Is nicotine replacement therapy for smoking cessation effective in the "real world"? Findings from a prospective multinational cohort study

Robert West Professor of Health Psychology
University College London
London WC1E 6BT
robert.west@ucl.ac.uk

Xiaolei Zhou RTI Health Solutions, RTI, Research Triangle Park, NC, USA xzhou@rti.org

Keywords: NRT, prospective, cohort, effectiveness

Abstract

Objective Increasing smoking cessation rates is an important goal in preventing lung cancer and COPD. Nicotine replacement therapy (NRT) has been found in clinical trials to improve the chances of success at stopping but recent cross-sectional survey data have raised doubts as to whether it is effective when used by smokers making quit attempts unsupervised outside of clinical trials. Because of biases inherent in cross-sectional surveys, this issue can only be adequately addressed using longitudinal studies and this paper reports the first study of its kind to examine the issue.

Design The ATTEMPT cohort is a multinational cohort study with data collection by internet which recruited smokers of five or more cigarettes per day, aged 35-65 years, intending to stop smoking within the next three months. Phase 1 of ATTEMPT began in Spring 2003 and involved 2009 smokers from the US, UK, Canada, and France. Phase 2 involved 3645 smokers and included the same countries plus Spain. Follow-ups were carried out every three months.

Participants From Phase 1 we identified 492 smokers who made a quit attempt without formal behavioural support or bupropion in the first three-month follow-up period, of whom 357 were followed up for a further six months. The Phase 2 sample involved 906 smokers making quit attempts of whom 732 were followed up.

Main outcome measures At baseline, demographic characteristics, smoking history and nicotine dependence were assessed. Smokers who made quit attempts were questioned on methods used to aid them. The main outcome measure was self-report of complete abstinence throughout both of the 3-month periods following the quit date.

Results A total of 35.6% of Phase 1 smokers followed up used NRT; the figure for Phase 2 was 29.6%. The odds ratios comparing six months' abstinence in those using versus not using NRT, adjusting for nicotine dependence, were 3.0 (1.2-7.5) for the Phase 1 sample and 2.1 (1.0-4.1) for the Phase 2 sample. The difference in success rates of those using NRT versus those not using it, adjusted for FTND score, was 6% in the Phase 1 sample and 3.7% in the Phase 2 sample. The improved odds of success were not explicable in terms of motivation to use some form of aid to cessation or differential loss to follow-up.

Conclusion NRT use by smokers making self-initiated quit attempts without formal behavioural support is associated with improved long-term abstinence rates.

Increasing smoking cessation rates is an important goal in preventing lung cancer and COPD (1) but the chances of success of any given quit attempt are typically very low at less than 5% (2). More than 100 double-blind randomised placebo-controlled trials have been conducted evaluating nicotine replacement therapy (NRT) in the form of nicotine gum, transdermal patch or other products (3) and a meta-analysis of these trials reveals an average effect of NRT on ability to remain abstinent for at least 6 months (the minimum duration of follow-up required by Cochrane) following a quit attempt of 7 percentage points (3). There have been clinical trials of nicotine patches in an 'over-the-counter' context, and these have also shown the efficacy of NRT (4). Longer-term follow-up indicates that this size of effect translates into between 3% and 4% of smokers achieving abstinence for at least 8 years (5). Although this is a modest effect, the cost of a treatment episode is low and the benefits of cessation are so great that NRT has been identified as one of the most cost-effective life-preserving interventions available to medical science (6).

An issue has been raised about effectiveness of NRT outside of clinical trials. Many smokers in the 'real world' may use the products sub-optimally leading to a lower level of effectiveness. In one large cross sectional survey in California it was reported that smokers who said they had attempted to stop with the aid of NRT were no more likely to have abstained for 6 months or more than those who had not (7). However, this design could not adequately test the hypothesis. This is partly because it is difficult to control adequately for a range of potential confounders (8). Of particular importance is nicotine dependence which would need to be measured before the quit attempt was made and not retrospectively several months later; more dependent smokers would be expected to be more likely to use NRT and less likely to succeed at stopping. In addition, this kind of study does not take into account the forgetting of failed quit attempts. The same team of researchers had already shown that forgetting was potentially a source of bias (9) that could reduce or eliminate the apparent difference between quit attempts using effective methods and those that do not. Quit attempts made using less effective methods will fail more often but the failures will be forgotten so the longer ago the quit attempt the higher the apparent success rates overall and the greater convergence between rates associated with more effective and less effective methods. An indication of the extent of bias created is that the Californian study yielded estimates of 6-month continuous abstinence rates in unaided quit attempts in excess of 20%, which is more than four times the rates found in prospective studies and wholly unrealistic. Thus, cross sectional surveys cannot answer questions of long-term effectiveness; longitudinal studies with frequent follow-up are required.

