone was not enough to maintain abstinence; self motivation, support from friends, family and formal support services such as the NHS SSS advisors were also important.

Table 5 Quotes illustrating 'Reasons for quit success'

Reasons for quit success	To start with it was because she was going to do the breathing test... and there was no way I was going to fail that...(F, 63, Retired)
	It's important to me (speaking to an advisor) because... I know someone is there that I can talk to...(F, 27, Routine / Manual)
	I think for me because I had been a smoker for so long... it was doing it over a long period of time. I think it did me good; I took longer to wean myself down. (F, 63, Retired)
	The government has given you...where they say...we are going to stop just after 12 weeks... it's too short...too short a time period...because my body has gotten used to say 29...39 years, nearly 40 years of smoking...you can't do that...stop in 12 weeks... (M, 56, Routine / Manual)
	Yeah, I found erm, I don't know whether it was just comfort, just to know it was there, you know what I mean? I think if someone had just stuck a plaster on my arm...whether that sounds a bit silly...I just felt I needed it... (Female, 55, Retired)

The concept of, and reasons for, relapse

Participants who had lapsed or relapsed to smoking often described feelings of guilt and occasionally mentioned feeling physically unwell after smoking. Several participants, regardless of smoking status, identified the theory of 'social smoking' or having 'just one' as not really being considered smoking. Reasons proffered for previous or current failure in quit attempts were usually related to personal stress. Some individuals recognized that lack of motivation or support from friends, family or partners was also a contributing factor, especially during previous quit attempts conducted on their own (Table 6).

Choice of service

NHS SSS face to face clinics were the preferred format and provider of support for relapse prevention treatment; this was because they were considered convenient, were free and the service was often considered to be better quality than at alternative providers such as pharmacies and general practices. Some patients mentioned the importance of not having to pay for prescriptions for NRT, and this often determined their response as to where they would like to receive medication from.

Whilst it was recognized that, for some people, face to face appointments at NHS SSS were more difficult to attend, the majority of interviewees felt that these were of added benefit because carbon monoxide readings could be performed and communication was easier. However, there was some enthusiasm for support provided via telephone amongst interviewees too (Table 7).

Concerns about prolonged NRT use

No patient stated concerns about continuing NRT for a longer period of time. However, being able to stop using nicotine replacement entirely was seen as desirable as a long-term goal.

Discussion

Main findings

To our knowledge this is the first study to attempt to quantify the potential demand for relapse prevention treatment within routine smoking cessation care. We found that 44% of eligible clients who had achieved cessation using NRT and NHS SSS support accepted an offer of extended treatment with NRT; of these 41% continued using NRT for 12 weeks. These findings suggest that there would be a reasonable demand for RPIs (at least among those using NRT for acute cessation) if they were to be routinely offered by NHS SSS. Overall, the qualitative research indicated that participants were generally satisfied with the RPI that they had received, welcoming both the extension of NRT supplies as well as the continuing contact with the NHS SSS advisors and there were few concerns about the extended use of NRT.

Strengths and limitations

The study was carried out in a selected sample of NHS SSS in one large city and may not therefore be representative of all smoking cessation services in the UK or elsewhere. Nevertheless, we selected services covering a range of socio-demographic areas and this is borne out

Table 6 Quotes illustrating 'Concept of, and reasons for, relapse'

Concepts and reasons for relapse	So I went outside...realized what I was doing...and got rid of it...and I felt guilty then for doing it... (F, 52, Routine/Manual)
	The last one was a month ago and before that I was smoking 20 a day. So although I have had one I don't really consider that as smoking...(F, 39, Routine/ Manual)
	There was one particular incident where I had given up, and then my father-in-law's step mum became seriously ill and I went to care for her. And in all fairness to get me through that I started smoking again...(F, 50, Sick/ Unemployed)
	I think it didn't work before because, I think it needed to come from me more. I don't think I put my heart into it before. (F, 39, Routine/ Manual)

Table 7 Quotes illustrating 'Choice of service'

Choice of service	I think it should be free though...for everyone not just people like me on benefits (F, 39, Routine/ Manual)
	For me it was the clinic and that was it. If it wasn't for the clinic I think I would still be smoking. (F, 60, Routine/ Manual)
	That protected time with a professional therapist. I think it's very important to have that protected time, even if it's for only a few minutes, where you know it's just you and your mentor (F, 56, Intermediate/ Professional)
	I think the (local NHS SSS) is better because... you get to talk to your advisor...if you just go to the pharmacy there's other people there...you might not get much time because the pharmacy is busy...(F, 21, Unemployed)
	No, I think it has to be face to face... and you have to blow into that carbon monoxide indicator...(F, 49, Intermediate/Professional)
	I don't mind the telephone thing at all... I finish work at 2 o'clock it saves me from going back out again...(M, 56, Routine/Manual)

by the data presented in Table 2. The inclusion and exclusion criteria were based mainly on the stop smoking service supply criteria for NRT but did result in around half of the clients being excluded. Further research is necessary with some of the excluded groups, such as those with psychiatric disease and for extended treatments may be particularly important, given the high rates of heavy dependent smoking in these groups. As such it excluded pregnant women and individuals younger than 18 years and older than 65 years and we were unable to assess the feasibility and acceptability of NRT for relapse prevention in these groups. On the other hand, we have no reason to believe that including individuals younger than 18 years and older than 65 years would have altered the findings in terms of feasibility and acceptability. NRT is used only on the advice of a health professional in pregnancy, and further research is still needed to demonstrate its effectiveness and safety as a relapse prevention intervention in pregnant smokers.

