

Programme of work April 2007-March 2012

Version 4 - 25 January 2007

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b) The research proposal

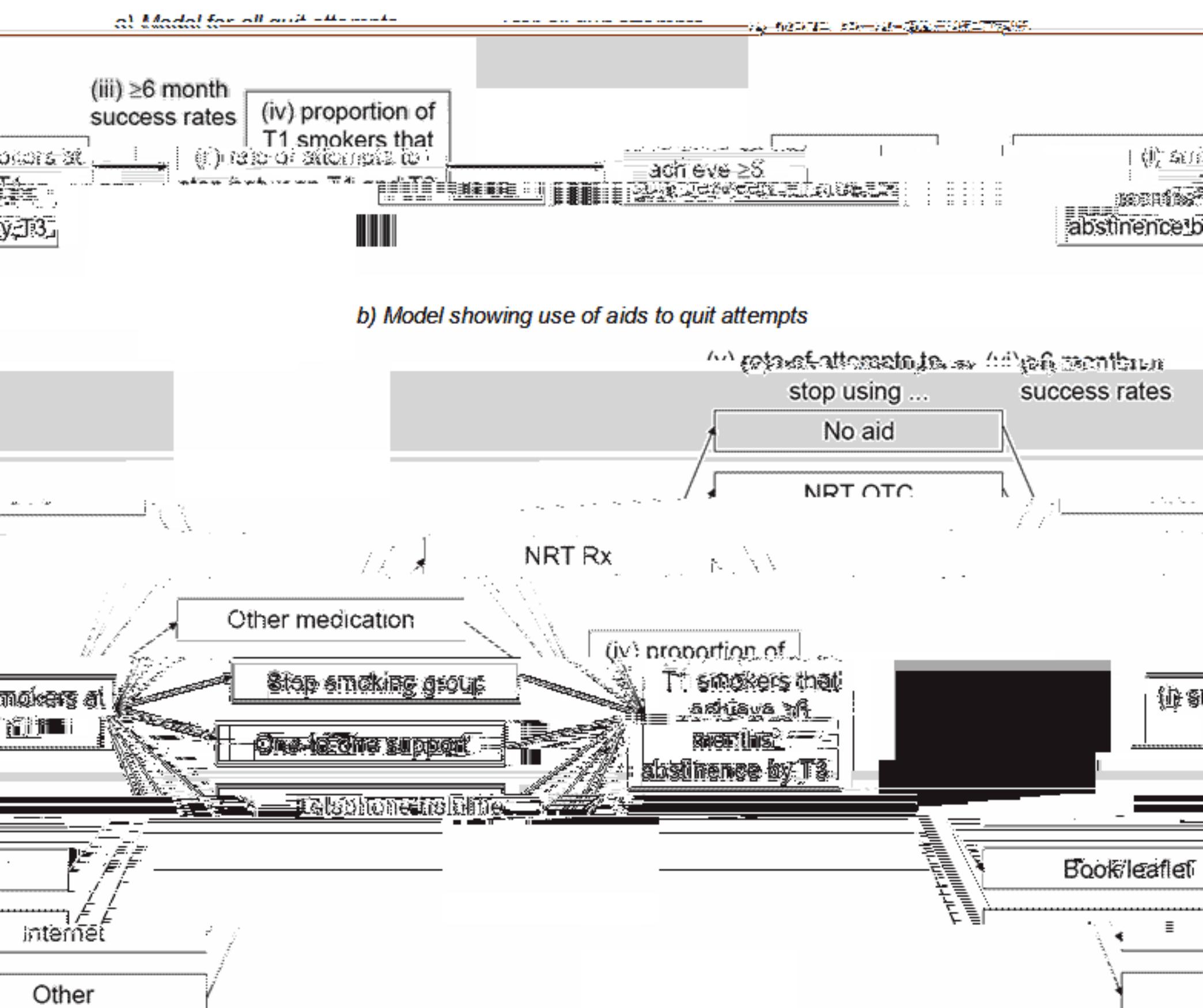
b) 1. Background

The overall aim of the programme is to produce research findings that will contribute to a reduction in tobacco-related harm through smoking cessation, first and foremost in the UK but also