While there are a number of prospective and cross sectional studies involving NRT in the literature (10-15), none of them directly address the crucial question of the difference in success rates between those using NRT and those not using it when they attempt to quit spontaneously outside of a clinical trial setting without formal behavioural support.

This issue is of major public health importance because an estimated 2 million smokers used NRT in 2005 in the UK alone (16). An evaluation of a programme in New York to give away free nicotine patches to callers to a toll-free helpline found significantly higher short-term abstinence rates than in comparable smokers who had called the helpline before the scheme was introduced (14, 15). If these rates translate into improved long-term abstinence, this approach could prevent large numbers of premature deaths very cheaply, but if they do not, it just represents a waste of public resources.

This paper reports findings from a multinational cohort study that examined prospectively the 6-month continuous abstinence rates in a population sample of smokers making self-initiated quit attempts with and without NRT, controlling for degree of nicotine dependence while smoking. NRT was available for purchase over-the-counter without prescription in all countries examined. Over

the period that the data were collected smokers in the UK could also get partial or full reimbursement for NRT if they obtained a prescription from a doctor.

Methods

The ATTEMPT cohort study is a multinational longitudinal cohort study carried out using the internet with three-monthly assessments of cigarette smokers who at enrolment smoked five or more cigarettes per day, were aged 35–65 years old and were intending to quit within the next 3 months. Phase 1 of the study was initiated in the spring of 2003 in Canada, France, the United Kingdom (UK), and the United States (US) with a sample of 2009 smokers. In Phase 2, a second sample of 3645 smokers was added from the same countries plus Spain in 2004. Full details of the ATTEMPT methodology for Phase 1 can be found elsewhere (17). The methodology for Phase 2 was similar. The study was designed to examine a range of issues concerning smoking cessation including the short- and medium term health effects of stopping and factors associated with success or otherwise of quit attempts.

At the first post-baseline wave for each sample (three months after enrolment), smokers were asked: "During the past 3 months (90 days), have you made a serious attempt to stop smoking cigarettes for good that lasted for at least a day (24 hours)? Yes/No". They were also asked to indicate from a list which of a range of methods they had used in that attempt. Among these methods were the various nicotine replacement therapies (NRT - patch, gum, lozenge, sublingual tablet, inhaler and nasal spray). Also among the methods were items relating to behavioural support: formal behaviour modification programs, counselling and help from a stop smoking clinic, and use of bupropion. In the Phase 1 sample, 578 reported making a quit attempt in the three months leading up to the first follow-up. In the Phase 2 sample the figure was 983. Only these participants who made a quit attempt were used in our analyses. A total of 214 participants (37.0%) in the Phase 1 sample and 308 (31.3%) in the Phase 2 sample reported that they had used some form of NRT. We were interested in the effect of NRT in smokers not receiving any form of behavioural support and we also wished to disentangle any effect from an effect of bupropion, so we excluded those that reported that they had used some form of behavioural support or bupropion (N=86 in the Phase 1 sample of whom 44 used NRT, and N=77 in the Phase 2 sample of whom 40 used NRT). There were not enough of those using behavioural support or bupropion to perform a separate evaluation of their association with success at stopping smoking.

We also wished to assess the effect of motivation to use some form of support to address the question of whether any NRT effect could be explained merely in these terms. We did this by determining those that had used any of hypnotherapy, acupuncture, herbal remedies, the internet and books into a single dichotomous variable. We chose these forms of support because using them can be presumed to reflect a level of motivation to stop smoking comparable with that of NRT users but these methods can be presumed in general to be minimally effective. We did not include telephone helplines because these have been found in a recent review to have levels of effectiveness comparable to face-to-face behavioural support (18). Note that we were not able to assess the specific effectiveness of the individual forms of support individually because of small numbers. The purpose of this analysis was only to assess the possible role of motivation to use some form of support with stopping. In the Phase 1 sample, 113 used some other form of support and in the Phase 2 sample the figure was 154.