Of those entered into the study, 32% (95% CI 24% to 42%) self-reported being abstinent at six month follow up, but the design of the study was such that it is not possible to determine the efficacy of the RPI treatments provided. This is because no control group (i.e. one not offered RPI) was included and, hence, one cannot be certain about the numbers of extra smokers who remained abstinent at six months because of the RPI. Self-reported smoking status has been shown to correlate well with biochemical measurements. Murray et al. (2002) [15] compared biochemical measures with self-report and found that the size of the differences suggests that self-report bias does not appear to result in "seriously misleading findings in a smoking cessation study". As the purposes of this feasibility study did not include assessing effectiveness, we only used self-reported smoking abstinence at six months.

The method of sampling for the qualitative study meant that only individuals who could be contacted were interviewed and only a few people who had relapsed to smoking were included. This is a potential source of selection bias and it seems likely that individuals interviewed may have been more motivated to quit and respond more favourably to the RPI. We were therefore unable to explore comprehensively the views of participants who had relapsed to smoking. However, the interviews were carried out with a mix of socio-demographics broadly reflecting those eligible for treatment.

The majority of interviews were conducted during the course of relapse prevention, but a few were conducted after relapse prevention treatment had ended. The interview findings do not suggest that the timing of the interviews had any impact on the perceptions of interviewees regarding relapse prevention.

Important emergent issues

This study demonstrates that with the support of the NHS SSS staff, a RPI involving NRT can be added to existing treatment protocols, and that around half of eligible smokers are likely to request it. This contrasts with the reported perception of likely low demand for RPIs that has previously been articulated by some NHS SSS staff [12], although these perceptions were largely based on the variable experiences of providing non-evidence based, largely non-pharmacological RPIs in the NHS SSS. The acceptance rate of the RPI offered in this study, in contrast to these negative views suggests that using extended courses of NRT is acceptable to NHS SSS clients.

Clients accepting the RPI in this study appeared to represent a relatively deprived group of smokers; around 40% were unemployed, sick or disabled or carers and a further third were routine or manual workers. This may be because Nottingham City is known to have high levels of deprivation [16]. A prospective cohort study of smoking cessation treatment in primary care found that smokers were more likely to receive smoking cessation treatment if they lived in deprived areas, and this may be due to the likelihood that more affluent smokers buy supplies of NRT over the counter [17]. The main

reasons given for declining the offer of relapse prevention treatment were that the clients were satisfied with the eight weeks of NRT they had already been supplied or that they were unable to attend the monthly follow ups. Older clients and clients who paid for their prescriptions were more likely to accept the offer of extended support. The former finding is not surprising as, in previous studies, older smokers have been found to be more motivated and more likely to quit smoking than their younger counterparts [18]. It possibly also suggests that RPIs may be more attractive to those who had been smoking for longer. Even though the sample of recent quitters appeared to represent quite a deprived group, the finding that clients who paid for their prescriptions were more likely to accept the offer of RPI may be because clients who paid for their prescriptions were more motivated to quit as they were willing to invest in the quitting process.

Nearly all those who participated in the study reported that they found it easy to use the NRT products. This finding is not surprising as the literature suggests that NRT products are generally easy to use [19]. The side effects reported were also similar to the established side effect profile of NRT and were all mild and transient [20].

Interviewees recognized that to remain successfully quit, multiple factors are involved including: self motivation, pharmacological help, support informally through family and friends and formally through services such as NHS SSS, factors which have been identified previously [21]. Most of the clients interviewed reported having several failed quit attempts before, had smoked for a long duration and tried various pharmacological and non-pharmacological methods previously. Overall clients were satisfied with the RPI they received; they identified that prolonged nicotine replacement and behavioural support were both key to their remaining quit.

Conclusion

It is feasible to offer a relapse prevention intervention in the form of an extended course of NRT to smokers through an NHS SSS and nearly half of those offered such a treatment are likely to accept it, with 41% using extended NRT for up to three months. This study also shows that abstinent quitters find extended courses of NRT acceptable and easy to use and they are positive about receiving extended NRT as well as extended behavioural support through NHS SSS. Future research should investigate the effectiveness of NRT used as a relapse prevention aid in routine healthcare settings.

Competing interests

TC declares that, in the last 5 years, he has been paid for consultancy work by Pierre Fabre Laboratories; manufacturers of nicotine replacement therapy. This manuscript has not been discussed with any third parties. None of the other authors declare any competing interests.

Authors' contributions

SA, AM, TC & J L-B designed this study; SA and JT conducted the data collection and analysis, and drafted the initial manuscript. All authors were involved in revising, reading and approving the final manuscript.

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Chapter 8 Contribution to knowledge

This section summarizes contribution to knowledge and highlights priorities for future research.