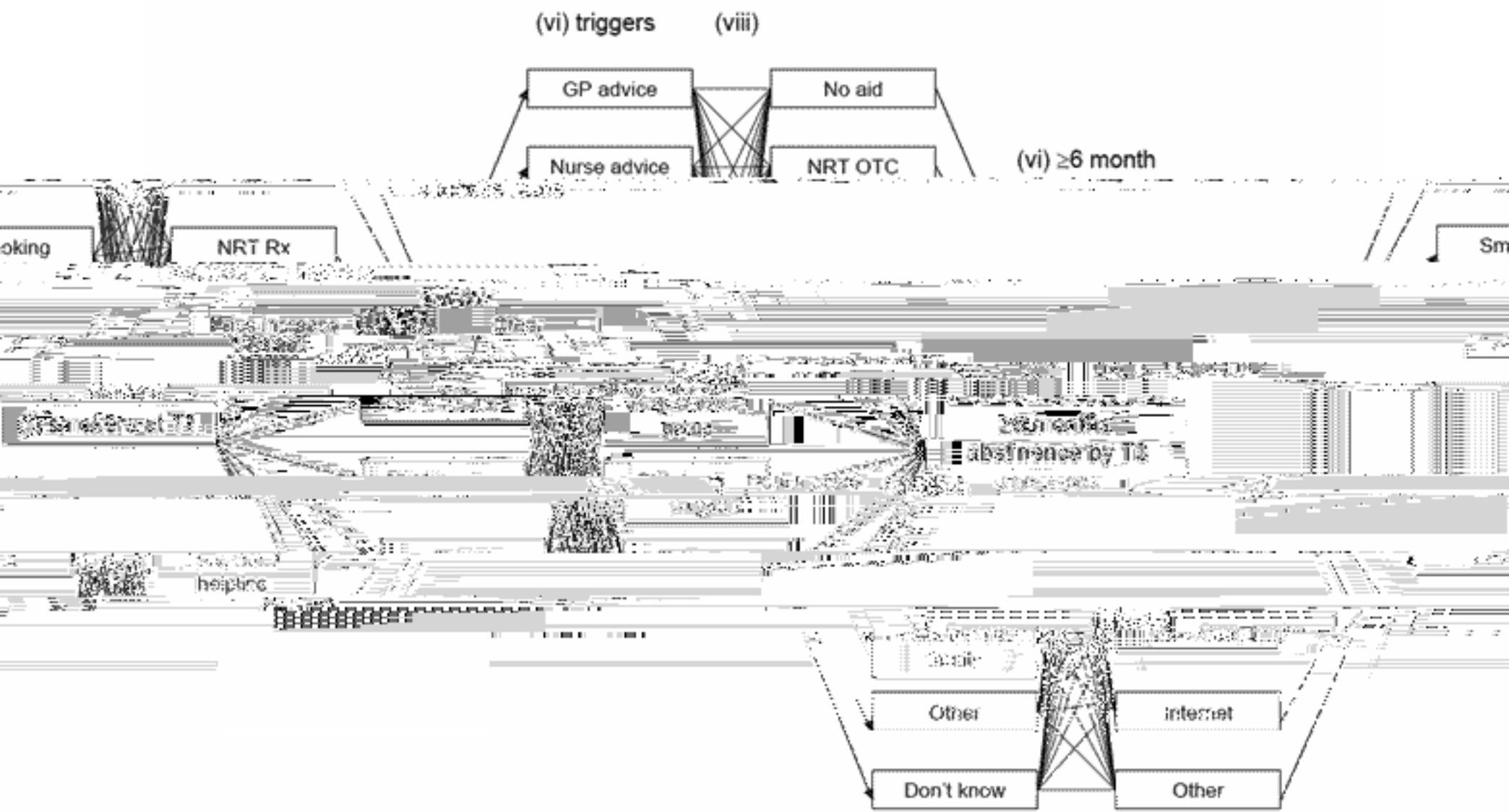
experience of the research team including members who are currently funded for specific projects.