At baseline (at the start of the cohort), we asked about age, gender, marital status, educational level and ethnic group. We also recoded daily cigarette consumption and measured their nicotine dependence using the Fagerstrom Test for Nicotine Dependence (19). Table 1 gives details of the two study samples.

Table 1: Characteristics of the samples (smokers who made a quit attempt without using

behavioural support or bupropion)

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Mean (SD) dependence: FTND ⁴ 5.0 (2.3) 5.1 (2.5) 5.0 (2.4) Percent (N) using NRT 35.6 (127) 31.9 (135) 34.6 (170) Percent (N) using other support 16.8 (60) 24.4 (33) 18.9 (93) Phase 2 sample N total 732 174 906 N from USA 162 16 178 N from Canada 29 2 31 N from France 259 60 319 N from the UK 188 71 259 N from Spain 94 25 119 Mean (SD) age (yrs)* 46.1 (7.5) 44.7 (7.1) 45.8 (7.4) Percent (N) married ⁵ 49.9 (364) 48.3 (84) 49.6 (448) Percent (N) female 46.3 (339) 47.7 (83) 46.6 (422) Percent (N) white ⁶ 95.0 (678) 94.6 (158) 94.9 (836) Percent (N) post secondary education ² 60.5 (443) 55.5 (96) 59.6 (539) Mean (SD) cigs per day ³ 18.0 (9.9) 18.2 (9.8) 18.0 (9.9)	16-20 cigs per day	34.4 (123)	34.8 (47)	34.6 (170)
Percent (N) using NRT 35.6 (127) 31.9 (135) 34.6 (170) Percent (N) using other support 16.8 (60) 24.4 (33) 18.9 (93) Phase 2 sample N total 732 174 906 N from USA 162 16 178 N from Canada 29 2 31 N from France 259 60 319 N from the UK 188 71 259 N from Spain 94 25 119 Mean (SD) age (yrs)* 46.1 (7.5) 44.7 (7.1) 45.8 (7.4) Percent (N) married ⁵ 49.9 (364) 48.3 (84) 49.6 (448) Percent (N) female 46.3 (339) 47.7 (83) 46.6 (422) Percent (N) white ⁶ 95.0 (678) 94.6 (158) 94.9 (836) Percent (N) post secondary education ² 60.5 (443) 55.5 (96) 59.6 (539) Mean (SD) dependence: FTND ⁷ 4.3 (2.4) 4.4 (2.7) 4.3 (2.5) Percent (N) using NRT 29.6 (217) 29.3 (51) 29.6 (268) P		4.2 (15)	3.0 (4)	3.9 (19)
Percent (N) using other support 16.8 (60) 24.4 (33) 18.9 (93) Phase 2 sample 174 906 N total 732 174 906 N from USA 162 16 178 N from Canada 29 2 31 N from France 259 60 319 N from the UK 188 71 259 N from Spain 94 25 119 Mean (SD) age (yrs)* 46.1 (7.5) 44.7 (7.1) 45.8 (7.4) Percent (N) married ⁵ 49.9 (364) 48.3 (84) 49.6 (448) Percent (N) female 46.3 (339) 47.7 (83) 46.6 (422) Percent (N) white ⁶ 95.0 (678) 94.6 (158) 94.9 (836) Percent (N) post secondary education ² 60.5 (443) 55.5 (96) 59.6 (539) Mean (SD) cigs per day ³ 18.0 (9.9) 18.2 (9.8) 18.0 (9.9) Mean (SD) dependence: FTND ⁷ 4.3 (2.4) 4.4 (2.7) 4.3 (2.5) Percent (N) using NRT 29.6 (217) 29.3 (51) 29		5.0 (2.3)	5.1 (2.5)	5.0 (2.4)