The conceptual model of relapse[12] upon which the papers in this submission are based suggests that factors that precipitate relapse fall into two categories: immediate determinants (e.g. high-risk situations, coping skills, outcome expectancies, and the abstinence violation effect) and covert antecedents. Marlatt also proposes a set of treatment strategies designed to limit relapse likelihood and severity.

Other factors which have been shown to increase risk of relapse include lower educational level, higher baseline nicotine dependence, social smoking cues, recently failed quit attempt, cessation related sleep disturbance, anxiety and depression[35].

The findings from the papers included in this thesis support Marlatt's model. A basic assumption in this model is that relapse events are immediately preceded by a high-risk situation, broadly defined as any context that confers vulnerability for engaging in the target behaviour[128]. This is aptly illustrated in the accounts of smokers who were interviewed as part of the feasibility study[50]; most relapse was attributed to personal stress which is one of the covert antecedents identified by Marlatt as a precursor of relapse. Relapse was also ascribed to immediate determinants such as high-risks situations, notably difficult family circumstances.

The qualitative paper[48] explored advisor perceptions and attitudes to relapse prevention, and showed that relapse prevention strategies being offered to smokers at the time were largely underpinned by Marlatt's model. Relapse prevention treatments were usually provided on an individual or group basis, and smokers were helped to identify situations and triggers that might lead to smoking lapses or relapse, taught strategies to help overcome the associated urge for a cigarette, and advised of steps to take to prevent lapses and, where lapses have occurred, steps to prevent full blown relapse. This is, again, in line with the assumption in Marlatt's model that relapse occurs following exposure to high-risk situations. This understanding underpins the strategies used to prevent relapse by smoking cessation advisors.

The systematic review and meta-analyses of relapse prevention[49] included papers that explored behavioural relapse prevention treatments that were underpinned by the Marlatt's model. For example, participants in the treatment group in the study by Victor et al[129] received a three-session skills-training programme in which they developed and actively rehearsed individually tailored coping strategies for likely relapse situations. Smith et al[130] used cognitive behavioural skills training therapy to assist smokers to develop coping skills for relapse prevention. According to Marlatt's

model, coping skills are immediate determinants of relapse, and smokers who are able to mount an effective coping response are less likely to relapse.

What is clear is that, without support, around half of all attempts to stop fail within the first week of attempted abstinence, regardless of underlying risks of relapse[7]. More worrying is the evidence that the typical smoker who seeks treatment for cessation has never managed more than a few weeks without smoking[131]. These underscore the importance of the publications included in this submission. A wide range of research also provides support for the need to incorporate relapse prevention strategies into smokers' treatment journeys [74 132 133].

In order to prevent smokers who have quit smoking from returning to smoking, effective relapse prevention strategies need to be integrated into routine smoking cessation practice. These studies have therefore contributed to an understanding of the views and beliefs of Stop Smoking Service professionals, who are at the forefront of providing smoking cessation support to smokers in the UK. The studies included in this submission have also contributed to the knowledge base on the effectiveness of smoking relapse prevention interventions and the feasibility of providing an effective RPI within a SSS setting. One of the papers used statistical techniques to quantify abstinence and relapse amongst smokers who use varenicline, an effective smoking cessation treatment. More specifically, the contribution of this body of work has been:

- To provide insight into the views, knowledge, and existing provision of RPIs by Smoking Cessation Service professionals in the UK. Qualitative research with 16 health professionals working in SSS in the UK indicated that there was no shared understanding of what relapse prevention meant, or the kinds of interventions that should be used for this. Despite this, managers were positively orientated towards their use, and indicated a willingness to provide them within the routine care delivered by their services. In the online survey, 96 NHS SSS managers from across the UK returned completed survey questionnaires (52% response rate). Of these, over half reported running services that already provided relapse prevention interventions for clients, despite the absence of evidence for their effectiveness at the time of survey completion, and there was a keenness to continue to do so, or, in services which did not currently offer RPIs, to start to provide such interventions in the future.

  Both publications provided a starting point in the quest for deeper insight into the field of smoking relapse prevention. Shortly after SSS were introduced, most of these services

offered programmes of behavioural support to smokers[134]. At the time, there was no up-to-date information available about what constituted 'treatment' for smoking cessation and relapse prevention in UK NHS SSS, such as the numbers and nature of sessions offered, their length and timing, and who delivers these. It was therefore essential to understand the length and timing of treatment programmes offered by these services and the completeness of smokers' attendance at these, mainly because these factors determine if and how relapse prevention interventions could be delivered in addition to current treatment programmes. Agboola et al (2009) and Agboola et al (2010) explored all of these issues using qualitative and survey methodology, and provided a foundation for subsequent research.

- To develop, for the first time, an understanding of the process and outcomes of providing relapse prevention within local Smoking Cessation Services. My work has demonstrated that it is feasible to deliver relapse prevention within local services, and perhaps, more importantly, delivery within Smoking Cessation Services is acceptable to smokers who wish to quit. It also provides vital knowledge for commissioners and providers of Smoking Cessation Services. The study was commissioned at a time when there was evidence that smokers trying to stop often use short and incomplete courses of NRT[135 136], and hence identifying the feasibility, uptake and acceptability of longer courses of treatment was of importance to inform both NHS and similar services internationally.