UK and overseas; 4) inform policy decisions, population level interventions and clinical practice (within 10 years); 5) be informed by, and contribute to, theoretical advances; 6) create synergy (beyond 10 years).

Figure b) 1.1.1: A population model of smoking cessation (see text for explanation)



c) Model showing triggers and aids to quit attempts



(ii) Success rates after 1 year for those who make at least one quit attempt

The success rate for those who make at least one quit attempt is about 4% (lasting abstinence for at least 1 year) (22). This estimate is based on the US National Health Interview Survey (NHIS) cross-sectional survey (23). Because quit attempts that fail are often very quick (going by single surveys looking back over 12 months to make estimates is not accurate).

Related to (iii) we currently have no adequate population-level data on the proportion who were successful quitters last year, or between consecutive 1-year periods.

Success rates for those who make at least one quit attempt

Success rates for those who make at least one quit attempt are shown in Table 1. The figure that is widely used of success of unaided quit attempts is about 4% lasting abstinence for at least 1 year (22). This estimate is based on the US National Health Interview Survey (NHIS) cross-sectional survey (23). Because quit attempts that fail are often very quick (going by single surveys looking back over 12 months to make estimates is not accurate), related to (iii) we currently have no adequate population-level data on the proportion who were successful quitters last year, or between consecutive 1-year periods.

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regard to the
smokers and gender

smoking (42-45). However, there are factors that messes up a 'smoker' identity and resistance to anti-smoking campaigns (47) and failure of attempts to stop smoking (48).

The theory is based on the likelihoods

to have begun to be explored.

would be expected given that brings together existing models and evidence. Within the role of identity for example, there is a large literature but mostly on adolescent smoking (42-45). However, there are factors that messes up a 'smoker' identity and resistance to anti-smoking campaigns (47) and failure of attempts to stop smoking (48).

What is the theory based on?

The theory has a number of implications for prediction about the success of interventions.

success of otherwise effective interventions to promote it. Four of these

are shown below. The first three are concerned with the process of quitting, the last one with the outcome of quitting.

1. Theory predicts that smokers who attempt to quit will have an unanticipated and unplanned attempt. If this is the case, then the greater the planned attempt, the less likely to result in lasting change than those that were planned. Evidence from PRIME Theory suggests that smokers who attempt to quit will have an unanticipated and unplanned attempt arises from a more complete transformation in identity (a kind of epiphany) rather than delay. In the early stages of the quit attempt,

new identity as a non-smoker would be expected to play a greater role:

50% of smokers attempting to stop who have succeeded in the first week label themselves as non-smokers. This suggests that the importance of self-labelling in achieving prolonged abstinence (49).

Theory predicts that the self-labelling is important, and that this association will be maintained once other potential confounding factors

are taken into account. The second prediction concerns the implementation of wanting to stop smoking performs better than 'IHM' (the smokers report intending to stop in the future) in predicting quitting (50).

Theory this is because the response to questions about future quitting do not reflect smokers actually think about this whereas smokers usually answer a question about the frequency of feelings of discomfort.

'Triggered' depends on factors that are difficult to predict, such as stress, illness, social cues, etc. and links to smoking.

The third prediction concerns the effect of urges. PRIME Theory suggests that smoking should outperform a

A fourth prediction concerns the effect of frustration of automated action schemes. PRIME Theory argues that individuals consciously experience urges when they exercise voluntary restraint over impulses. Work that is ongoing in the current programme is a first attempt to test this hypothesis (see Section A).

Box b) 1.3. Theme 3: Developing and testing better interventions

Methods to aid cessation: The top line conclusions regarding aids to aid cessation are summarised in Box b) 1.3.1.