Phase 2 sample 732 174 906 N from USA 162 16 178 N from Canada 29 2 31 N from France 259 60 319 N from the UK 188 71 259 N from Spain 94 25 119 Mean (SD) age (yrs)* 46.1 (7.5) 44.7 (7.1) 45.8 (7.4) Percent (N) married ⁵ 49.9 (364) 48.3 (84) 49.6 (448) Percent (N) female 46.3 (339) 47.7 (83) 46.6 (422) Percent (N) post secondary education ² 60.5 (443) 55.5 (96) 59.6 (539) Mean (SD) cigs per day ³ 18.0 (9.9) 18.2 (9.8) 18.0 (9.9) Mean (SD) dependence: FTND ⁷ 4.3 (2.4) 4.4 (2.7) 4.3 (2.5) Percent (N) using NRT 29.6 (217) 29.3 (51) 29.6 (268) Percent (N) using other support 15.4 (113) 13.2 (23) 15.0 (136)		35.6 (127)	31.9 (135)	34.6 (170)
N total 732 174 906 N from USA 162 16 178 N from Canada 29 2 31 N from France 259 60 319 N from the UK 188 71 259 N from Spain 94 25 119 Mean (SD) age (yrs)* 46.1 (7.5) 44.7 (7.1) 45.8 (7.4) Percent (N) married ⁵ 49.9 (364) 48.3 (84) 49.6 (448) Percent (N) female 46.3 (339) 47.7 (83) 46.6 (422) Percent (N) white ⁶ 95.0 (678) 94.6 (158) 94.9 (836) Percent (N) post secondary education ² 60.5 (443) 55.5 (96) 59.6 (539) Mean (SD) cigs per day ³ 18.0 (9.9) 18.2 (9.8) 18.0 (9.9) Mean (SD) dependence: FTND ⁷ 4.3 (2.4) 4.4 (2.7) 4.3 (2.5) Percent (N) using NRT 29.6 (217) 29.3 (51) 29.6 (268) Percent (N) using other support 15.4 (113) 13.2 (23) 15.0 (136)	Percent (N) using other support	16.8 (60)	24.4 (33)	18.9 (93)
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N from the UK 188 71 259 N from Spain 94 25 119 Mean (SD) age (yrs)* 46.1 (7.5) 44.7 (7.1) 45.8 (7.4) Percent (N) married ⁵ 49.9 (364) 48.3 (84) 49.6 (448) Percent (N) female 46.3 (339) 47.7 (83) 46.6 (422) Percent (N) white ⁶ 95.0 (678) 94.6 (158) 94.9 (836) Percent (N) post secondary education ² 60.5 (443) 55.5 (96) 59.6 (539) Mean (SD) cigs per day ³ 18.0 (9.9) 18.2 (9.8) 18.0 (9.9) Mean (SD) dependence: FTND ⁷ 4.3 (2.4) 4.4 (2.7) 4.3 (2.5) Percent (N) using NRT 29.6 (217) 29.3 (51) 29.6 (268) Percent (N) using other support 15.4 (113) 13.2 (23) 15.0 (136)	N from Canada	29	2	31
N from Spain 94 25 119 Mean (SD) age (yrs)* 46.1 (7.5) 44.7 (7.1) 45.8 (7.4) Percent (N) married ⁵ 49.9 (364) 48.3 (84) 49.6 (448) Percent (N) female 46.3 (339) 47.7 (83) 46.6 (422) Percent (N) white ⁶ 95.0 (678) 94.6 (158) 94.9 (836) Percent (N) post secondary education ² 60.5 (443) 55.5 (96) 59.6 (539) Mean (SD) cigs per day ³ 18.0 (9.9) 18.2 (9.8) 18.0 (9.9) Mean (SD) dependence: FTND ⁷ 4.3 (2.4) 4.4 (2.7) 4.3 (2.5) Percent (N) using NRT 29.6 (217) 29.3 (51) 29.6 (268) Percent (N) using other support 15.4 (113) 13.2 (23) 15.0 (136)	N from France	259	60	319