- To develop and utilise a refined approach to reviewing the effectiveness of relapse prevention interventions. The papers included in this submission have demonstrated evidence for long-term effectiveness of bupropion, nicotine replacement therapy and varenicline which had not previously been apparent. These medications are commonly used within local Smoking Cessation Services, and introducing them as relapse prevention treatments after a period of sustained abstinence reflects how relapse prevention would be likely to work within these services. The evidence review demonstrates that these interventions are effective for relapse prevention, and can be woven into current treatment protocols within local Smoking Cessation Services.

- For the first time, to report evidence, using pooled data from randomized controlled trials, abstinence and relapse patterns in smokers who have used varenicline. This study expands on current knowledge regarding abstinence patterns and relapse curves in 'treated' smokers. The study notably shows that the high relapse rate following treatment

discontinuation underscores the need for extended treatment with varenicline, beyond the recommended 12-week period.

Cost-effectiveness of smoking relapse prevention interventions

A few studies have investigated the cost-effectiveness of smoking relapse prevention interventions. Ruger et al[137] examined the cost-effectiveness of motivational interviewing and found that motivational interviewing helps prevent relapse at a relatively low cost, and may be cost-saving when net medical cost savings are considered. Brandon et al[72] also showed that a series of relapse prevention booklets mailed to ex-smokers were highly cost-effective. Taylor et al[138] used cohort simulation and sensitivity analyses, and combined cost and health service data with systematic review estimates for the effectiveness of nicotine replacement therapy, bupropion and varenicline when used by abstinent quitters to prevent their relapse to smoking. They found that bupropion, NRT and varenicline appeared cost effective at preventing relapse to smoking by smokers who are in quit attempts and have recently become abstinent; they suggest that widespread use of these effective relapse prevention treatments could promote substantial health gain at an acceptable cost to health providers.

Implications for policy and practice

Several national policies have recommended a wide range of evidence-based approaches for supporting smokers who wish to quit. For example, the National Institute of Health and Care Excellence (NICE) Guidance recommends that strategies and policies for smoking prevention and cessation should be underpinned by the use of mass media campaigns, a focus on disadvantaged groups, use of Smoking Cessation Services and enforcement of legislation to prevent children and young people from taking up smoking. The guidance includes robust recommendations for reducing smoking prevalence in a wide variety of settings, including schools, the workplace, in hospitals, in prisons and in military establishments.

The guidance also explores the commissioning of Smoking Cessation Services by local authorities and includes 16 recommendations on provision of effective interventions for smoking cessation by Smoking Cessation Services. The recommendations provide direction on the use of effective smoking cessation treatments including NRT, bupropion, varenicline and behavioural support, provision of

smoking cessation support for people with cardiovascular disease, pregnant women, mothers of infants or children, young people and training information for smoking cessation advisors. It is disappointing to note that NICE guidance currently does not include recommendations for smoking cessation advisors on how they can support smokers to reduce the risk of lapses or to deal with relapse.

Helping tobacco users to quit is one of the six key strands identified in the Tobacco Control Plan for England[52]. None of the actions encompassed within this strand includes relapse prevention. Whilst the plan acknowledges that one of the most effective ways to reduce smoking prevalence is to work to increase the number of tobacco users offered advice to quit smoking and referral to stop smoking services, there is no reference to the role of relapse prevention in achieving this aim.

The Local Stop Smoking Service Monitoring and Delivery Guidance[54] considers the role of relapse prevention, and states that "there is currently little evidence suggesting which behavioural interventions are most likely to prevent people partially or totally resuming smoking. However, extended use of varenicline may be helpful, and further research is required to ascertain the benefits of prolonged behavioural support and extended use of NRT". This suggests that there may be an appetite for further exploration of the feasibility of provision of varenicline for relapse prevention within the Smoking Cessation Service setting.

It therefore appears that policies that have so far underpinned the provision of smoking cessation support in the UK have, to a large extent, been lacking in information on relapse prevention. This is partly due to the unavailability of irrefutable evidence of the effectiveness of smoking relapse prevention interventions at the time these policies were produced. For example, even though the Tobacco Control Plan for England was published in 2011, the Cochrane Review of relapse prevention interventions which had been published in 2009 did not show evidence for the effectiveness of any smoking relapse prevention.

However, one of the systematic reviews included in this submission was published in 2010, and this review demonstrated evidence for the effectiveness of NRT and varenicline for relapse prevention.

These findings have not been reflected in policy to date, and there is no reference to this paper or its constituent studies in the NICE guidance which was updated in 2013.

There is therefore a need to understand the policy-making process with a view to influencing future direction of smoking cessation and relapse prevention practice. This influence may perhaps start at a local level, through direct involvement in the commissioning activities of local authorities. Since 2013, local authorities have had a responsibility for tobacco control, which includes commissioning of local Smoking Cessation Services, prevention activity, enforcement and communications. According to the Local Stop Smoking Service Delivery Guidance[54], four-week quits remain the national outcome measure for Stop Smoking Services, and local areas are advised to continue to collect and submit this data. This is at odds with the evidence that demonstrates that 85% of smokers who quit at four weeks have relapsed by one year, and suggests a real need for a review of the indicators and measures of success which are currently used to assess performance of local areas. Indeed, this was highlighted as a significant barrier to implementation of relapse prevention in two of the papers included in this submission[47 48].