Studies have found that individual counselling given to smokers seeking to stop smoking improves ability to sustain abstinence for at least 6 months by an average of 10% compared to face-to-face and a similar amount when delivered according to a pre-scheduled telephone contact – this is compared with minimal support in the form of a brief intervention (52, 53). There is insufficient information to determine what are the active ingredients? The evidence suggests that the effect of NRT is additive to the effect of PRIME. Evidence from

b) 1.3. Theme 3: Developing improved methods to aid smoking cessation

Box b) 1.3.1

1. Randomised controlled trials comparing different forms of support help with stopping smoking. Evidence shows that 4% improvement in abstinence rates can be achieved when delivered face-to-face or via telephone arranged schedule by telephone or computer.

motivational session or written materials alone cannot determine whether one particular approach (e.g. behavioural therapy) is better than another or whether the effect of one approach is broader than another.

real-world application of behavioural support methods suggests that the benefits of behavioural support translate from the experimental trials into the routine clinical situation (54).

2. There is no evidence from randomised controlled trials indicating a greater range of abstinence than self-help groups (55).

3. There is no evidence that seeking help with stopping improves ability to remain abstinent for at least 6 months by an average 17% compared with placebo (56). There is evidence more strongly suggesting that using

so that best practice can be established and disseminated. Key areas of enquiry are: use of specialist staff to treat smokers versus practice nurses or pharmacists, group versus one-to-one appointment-based clinics.

b) 2. Studies

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primary aim of the study is to provide
relating to smoking cessation to guide
toolkit for understanding the process of
GP advice and aids to cessation such
as nicotine replacement therapy,
provide national data on the
use of aids to cutting down.

The unique feature of the study involves recognising that many smokers make multiple quit attempts within a short space of time, and that unsuccessful quit attempts are often rapidly forgotten. This means that surveys need to be carried out frequently and to concentrate on a more limited time period for recall. In addition, the respondent needs to be able to cater for multiple quit attempts and the possibility that different quit attempts involve different triggers, use different

draw participants for other studies in
the questionnaire, not doing

Methodology

This study involves repeated cross-sectional household surveys of national samples of smokers and recent ex-smokers for a period of 5 years with each cross-sectional sample followed up after 3 months and 6 months by postal questionnaire.

There will be between 4 and 12 household surveys per year (ideally 12 depending on funding available) for 5 years, drawn using an established quota sampling method by the social research

company BMIRB. To keep the costs to a minimum the baseline surveys will use the BMIRB omnibus questionnaire. Figure 2.1.1 shows the quarterly baseline household surveys or ideally monthly baseline

whether or not it involved cutting down gradually; f) whether it was planned in advance; 3) current smoking behaviour (or past smoking behaviour in those that have recently stopped); 4) current (or since the Fagerstrom Test for Nicotine Dependence (Fagerstrom, 1989); 5) past smoking history (ever smoked, age smoking began, regularity, status, environment); 6) whether they had quit (if so, when, "try on"); 6) whether trying to 'cut down'; 7) NR (never tried to quit); 8) personal history of depression; 9) family history of depression; 10) service patient state, associated with smoking.

the household survey will be repeated

uration of any quit attempts that were ongoing at the time of the definitive abstinence dental visit with the . Saliva samples will be obt

Saliva samples will be obtained by including a specimen tube and cotton postal questionnaire together with instructions on use (as in the SIPP).

In the follow-up postal surveys the key assessments in

encountered are follows: (i) the

Diagram 6a. 2.4.1.1. Diagram of process priority for soft real-time scheduling, showing the relationship between priority and deadline.



(EBC: Household household survey; 70%: 30%); 3-month post-treatment follow-up survey for households that have moved away

b) Years 4 and 5



participant will be: 1) the annualised rate at which quit smoking after their quit date plus one year, plus the annualised rate at which they quit smoking after their quit date plus two years.

The key derived variables for each user quote describe user activity, frequency, and length of time spent on the platform.

The analyses will focus on:

b) 2.2 Study group 2: Analysing data from and reporting findings from ongoing and existing datasets

gathering evidence to answer key questions.