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Percent (N) married ⁵ 49.9 (364) 48.3 (84) 49.6 (448) Percent (N) female 46.3 (339) 47.7 (83) 46.6 (422) Percent (N) white ⁶ 95.0 (678) 94.6 (158) 94.9 (836) Percent (N) post secondary education ² 60.5 (443) 55.5 (96) 59.6 (539) Mean (SD) cigs per day ³ 18.0 (9.9) 18.2 (9.8) 18.0 (9.9) Mean (SD) dependence: FTND ⁷ 4.3 (2.4) 4.4 (2.7) 4.3 (2.5) Percent (N) using NRT 29.6 (217) 29.3 (51) 29.6 (268) Percent (N) using other support 15.4 (113) 13.2 (23) 15.0 (136)	N from Spain	94	25	119
Percent (N) female 46.3 (339) 47.7 (83) 46.6 (422) Percent (N) white ⁶ 95.0 (678) 94.6 (158) 94.9 (836) Percent (N) post secondary education ² 60.5 (443) 55.5 (96) 59.6 (539) Mean (SD) cigs per day ³ 18.0 (9.9) 18.2 (9.8) 18.0 (9.9) Mean (SD) dependence: FTND ⁷ 4.3 (2.4) 4.4 (2.7) 4.3 (2.5) Percent (N) using NRT 29.6 (217) 29.3 (51) 29.6 (268) Percent (N) using other support 15.4 (113) 13.2 (23) 15.0 (136)	Mean (SD) age (yrs)*	46.1 (7.5)	44.7 (7.1)	45.8 (7.4)
Percent (N) white ⁶ 95.0 (678) 94.6 (158) 94.9 (836) Percent (N) post secondary education ² 60.5 (443) 55.5 (96) 59.6 (539) Mean (SD) cigs per day ³ 18.0 (9.9) 18.2 (9.8) 18.0 (9.9) Mean (SD) dependence: FTND ⁷ 4.3 (2.4) 4.4 (2.7) 4.3 (2.5) Percent (N) using NRT 29.6 (217) 29.3 (51) 29.6 (268) Percent (N) using other support 15.4 (113) 13.2 (23) 15.0 (136)	Percent (N) married ⁵	49.9 (364)	48.3 (84)	49.6 (448)
Percent (N) post secondary education ² 60.5 (443) 55.5 (96) 59.6 (539) Mean (SD) cigs per day ³ 18.0 (9.9) 18.2 (9.8) 18.0 (9.9) Mean (SD) dependence: FTND ⁷ 4.3 (2.4) 4.4 (2.7) 4.3 (2.5) Percent (N) using NRT 29.6 (217) 29.3 (51) 29.6 (268) Percent (N) using other support 15.4 (113) 13.2 (23) 15.0 (136)		46.3 (339)	47.7 (83)	46.6 (422)
Mean (SD) cigs per day³ 18.0 (9.9) 18.2 (9.8) 18.0 (9.9) Mean (SD) dependence: FTND³ 4.3 (2.4) 4.4 (2.7) 4.3 (2.5) Percent (N) using NRT 29.6 (217) 29.3 (51) 29.6 (268) Percent (N) using other support 15.4 (113) 13.2 (23) 15.0 (136)	Percent (N) white ⁶	95.0 (678)	94.6 (158)	94.9 (836)
Mean (SD) cigs per day³ 18.0 (9.9) 18.2 (9.8) 18.0 (9.9) Mean (SD) dependence: FTND³ 4.3 (2.4) 4.4 (2.7) 4.3 (2.5) Percent (N) using NRT 29.6 (217) 29.3 (51) 29.6 (268) Percent (N) using other support 15.4 (113) 13.2 (23) 15.0 (136)		60.5 (443)	55.5 (96)	59.6 (539)
Percent (N) using NRT 29.6 (217) 29.3 (51) 29.6 (268) Percent (N) using other support 15.4 (113) 13.2 (23) 15.0 (136)	Mean (SD) cigs per day ³	18.0 (9.9)	18.2 (9.8)	18.0 (9.9)
Percent (N) using NRT 29.6 (217) 29.3 (51) 29.6 (268) Percent (N) using other support 15.4 (113) 13.2 (23) 15.0 (136)	Mean (SD) dependence: FTND ⁷	4.3 (2.4)	4.4 (2.7)	4.3 (2.5)
		29.6 (217)		29.6 (268)
	` ' U	15.4 (113)	13.2 (23)	15.0 (136)