This influence may be best exerted during re-commissioning and re-procurement activity, where the commissioner has greater freedom to design a service specification that incorporates principles of relapse prevention before going out to tender. Key performance indicators within such contracts can be aligned to performance of the chosen provider in the area of relapse prevention, such as the number of smokers who are offered relapse prevention or the number of smokers who are smoke-free at six months.

There may also be scope to explore the use of new approaches to relapse prevention outside the clinical context. E-cigarettes may be one of such methods, and appear to show promise in supporting quitters to remain quit and reducing the risk of relapse. Etter and Bullen[139] assessed smoking behaviour and relapse rates amongst users of electronic cigarettes over a 12-month period, and concluded that e-cigarettes may contribute to relapse prevention in former smokers. A recent Cochrane Review[140] also found that electronic cigarettes help smokers to stop smoking in the long term, which implies that it may be suitable for relapse prevention. Public Health England recommends that Stop Smoking Services should offer support to people who are using e-cigarettes in a quit attempt[141]. The National Centre for Smoking Cessation and Training also acknowledges

that e-cigarettes can support people to quit smoking, and reports that clients of Stop Smoking Services who combined e-cigarettes with behavioural support had the highest quit-rates in 2014-15[142] Many Stop Smoking Services have now declared themselves "E-cigarette friendly Stop Smoking Services"[142].

In 2013, the National Institute for Health and Care Excellence (NICE) published guidance on a harm reduction approach to smoking, which supports the use of licensed nicotine containing products (NCPs) to help smokers cut down, for temporary abstinence and as a substitute for smoking, possibly indefinitely[143].

E-cigarettes are also typically cheaper than licensed stop smoking medicines, and a proportion of users report that they do not need any other smoking cessation medication[144]. E-cigarettes have become the most popular stop smoking aid in England, and Stop Smoking Services are advised to be open to e-cigarette use in people keen to try them to help them quit. There is therefore scope for further research into the use of e-cigarettes within local settings for relapse prevention.

Conclusions and priorities for future research

This submission has provided an overview of the findings from a series of published research papers on smoking relapse prevention interventions. It has shown, in a coherent way, what Smoking Cessation Service professionals know about smoking relapse prevention, the evidence for the effectiveness of a wide range of relapse prevention interventions, the feasibility of offering a RPI that has been found to be effective, and the nature of relapse and abstinence in smokers who have used an evidence-based smoking cessation treatment.

The longer term objective is to continue to build on the work included in this submission.

Specifically, it is clear that:

- There is a need to update the review of interventions to prevent smoking relapse with recently published trials. A number of new behavioural and pharmacotherapy trials have been published since the systematic review included in this submission was published. The findings from these new trials largely support the findings from the systematic review

included in this submission[49]. They include research into the effectiveness of WhatsApp and Facebook for smoking relapse prevention[145], the effectiveness of text messaging for relapse prevention[146] and the use of varenicline for relapse prevention in patients with schizophrenia[147]. Daniel et al explored an interactive voice response (IVR)-supported protocol versus standard Quitline treatment to prevent relapse among recently quit smokers[148], while Unrod et al[149] investigated the effectiveness of relapse prevention booklets as an adjunct to a tobacco Quitline.

A number of new trials[150 151] have also explored the effectiveness of relapse prevention interventions in pregnant and post-partum women[150], and one of them found that exogenous progesterone appeared to be effective at reducing post-partum smoking relapse. This particular finding is significant because the systematic review of RPIs included in this submission did not find evidence for the effectiveness of any intervention delivered during pregnancy and post-partum.

- There is a need to explore the feasibility of provision of other evidence-based treatments as relapse prevention interventions within local Stop Smoking Services.

- There is a need to explore abstinence and relapse patterns in smokers who have used other evidence-based smoking cessation treatments, such as NRT and bupropion for smoking cessation.

- There is also scope for research into the effectiveness of smoking relapse interventions in specific sub-groups of smokers, for example in smokers with mental health conditions and smokers who find it simply impossible to quit long term.

- There may be opportunities to explore the effectiveness of electronic cigarettes for maintaining smoking abstinence and preventing relapse.