This involves using existing acts and ongoing data collection to support the development of a new act.

b) 2.2.1. The ATTEMPT Cohort (JF, RW, LS) Aims and methodology

This data set (see earlier discussion) is a sample of smokers drawn from the general population. Given this complexity and potential value, it will require a range of key questions about smoking and smoking behaviour, as well as continuous monitoring over time.

on) involved follow-up every 3 months for up to 2.5 years of a
countries: UK, US, Canada, France and Spain. Data collection
completed in late 2005 but with a dataset of
considerable research effort to address the
question efficiently but the results will remain unanswered. This research
is currently being repeated in the United States.

b) 2.2.7. Health Survey for England (JF, LS, RW, DB)

Aims and methodology

The HSE is a rolling survey of a large nationally representative sample in England that involves a

followed by a review and detailed assessment of each

participating local authority. Evaluation operations are

carried out by a team, based in our department at JG, who write a report of the top

team manager is required to analyse data to answer important

questions about smoking behaviour in England.

From 1990 onwards it has sought to collect data on more than 100,000 saliva cotinine values to produce definitive parameters of the distribution of cotinine

in smoking children and adults and smoking adults, stratified by age, socio-economic group,

and gender. This will allow us to monitor trends in smoking behaviour over time.

Secondly, assessing changes in

smoking behaviour in England.

Household Survey of a large sample of

households in England for the

obtained on subsamples. The SE

line results each year, but addi-

questionnaire, and a community

approach that data from surveys carried out

than 100,000

in non-smokers.

Thirdly, to evaluate economic costs associated with smoking

and passive smoking. It will also provide a starting point for a

smoke exposure following introduction of the smoke-free legis-

b) 2.2.8. International Tobacco Control (ITC) study (LS, RW)

Aims and methodology

The ITC is a large multi-national cohort stu-

the University of Waterloo. This ambitious

generate publications at a high rate (40).

McNeill, who is a collaborator

together with Professor

2000 smokers surveyed in the

UK cohort. LS has formed

evaluating whether the

study of smokers coordinated by Professor Geoff Fong at

us project has reached a stage where it has begun to

75-85). The focus is very much on attitudes and their

relationship with the use of tobacco products.

relationship with the use of tobacco products.

collaboration on the proposed programme is one of the UK leads on the project

or Gerard Hastings at the University of Stirling. The UK cohort consists of

surveys by telephone approximately annually. CRUK contributes to funding of the

UK cohort and works with Dr McNeill and others in

UK's national strategy of cessation services and reimbursement of smoking

cessation services. Results from different studies and behaviour among UK smokers than smokers in the

USA, Canada and Australia. For the last wave of data, we would also be interested to see whether

there is any difference in cutting down to stop as opposed to complete cessation given the UK's

recent policy change with regard to NRT.

Aims and justification

The NHS stop smoking services provide both a resource and

ways of implementing effective smoking cessation interventions closely with the services since their instigation providing training bonds have been established. It is apparent that implementation

efficacy when it comes to the effectiveness of the treatment appear to have led to distortions in the implementation of se

cessation services and a general improvement in the provision of high quality

cessation services in the UK.

However, there is a lack of quality data to understand how far well-motivated patients from the

UK's different types of services.

It is difficult to fulfil this role because it is

so variable that the figures do

not allow comparisons between them (65).

There is no monitoring undertaken by the Department of Health (67) so

it is apparent that the calculations of success rates used by PCTs

not allow comparisons between them (65).

We have established a network of clinics that are collecting data of sufficient quality to form a

basis for establishing best practice. Currently 4

clinics have signed up with a combined annual

throughput of 7000 smokers. This constitutes a unique resource to assess what

programme). The network will also offer access to NHS Stop Smoking Service staff, whose knowledge and attitudes can be evaluated routinely and in response to specific interventions. Finally, the network will be a major tool for building research capacity within the N-S Stop Smoking Services. The website (www.scsrn.org) provides valuable resources for services wanting to undertake their own audits of research projects and these need to be updated regularly which are 'catalogued' under 'Audit'.

The website also provides a simple system whereby services can upload reports in different headings so that other services can see what has been done.