Notes: *Significant difference between groups, p<.05 by t-test; ¹ Data missing for 19 people; ² Data missing for 1 person; ³ In the Phase 1 sample, respondents reported daily cigarette consumption in categories while in the Phase 2 sample it was reported as a number; ⁴ Data missing for 3 people; ⁵ Data missing for 3 people; ⁶ Data missing for 25 people; ⁷ Data missing for 9 people.

A total of 357 (72.6%) were followed up three months and six months later from the Phase 1 sample; 127 used NRT and 230 did not; 60 used what was deemed a likely ineffective method of support and 297 did not. A total of 732 (80.8%) were followed up from the Phase 2 sample; 217 used NRT and 515 did not; 113 used what was deemed a likely ineffective method of support and 619 did not. Note that the categories of NRT use and use of 'ineffective' support were not mutually exclusive. FTND data were missing on 3 smokers in Phase 1 and 9 in Phase 2 so the sample sizes for the logistic regression analyses were 354 for Phase 1 and 723 for Phase 2. There were no

differences between those successfully followed up and those that were lost to follow-up in either sample, except that in the Phase 2 sample those followed up were slightly older.

At the survey points three months and six months after the period in which the quit attempt was made, participants were asked whether they had been abstinent throughout the preceding 90 days. We designated as abstinent for six months those who reported that they had been abstinent for the full 90 days (without any lapses) at both follow-ups. This was the primary outcome measure. Note that in principle those designated as abstinent for 6 months had been abstinent for at least 6 months but it could have been up to 9 months depending on when they began their quit attempt relative to first survey point.

The statistical power to detect a 7% difference (the size of effect found in clinical trials (3) between those using versus not using NRT was 60% in the Phase 1 sample and more than 80% in the Phase 2 sample. T-tests for continuous variables and χ^2 tests for categorical variables were used to compare groups. For the primary analyses, logistic regression analyses were used to assess the effectiveness of NRT among subjects who made a quit attempt. A second logistic regression analysis was used to assess the association between use of 'ineffective' aids and success.

Results

The mean FTND scores were higher in those using NRT versus those not using it: 5.4 (SD=2.3) versus 4.8 (SD=2.3) in the Phase 1 sample (p=0.02 by analysis of variance), and 4.8 (SD=2.3) versus 4.1 (SD=2.5) in the Phase 2 sample (p<.001). It was also somewhat higher in those who used other forms of support versus those who did not use them: 5.4 (SD=2.1) versus 5.0 (SD=2.0) in the Phase 1 sample (p=ns), and 4.8 (SD=2.3) versus 4.2 (SD=2.5 in the Phase 2 sample (p<.02).

Table 2 shows the results of logistic regression analyses predicting six-month continuous abstinence as a function of use of NRT and other support, adjusting for FTND. It is clear in both samples that use of NRT was associated with an increase in success rates. In neither the Phase 1 nor the Phase 2 samples were educational level, age or gender significantly, associated with NRT use. However, in the Phase 2 sample, but not the Phase 1 sample, NRT use was significantly associated with country (chi-squared=22.7, p<.001); therefore the logistic regression was repeated including both country and FTND as covariates. This did not alter the findings; the odds ratio remained 2.1 (p<.05).

The adjusted difference in likelihood of achieving six months of abstinence between NRT users and non users was 6.0% in the Phase 1 sample and 3.7% in the Phase 2 sample. In Phase 1, the unadjusted difference was 5.9% (9.4% in the NRT group and 3.5% in those not using NRT). In Phase 2 the unadjusted difference was 2.6% (6.9% in the NRT groups compared with 4.3% in those not using NRT).

Combining the data from the two samples and including Phase as a covariate along with FTND, the odds of achieving 6 months of abstinence among those using NRT were 2.2 (95% CI: 1.3-3.9) times higher than those not using it (p<.005). The adjusted difference in success rates (with phase and FTND as covariates) was 4.3%. The unadjusted difference in success rates was 3.8% (7.8% in the NRT group and 4.0% in those not using NRT).

There was no evidence that use of forms of support that would not be expected to have specific efficacy, but which could be presumed to signal a high level of motivation to quit, was associated with an increase in success rates (Table 2).