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Appendix 1 Number of citations for the published papers included in this PhD submission

Source: (https://scholar.google.co.uk/citations)

Article	Citations
S Agboola, A McNeill, T Coleman, J Leonardi Bee. 2010. A systematic review of the effectiveness of smoking relapse prevention interventions for abstinent smokers Addiction 105 (8), 1362-138	91
SA Agboola, TJ Coleman, AD McNeill. 2009. Relapse prevention in UK Stop Smoking Services: a qualitative study of health professionals' views and beliefs. BMC health services research 9 (1), 67	9
SA Agboola, TJ Coleman, JA Leonardi-Bee, A McEwen, AD McNeill. 2010. Provision of relapse prevention interventions in UK NHS Stop Smoking Services: a survey. BMC health services research 10 (1), 214	4
SA Agboola, T Coleman, A McNeill, J Leonardi-Bee. 2015. Abstinence and relapse amongst smokers who use varenicline in a quit attempt–a pooled analysis of randomized controlled trials. Addiction 110, 1182–1193	3
J Turner, A McNeill, T Coleman, JL Bee, S Agboola. 2013. Feasibility of offering nicotine replacement therapy as a relapse prevention treatment in routine smoking cessation services. BMC health services research 13 (1), 38	1

Appendix 2 Qualitative Study Interview Guide

Relapse prevention in UK Stop Smoking Services: a qualitative study of health professionals' views and beliefs

Interview Guide

The interview schedule

1 What interventions are currently being used by your service to help smokers who wish to stop smoking?

2 In your experience, at what point do smokers who have quit smoking most often relapse to smoking?

3 What do you understand by smoking relapse prevention interventions?

Experiences of delivering Relapse Prevention Interventions within Stop Smoking Services

4 Do you routinely provide relapse prevention interventions to smokers in your service?

5 What types? (Content)

6 To whom, is it to those who have already relapsed or to all smokers after the four week quit date, regardless of smoking status at the time?

7 For how long is the relapse prevention intervention provided for? (Duration)

8 What percentage of smokers who relapse to smoking take advantage of relapse prevention treatments? (Uptake)

9 Are your staff trained to provide relapse prevention support?

10 Do you collect any data so as to monitor the effectiveness of relapse prevention support you provide?

Feasibility

11 What do you think about the effectiveness of.....? Varenicline (champix); bupropion (zyban); extended treatment with NRT; behavioural sessions after the four week quit date; extended telephone contact after the four week quit date; (**This question depends on the answer to questions 4 and 5)**

Challenges Experienced

12 Is it difficult to get smokers to attend any clinics or sessions after the four week quit date?

13 Are there any groups of smokers who pose a challenge in particular?

14 What other challenges do you face with respect to preventing relapse in smokers?

Service Provision

15 What is the nature and number of sessions offered?

16 What is the length and timing of these sessions?

17 What is the actual uptake of these treatment sessions by smokers?

18 What kind of staff are involved in providing these services for smokers who wish to quit?

Appendix 3 Survey Questionnaire

Provision of relapse prevention interventions in UK NHS Stop Smoking Services – A Survey

Survey Questionnaire
Greeting and introduce yourself as a researcher working for the Relapse Prevention in UK Stop Smoking Services Survey

"This Relapse Prevention Survey aims to find out about current provision of relapse prevention interventions which are also known as relapse prevention treatments that your smoking cessation service currently offers or has previously offered. Do you manage your service? (If not, ask to speak with the manager. If not available, request contact details of manager. If respondent is manager, continue.

"The survey will take less than 10 minutes to complete and we can do it now over the telephone if you like?"

If not arrange a time for a follow-up call and/or direct to website
www.smokingcessationmanagers.org.uk

Date:…… Time:……

"**The responses that you give will be treated in the strictest confidence and reported anonymously".**

Before we can ask questions about Relapse Prevention Interventions we need to ask you a few questions about your current service provision to put your answers in context (i.e. support you currently provide to help smokers quit).

1. What types of behavioural smoking cessation interventions are delivered by your SCS?**(tick all that apply)**	
Individual behavioural counselling	
Group behavioural counselling	
Self-directed sessions using computer software	
Telephone advice/counselling	
Self-help materials (i. e. booklet)	
Peer led sessions	
Other (specify)	

2. Does your service deliver advice/counselling in **groups?**	**YES**	**NO**
3. If **YES,** which of the following types of group treatments does your service provide? **(tick all that apply) (if no, continue from 7)**		
Open groups (clients can join and leave at any time)		
Closed groups (fixed number of sessions that run sequentially; usually only joined at the first one)		
Other (specify)		
4. On average how long are the group sessions? Number of minutes =		
5. Is there a specific number of group sessions that constitutes a complete course of treatment?	**YES**	**NO**
6. If **YES**, how many sessions constitute a complete course of treatment? Number of sessions =		
7. Does your service deliver advice/counselling to individuals?	**YES**	**NO**
8. If YES, how long are the individual sessions? Minutes =		
9. Is there a specific number of individual sessions that constitutes a complete course of treatment?	**YES**	**NO**
10. If YES, how many sessions constitute a complete course of treatment? Number of sessions = **(if no, continue)**		
11. Roughly, what percentages of clients attending your service receive individual or group support? (please write in box)	**%** receiving group support	**%**receiving individual support

12. Which of the following drugs does your service recommend to clients? (**tick all that apply)**	Bupropion Varenicline Nicotine replacement therapy Combination NRT (e.g.patch+oral product) Other (specify)……