Methodology

The website is currently being hosted for free by Exchange Supplies
www.exchangesupplies.com

with whom AM has close ties

organising the UK National Smoking Cessation Conference and are happy to continue this relationship. However, the work involved in maintaining and developing the website and working with busy service managers to ensure that they make most effective use of it is more than can be

undertaken on present resources. This is a role that will be taken by other members of the research team, the programmer (ML) and the PA and HRRC administrator with supervision by AM.

that members can report findings and share experiences and resources. Studies proposed for the network include:

1. Comparison of long-term success rates as a function of interventions
 2. Comparison of 4-week success rates as a function of mode (one-to-one, practice nurse one-to-one, rolling group, fixed group)
 3. Comparison of retention and outcome as a function of stop-shop via a Patient Group Direction, prescription from GP or pharmacist
 4. Demand for, use of, and effectiveness of, different NRT products under different prescribing policy (e.g. with all NRT available on PGD or one purchased by the client separately).

tion of different relapse prevention

Mode of delivery (drop-in clinic, pharmacy and group etc.)

method of acquiring medication (one-on GP, direct supply etc.)

NRT combinations, as a function of NHS prescription or with one available

Any care sources and their association

and success rates.

or these studies will typically involve multiple random effects logistic regressions with dependent variables entered together with measured confounders (including free availability and age) and with the stop smoking services as a random variable and where practice as another nested variable. These analyses will be complex and require

The analyses focus on the relationship between the number of prescriptions issued by a general practitioner and the number of prescriptions issued by a pharmacist, with the key indicator being the percentage of prescriptions eligible for a prescription discount.

depends on the quality of data collection by the stop smoking undertaken work with these services to bring data collection up. Using this liaison and training will represent a significant part of

Technical feasibility

The success of this series of studies services involved. AM has already u to the required standard and continu his workload in the early part of the p

b) 2.4. Study group 4: Evaluation of the Nicotine Cannon (AM, RW, JF, LS, EV, JS)

Aims and justification

We have been undertaking preliminary research with a novel nicotine delivery device that may help some smokers to stop more effectively than existing products. This is an area in which there is already a great deal of research and development (e.g., 88, 89). However, to date, no single form of currently believed that a device that could deliver abstinence in unselected smokers (58).

also be important...the ability of smokers to adjust on a moment-to-moment basis the delivery of nicotine and comfort attached to this. The Nicotine Cannon is a device that allows this to a greater degree than existing nicotine delivery systems. It involves cartridges arranged in parallel in a wide bore tube (the diameter of a cigarette) around a central delivery core. The user controls the concentration of nicotine covering the central core more or less with a finger.

It is suggested that it may be necessary to examine the acceptability of the Nicotine Cannon to smokers before proceeding to the pharmacokinetic studies.

Methodology

Three studies are planned:

1.1.2.4.1. Biavailability study (Year 1)

The methodology will be the same as has been adopted for the pharmacokinetic studies undertaken in the UK (see Section 1.2.2.1). This will involve the use of C14-labelled nicotine and will be conducted in the UK. There is evidence that smoking

(given that smokers will be the ultimate users of the product and individual differences in metabolism will be small).

This study will also assess ratings of acceptability of the products, subjective effects and acute side effects. The double-blind study will consist of 24 healthy non-smokers (N=12) who will be instructed according to the manufacturers' instructions for the same length of time (10 minutes). In the case of the Cannon the subjects are instructed to take 10 puffs per minute. Blood will be taken for measurement of nicotine at baseline, halfway through administration (5 minutes), and at 1, 5, 10, 15, 30 and 60 minutes after administration of nicotine has ceased. In addition the subjects will complete a 10-point rating scale on the presence of any of the following symptoms: nausea, throat irritation, dizziness, feeling unwell, pleasant feelings and agitation. These self-report ratings are made at the same intervals that blood is taken and are marked between 1 (none) and 10 (extreme).

The study will also report secondary outcomes according to the WHO definition of health, including quality of life, acceptability of the products and income of the conductors.

effect of the nicotine cannon on abstinence (Years 3 to 5)

b) 2.4.3 RCT of

programme expect to extend the involvement of the IUPAC in this sector. This will involve a programme of co-operation, data exchange, time, in evidence generation, and the consequences, developing analysis and disseminating the findings. An IUPAC panel of experts will be appointed to do this. The reason is that the manufacturers are not in a position to provide a safeguard against cross-feeding should the programme of research prove successful.