Table 2: Results of logistic regression analyses to test associations between NRT use or use of other aids and 6 months' continuous abstinence

	Odds ratio (95% confidence interval) adjusting for FTND			
	Phase 1 sample	Phase 2 sample	Combined sample	
Model 1				
NRT versus no NRT	3.0* (1.2-7.5)	2.1* (1.0-4.1)	2.2* (1.3-3.9)	
Model 2				
Other aid versus no other aid	0.8 (0.2-3.1)	1.6 (0.7-3.7)	1.4 (0.7-2.7)	

^{*}Significant difference between groups, p<.05 2-tailed

Other aid= hypnotherapy, acupuncture, herbal remedies, the internet or books

Discussion

NRT use was associated with improved chances of long-term abstinence with nicotine dependence controlled for. The abstinence rates in those not using NRT were similar to estimates from untreated samples in clinical trials and other longitudinal studies. The size of effect is broadly what would be predicted from the clinical trials. The effect did not appear to be a function of motivation to use some form of support. A strong feature of this study was the fact that the finding was replicated in two separate samples. Another was that the frequent follow-up (every three months) which we believe is unique in population studies of this kind.

A potential problem with cohort studies is a bias caused by loss to follow-up. We showed that those lost to follow-up did not differ at baseline from those followed up. There was no differential loss to follow-up in those using NRT and those not using it so this could not underpin the findings. The fact that the sample was recruited by internet is another obvious potential source of bias in that internet users may be more likely to use NRT appropriately because they are more likely to have more education. In fact, the sample was very close in terms of demographic and smoking characteristics to samples drawn from household surveys (17) and while they did tend to have a higher educational level, there was no suggestion of an interaction between education level and NRT effectiveness in either sample. A third potential source of bias is reliance on self-reported quit rates. This may lead to an overestimation of successful quitting but there is no reason why it should contribute to a difference in success rates as a function of NRT use versus non-NRT use. Indeed, if there were greater motivation to report abstinence in those using NRT, one would also expect to see this with other forms of support and that is not what was observed. Fourthly, the sample was drawn from smokers expressing an intention to try to stop within the next 3 months and it remains possible that NRT is less effective in smokers who make quit attempts without having formulated any intention to do so previously (see 20).

The fact that the sample was limited to smokers of 5 or more cigarettes per day means that it cannot address the potential effectiveness of NRT in very light smokers but the product labels indicate that they are suitable for smokers of 10-15 or more cigarette per day anyway and we do not have evidence from randomised trials of efficacy in light smokers.

The questionnaire did not permit matching NRT usage to individual quit attempts if respondents made more than one quit attempt in the 3-month window. Where smokers made more than one quit attempt there may therefore have been some noise introduced into the data. However, this would, if anything, weaken any associations found.

There are many questions that we were not able to answer because of lack of statistical power. We were not able to assess the effectiveness of bupropion or face-to-face behavioural support in addition to NRT nor whether there was an interaction between NRT use and the country of residence of the smokers. Similarly we were not able to determine whether NRT was more or less

effective in smokers with different socio-demographic characteristics. These issues are all important but will require additional studies.

In conclusion, this paper contradicts findings from cross sectional surveys requiring recall of quit attempts over an extended period, and supports the findings from the clinical trial literature, in finding that NRT use is associated with a greater likelihood of remaining abstinent for at least 6 months in smokers making self-initiated quit attempts without additional behavioural support. This association does not appear to be explained by a greater commitment to stopping smoking.

Acknowledgements

We are grateful to Sanofi-Aventis Recherche for making the data available for this analysis and Alicia Gilsenan and Elizabeth Sherrill from RTI International for their helpful comments on a draft and contribution to data collection. We are also grateful to Cancer Research UK for providing part funding for this paper.

Competing interest statement

Robert West has undertaken paid research and consultancy, and received hospitality from, manufacturers of smoking cessation medications. He also has a share in a patent for a novel nicotine delivery device.

Xiaolei Zhou is employed by RTI International which was paid by Sanofi-Aventis to implement the ATTEMPT cohort study.

Funding

Sanovi-Aventis made the data available for this paper and funded the ATTEMPT cohort study. Robert West's salary is mainly paid by Cancer Research UK.

Ethical Approval

Ethical approval was granted by RTI International's Institutional Review Board.

Statement of funding independence

The research is independent of the funder.

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