13. Which of the following drugs can be issued directly to clients attending your service (e.g. by PGD, voucher or prescription)? ***(tick all that apply)***	Bupropion. Varenicline Nicotine replacement therapy Other (specify)……..	
The next few questions ask about relapse prevention interventions provided by your service to abstinent quitters. **Relapse Prevention Interventions (or Relapse Prevention Treatments) are behavioural or drug therapies delivered after acute smoking cessation treatment has ended and resulted in abstinence from smoking. Relapse Prevention Interventions therefore seek to reduce relapse to smoking among abstinent smokers. We are distinguishing relapse prevention interventions from interventions that aim to prevent a lapse becoming a full relapse to smoking (such interventions are addressed in questions 19 and 20)**		
14. Does your service provide relapse prevention interventions to **<u>abstinent quitters?</u>** **(If no, go to question 18)**	**YES**	**NO**
15. If **YES**, what types of relapse prevention interventions do you provide to **<u>abstinent quitters</u>**? **(tick all that apply)**	NRT Bupropion Varenicline Individual behavioural counselling Group behavioural counselling Telephone contact Self-help materials Regular motivational letters Other	

16. How soon after completion of acute cessation treatment can an abstinent smoker access relapse prevention interventions from your service?(**tick one box)**	Immediately	After a period of time has elapsed
If answer is **"after a period of time has elapsed",** what is the length of this period? (please write in box) **17**. For how long are relapse prevention interventions offered to **abstinent quitters** who received smoking cessation treatment from your service? **(tick one response)**	Weeks = 3 months or less Greater than 3 months and up to 6months Indefinitely Other (specify)	
18. Has your service ever provided relapse prevention interventions to **abstinent quitters** in the past?	**YES**	**NO**
If **YES,** indicate reasons why you longer provide relapse prevention interventions (**tick all that apply)**	Poor client attendance Lack of relapse prevention training courses for staff Inadequate funding Relapse prevention treatments are not effective Pressure to meet targets Other	
19. Does your service offer any intervention for someone who has experienced a brief lapse to smoking to prevent full-blown relapse?	**YES**	**NO**
If **YES,** what intervention is offered? (please write in box)		

The next few questions ask about the feasibility and potential challenges of introducing / continuing to provide relapse prevention interventions within the routine care provided by your SCS. **Relapse prevention interventions seek to reduce relapse to smoking among abstinent smokers.**		
20. Are you currently offering relapse prevention interventions?	**YES**	**NO**
21. If **YES** how likely is it that your service will continue to provide relapse prevention interventions? **(tick one response)**	Very likely Likely Not sure Unlikely Definitely not	

22. If **NO**, how likely is it that your service will START to provide relapse prevention interventions? **(tick one response)**	Very likely Likely Not sure Unlikely Definitely not
23. If answer to either of above is **Not sure, Unlikely, or Definitely not**, please state reasons why **(tick all that apply).**	Inadequate funding Dept. of Health focus on 4-week quits rather than long term cessation Clients usually relapse before they contact the service Few clients contact the service after acute cessation treatment whilst still abstinent Inability to provide drug treatment within the service Other (Specify)

24. Assuming that the above issues were resolved, how likely is it that the following interventions **could** be offered to abstinent quitters who have completed smoking cessation treatment -as a form of relapse prevention in your service? **(tick all that apply)**

Intervention	**Very likely**	**Likely**	**Not sure**	**Unlikely**	**Definitely not**
NRT					
Varenicline					
Bupropion					
Group counselling					
Individual counselling					
NRT combinations					
Other RPIs **(write below)**					

24. If you answered 'probably not' or 'definitely not', for any of the listed interventions please provide reasons (please write below).

Appendix 4 Feasibility Study Interview Guide for Abstainers

Feasibility Study of relapse prevention treatment in Nottingham's New Leaf Smoking Cessation Service

Semi-Structured Interview Guide FOR ABSTAINERS

Version 1.2 Date 23/11/09

Introduce self, tell interviewee about the purpose of the interview, ask for permission to record, assure interviewee of anonymity, inform interviewee about interview length.

Clinic Location:

Participant study number:

Are you still abstinent? (If YES use this guide. If NO, use other guide)

1. **Smoking History**

- It's great that you're still abstinent, so you are saying that you haven't smoke one cigarette since quitting?
- At what age did you start smoking regularly?
- Did you reduce your cigarette use in the month prior to accessing the smoking cessation service?
- How many quit attempts have you made prior to this one?

2. **Experience of taking NRT for relapse prevention**

Convenience

- Which type of NRT are you using? (**gum, lozenge, inhalator, patch, microtabs**)What dosage?
- How convenient is it to use this type? (**Do you find this convenient?)**
- Have you used any other type of NRT in the past?
- Is there any other type of NRT you'd prefer to use to remain smoke free? **(Are you aware of any other types, and if so are there any types you'd like to use?)**

Usage

- How have you been using the NRT product? Eg put it on/chew/swallow/inhale /spray at the **start of the day or when felt urge to smoke?**

- Have you been using you NRT patches/gum/inhaler/microtabs/lozenges as directed by your advisor? Are you using it based on the dosage and prescription you were given? **(This assesses compliance)**

Effectiveness

- Do you think the NRT product **(whatever the person says he/she's using)** has helped you to remain smoke free?
- Have you experienced any side effects to NRT?
- Overall, how will you describe the process so far of using NRT for an extended period/for longer than you would have used it if you had not been part of the study?