Methodology

Follow-up using the Russell Standard outcome assessment, as specified in the labelling for the drug in Poland where the trial will be carried out. Models of subsequent trials and studies will be developed with the participation of the pharmaceutical industry. The methods will be based on existing smoking cessation trials, calculating the existing dosage regimen. Other studies comparing, and comparing oxycine against existing smoking cessation medications. Further phase I and phase II studies are desirable but these can be done by other partners in the working group.

Technical feasibility

Extensive work has gone into ensuring that the MRPI funded Tabox trial runs successfully. The feasibility of the remaining studies in the programme depends on external funding, but given the worldwide impact of this programme of research, there is considerable interest from a number of quarters and confidence is high that funding will be secured.

1.2.6 Study group 6: The Design of Clinical studies (EV, IE, L, S, AM, DWA)

urges to smoke that come unexpectedly or when there is a crisis or situation normally associated with smoking; 4) Evidence of chronic or acute distress that depletes mental resources necessary for the exercise of self control, and the expectation of escape from which may make a resumption of smoking attractive; 5) Evidence of continued feelings of attraction to smoking; 6) Evidence of social and physical environment is polluted by triggers, including other people smoking. This has been an area that has been most studied to date and the importance of situational factors established (see e.g. 36).

The theory also suggests themes relevant to the relapse process. These include: 1) How

first lapses occur, from a conscious decision to consume smoking thoughts, not or a decision to make a temporary exception to the rule of abstinence. Surprisingly we could find no studies that examined this issue. Preliminary analysis of this concept elicited in the co-investigator's

notes that conscious decisions to resume smoking are rare but

current work on another study indi-

cates that "abstinent smokers have different expectations than smokers about their own behaviour." They know the "importance of having a cigarette when they expect it" and expect to feel better. This is an area that has also received little attention. There has been extensive research on the "abstinence violation effect" in which a lapse creates dissonance and feelings of

3) Changes in identity

in terms of recovery of

smoked. The stress of abstinence actually relieved the stress, for example

following lapses. The patterning of smoking behaviour following the lapses abstinence or patterns of transition to regular smoking has been studied (e.g. 37). PRIME Theory proposes a focus not only on rekindling of habit mechanisms and effects on self-affir-

mation and self-esteem (see section 2.6.2), but also on the effects of smoking on self-concept, resumed smoker etc.)

The four projects currently under way that will feed into the studies for the new programme are:

the hypnotherapy pilot study (section 1b) 38); and a study being

smoking urges (section 1b) 39); the

and not to smoke.

studies on process of change would build on the findings from the

and take full account of such issues as development release 42-4-22

work, etc. It is hoped that the findings will be informing the 39).

of their motivation to smoke

The proposed series of

work. It will also be informed by the results of the current work on the

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Table 4.2.1.1.5. A model of smoking behaviour according to the SDT model

Theory	Factors that motivate smoking	General dispositions	Environmental factors	Smoking-related cognitions	Implementation
SDT	Self-determination theory	General dispositions	Environmental factors	Smoking or no/less smoking against self-control stop or avoidance of self-control	Proactive implementation
	castigate, failure to implement plans, e.g. initiative, motivation	space to develop plans	self-control (e.g. stopping aversive smoking behaviour)	resistances	de-inhibition
	smoking	e.g. presence of smoking 'modes'	e.g. disposition to copy smoking behaviour	patterns directly generating impulses	inhibitory cue control
	internalized drives, e.g. learned triggers, e.g. stress, pain	e.g. learned triggers, e.g. stress, pain			
	external forces (often driven)	control impulses			

questionnaire will be given to a sample of 500 smokers from the STS and use a fixed format version of the comprehensive motivational assessment grid to determine for each smoker their temporal profile of motivational tension regarding smoking... It...will...specifically...compare...the...