Concerns

- Do you have any worries with regard to the use of the NRT for an additional 12 weeks?
- If this had not been a research study, would you have preferred that NRT is provided differently? E.g., through your GP by prescription, or bought from a pharmacist? **(If client answers "through GP", ask why. If "through pharmacist" ask why. If they'd rather receive NRT through advisor at Stop Smoking Clinic, ask why)**
- Would you have wanted to receive smoking cessation advisor support differently? E.g. via telephone, or more frequent unscheduled drop-ins. **If by telephone**, would you prefer to be contacted at regular intervals or would you rather have a dedicated number to phone when you need it? If more frequent unscheduled drop-ins, why?
- How much behavioural support/counselling were you given each time you visited the Stop Smoking Clinic?
- Was the behavioural support/counselling about right, or would you have preferred more or less of it?

3. Use of other drug treatments for relapse prevention

- Are you willing to use other drug treatments for longer periods to help you remain smoke free? (Mention the available drug treatments if client is not aware of these – zyban™, champix™).
- **If client says yes to above question** - Would you prefer to have these drugs dispensed by the smoking cessation service or by your GP?

Appendix 5 Feasibility Study Interview Guide for Non-Abstainers

Feasibility Study of relapse prevention treatment in Nottingham's New Leaf Smoking Cessation Service

Semi-Structured Interview Guide for NON-ABSTAINERS

Version 1.2 Date 23/11/09

Introduce self, tell interviewee about the purpose of the interview, ask for permission to record, assure interviewee of anonymity, inform interviewee about interview length.

Clinic Location:

Participant Study number:

Topics

Are you still fully abstinent? (If NO, use this guide, if YES, use the other guide)

1. **Smoking History**

- At what age did you start smoking regularly?
- Did you reduce your cigarette use in the month prior to accessing the smoking cessation service?
- How many quit attempts have you made prior to this one?

2. **Smoking Status/Relapse process**

   Now that you've told me you've experienced a lapse/relapse, I'd like to ask you a few questions about this.

- How many cigarettes have you had in the past four weeks? (**One to five cigarettes** in the past month is a **lapse**).

- Are you smoking as much as you used to smoke before becoming abstinent? (Client has **relapsed** fully)

- **If client has relapsed fully, was it sudden?** Was it gradual? Is there any point you think a full blown relapse might have been prevented? How do you think a full blown relapse might

have been prevented? What do you think was responsible for the relapse? **Do you want to start the quit process again?** If **yes,** how soon? How will they prefer to re-start the quit process? Continue taking NRT?

- **If you do not want to re-start the quit process, why?** Will you be willing to start again in the future? If you do decide to, will you return to the stop smoking service? **If no, why?**

- **<u>If client has NOT relapsed fully,</u>** how confident are they that they'll continue to remain smoke free? Do you feel you need stronger doses of NRT to prevent a lapse from recurring?
- Have you informed your advisor about your lapse (or relapse)?

3. Use of other drug treatments for relapse prevention

- Are you willing to use other drug treatments for longer periods to help you remain smoke free? (Mention the available drug treatments if client is not aware of these – zyban™, champix™).
- **If client says yes to above -**Would you prefer to have these drugs dispensed by the smoking cessation service or by your GP?

4. Experience of taking NRT for relapse prevention

Convenience

- Which type of NRT are you using/have you used (*in the case of individuals who have relapsed fully)*? (**gum, patch, lozenge, inhalator, microtabs)**What dosage?
- How convenient is it/was it to use this type? **(Do you/did you find it easy, straightforward, convenient?)**
- Prior to this quit attempt, have you used any other type in the past?
- Is there any other type of NRT you'd prefer/would have preferred to use to remain smoke free? (Are you aware of any other types, and if so is there any type you'd have preferred instead?)

Usage

- How have you been using the NRT product? E.g. put it on/chew/swallow/inhale/spray at the start of the day or when felt urge to smoke?

- Have you been using you NRT patches/gum/inhaler/microtabs/lozenges as directed by your advisor? Are you using it based on the dosage and prescription you were given? **(This assesses compliance)**

Effectiveness

- Did you experience any side effects to NRT?
- Overall, how will you describe the process so far of using NRT for an extended period/for longer than you would have used it if you had not been part of the study/for an additional 12 weeks

Concerns

- Do you/did you have any worries with regard to the use of the NRT for 12 weeks?
- If this had not been a research study, would you have preferred that NRT is provided differently? E.g., through your GP by prescription or bought from a pharmacist? (**If client answers through GP, ask why. If through pharmacist, ask why. If through advisor at Stop Smoking Clinic, ask why).**
- Would you have wanted to receive smoking cessation advisor support differently? E.g. via telephone, or more frequent unscheduled drop-ins. **If by telephone**, would you prefer to be contacted at regular intervals or would you rather have a dedicated number to phone when you need it? **If more frequent unscheduled drop-ins, why?**
- How much behavioural support/counselling were you given each time you visited the Stop Smoking Clinic?
- Was the behavioural support/counselling about right, or would you have preferred more or less of it?