Methodology

Because this study focuses on the cardiovascular system, we are seeking funding from the BHF. The following sections outline the study design, protocol development and recruitment relating to the study. The study aims to include two groups. In the treatment group, smokers attending a designated GP practice will be provided with feedback of their cardiovascular risk using a computerised scanner and a smoking cessation intervention. Participants will be encouraged to quit smoking. In the control group, participants will also receive a standard cardiovascular risk assessment and be advised to quit smoking. The control group will also be advised to quit. Participants would be followed up 6 months after the intervention to ascertain biochemical validation smoking status, quit attempts and cessation behaviours.

Technical feasibility

The technical feasibility of this study depends on securing external funding and co-operation with general practices involved. BML has close links with local general practices so this is not a problem.

Method and a highly experienced researcher who works in a known cardiovascular research centre with extensive experience of the lasting motivational effect of these kinds of images using the kind of motivational grid described in section b) 2.6.

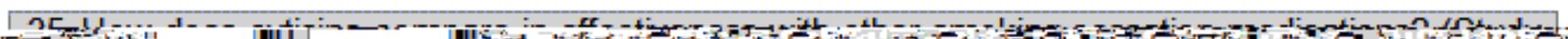
with extensive experience of the

b) 3. Overview

A summary of the key research questions is given in Box b) 3.

Box b) 3. Key research questions:

	and success of quit attempts? (Study 2.1F)	18. How
	does experience of illness influence quitting behaviour? (Study 2.1, Study 2.7)	11. What
	What are the short- and medium-term gains in physical and mental health associated with smoking cessation? (Study 2.1, Study 2.3)	smo
	What is the consistency of the experience of withdrawal symptoms over different quitting episodes? (Study 2.1, Study 2.5)	12. What
	What is the consistency of the experience of withdrawal symptoms over different quitting episodes? (Study 2.1, Study 2.5)	episodes? (Study 2.1, Study 2.5)
	What is the consistency of the experience of withdrawal symptoms over different quitting episodes? (Study 2.1, Study 2.5)	13. Does the UK's national strategy of providing free nicotine replacement medications result in different smokers in other countries such as the US and Canada? What are the most important cross-national differentials predicting cessation? (Study 2.1, Study 2.8)
	What is the consistency of the experience of withdrawal symptoms over different quitting episodes? (Study 2.1, Study 2.5)	14. How effective is nicotine nasal support? (Study 2.2)
	What is the consistency of the experience of withdrawal symptoms over different quitting episodes? (Study 2.1, Study 2.5)	15. To what extent do predictors of smoking cessation differ between smokers and non-smokers? (Study 2.3)
	What is the consistency of the experience of withdrawal symptoms over different quitting episodes? (Study 2.1, Study 2.5)	16. What is the best measure of addiction? (Study 2.3)?
	What is the consistency of the experience of withdrawal symptoms over different quitting episodes? (Study 2.1, Study 2.5)	17. Is there a difference in efficacy between nasal spray and patch? (Study 2.4)
	What is the consistency of the experience of withdrawal symptoms over different quitting episodes? (Study 2.1, Study 2.5)	18. Does pack-shape matter? (Study 2.4)
	What is the consistency of the experience of withdrawal symptoms over different quitting episodes? (Study 2.1, Study 2.5)	19. Do smokers who have never smoked before have a better prognosis after controlling for other predictors? (Study 2.5)



6. Continue as Assistant Editor, Addiction

John Stapleton:

1. Contributing to NICE guidance

Reviews
Guidelines

2. Contributing to Associate sys

3. Contributing to ASH working

4. Expert statistical advice for Addiction

5. Advising on Department of Health

b) 5. Building capacity

Smoking Cessation Service Research Network (SCORN): The SCORN will promote clinical good practice. The network will also nurture and support NHS Stop Smoking Services in collecting reliable data for research purposes.

Research UK (TRUIK): The team will also continue work that has been started on TRUIK, a network of tobacco researchers in the UK, and an associated website that aims to provide advice and resources. This project was started with initial funding of £100k of additional resources, preventing it from developing further.

Tobacco

This is a

programme built on

Post-doctoral researchers: This programme aims to create the next generation of world-class

Post-doctoral research

researchers with the new and the generation expertise with resources the next generation. LS and EV represent the following generation. We are fortunate in having attracted these researchers to the field and the next task is to retain them and develop their expertise.

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