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**Characterisation of Long-term Users of Nicotine Replacement Therapy: Evidence from a
National Survey.**

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ABSTRACT

Introduction: Harm reduction involving partial or complete substitution of cigarettes with NRT (Nicotine Replacement Therapy) is likely to benefit smokers by reducing exposure to carcinogens and increasing the likelihood of permanent cessation. This paper aimed to assess the determinants of short and long-term NRT use for harm reduction in order to inform interventions aimed at helping smokers struggling to quit to switch to complete NRT substitution.

Methods: Data were used from the Smoking Toolkit Study, a population based survey of adults in England aged 16+ (n=9,224). Participants were asked about their socio-demographic characteristics and tobacco use. Attitudes towards smoking were also assessed using questions covering four factors: motives, identity, evaluations and plans.

Results: Concurrent short-term (<3 months) and longer-term (≥3 months) NRT use was uncommon among smokers at 10.8% (95%CI 10.1-11.4) and 5.0% (95%CI 4.6-5.4), respectively. Longer-term NRT users had higher odds of being older, in non-manual occupations and more addicted than smokers with short-term or no NRT use (all $p<0.01$). They reported lower odds of attempting to stop and higher odds of exhibiting a positive smoker identity than short-term users ($p<0.001$). Conversely, longer-term NRT users had higher odds of having made a recent quit attempt, to have plans to stop and lower odds of a positive smoker identity than smokers not using NRT (all $p<0.001$).

Conclusion: Whilst users of NRT for harm reduction purposes are a heterogeneous group, it appears they are more critical of smoking than never users and tend to positively modulate their behaviour, setting them on a path towards cessation.

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INTRODUCTION

Tobacco smoking remains one of the leading causes of preventable mortality and morbidity worldwide, accounting for 12% of all deaths globally among adults aged 30 years and over – (World Health Organisation, 2012). Consequently, although traditional tobacco control strategies, i.e. prevention and cessation, have proved effective, it has been argued that newer innovative strategies are needed to tackle the worldwide tobacco problem. One proposed approach is harm reduction, which involves any attempt to lessen the harm from smoking without complete cessation of one or more tobacco constituents (Beard, McNeill, Aveyard, Fidler, Michie, & West, 2011a).

A specific type of harm reduction is the substitution of cigarettes with nicotine replacement therapy (NRT). This may be partial, i.e. use of NRT for smoking reduction (SR) or temporary abstinence (TA) when one is unable to smoke, or long-term, i.e. the complete substitution of cigarettes with medicinal nicotine products. In the UK NRT has been licensed for these purposes since 2005/2006 (MHRA, 2009) and guidance was released by the National Institute of Health and Care Excellence in 2013 which recommended that provisions be put in place for English Stop Smoking Services to extend their offer of support and guidance to smokers who are unable or unwilling to stop smoking and who were interested in harm reduction.

Partial substitution was initially endorsed as a consequence of findings from clinical trials (Wang, Connock, Barton, Fry-Smith, Aveyard & Moore, 2008; Moore et al., 2009) and population based studies (Beard et al., 2011a) which suggest that the use of medicinal nicotine for such purposes increases smokers' likelihood to quit, and in some cases, results in significant reductions in cigarette consumption and toxic intake; complete substitution is

advocated due to the acknowledgment that it is safer to use NRT than to smoke and that the long-term use of NRT is effective for preventing relapse following a quit attempt (Agboola, McNeill, Coleman, & Bee, 2010).

While a substantial minority of smokers report that they are attempting harm reduction with the aid of NRT (Beard, Bruguera, Brown, McNeil, & West, 2013a), this does not appear to have been a consequence of recent licence changes, with a similar prevalence of NRT use for smoking reduction and temporary abstinence in England pre and post these adaptations (Shahab et al., 2009; Beard et al., 2013a). Indeed, most smokers are attempting SR and TA without pharmacological help (Beard et al., 2011a), and fail to use medicinal nicotine to prevent relapse following a quit attempt (Etter & Perneger, 2001). This might be due to various reasons, including lack of awareness of the licence change, concerns about the safety of medicinal nicotine or the cost of buying NRT concurrently with cigarettes (e.g. Basal et al., 2004; Beard et al., 2012a; Carpenter, Ford, Cartmell, & Alberg, 2011). As attempts at SR, TA and cessation are more effective with the aid of medicinal nicotine (Moore et al., 2009) and given that switching fully to NRT is likely to be less harmful to health than continued smoking (Benowitz et al., 1998), there is a need to identify ways in which usage can be increased among current smokers.

A suitable first step is the development of a typology of smokers who use NRT for harm reduction to identify their beliefs, characteristics and views. Previous work shows that smokers using NRT for SR or TA had suffered substantial difficulties with smoking cessation, relied heavily on NRT, were more dependent smokers and hostile towards stop smoking policies and services (Beard et al., 2012a; Beard et al., 2013b).

However, these studies occurred before many of the recent licensing changes and did not try to differentiate between smokers with different temporal usages of NRT. Consideration of these groups separately is important as smokers using NRT in the short-term may be qualitatively different and require different levels of support than those using NRT long-term. Understanding the beliefs and characteristics of users will help to inform future interventions aimed at encouraging smokers not only to switch to concurrent NRT use and partial substitution but, eventually, to complete substitution and stopping smoking.

As a consequence, the current study attempts to devise a preliminary typology of smokers using NRT both short- and longer-term. We aim to identify ways to modify current smokers' attitudes and behaviours in order to encourage harm reduction. Smokers were compared quantitatively in a population-based household survey to assess socio-demographic and attitudinal characteristics associated with NRT use and length of use to provide information about ways to encourage partial substitution.

METHODS

Design and Procedure

A quantitative study using data from the Smoking Toolkit Study (STS; www.smokinginengland.info), which provides up to date information on smoking behaviour and smoking cessation patterns among adult (aged 16+) smokers and recent ex-smokers in England. Further details of the design and method are described elsewhere (Fidler et al., 2011). Data used for the current paper were obtained between August 2010 and April 2012.

Measures

Smoking status was assessed by asking: ‘Which of the following best applies to you? – (I smoke cigarettes (including hand-rolled) every day; I smoke cigarettes (including handrolled), but not every day; I do not smoke cigarettes at all, but I do smoke tobacco of some kind (for example: pipe or cigar); I have stopped smoking completely in the last year; I stopped smoking completely more than a year ago; I have never been a smoker (i.e. smoked for a year or more); don’t know). Those who responded that they smoked cigarettes every day, or that they smoked but not every day, were coded as current cigarette smokers. Current smokers were asked if they had used NRT and if they answered yes: ‘How long have you used nicotine replacement products for?’ – (Less than one week; one to six weeks; more than six weeks up to twelve weeks more than 12 weeks).’ Those who had used NRT for less than 3 months were classified as short-term users and those who had used NRT for at least 3 months as longer-term users. Participants were then further asked about harm reduction and NRT use. They were asked “Whether they are currently trying to cut down amount smoked”; “Whether they are attempting to cut down amount smoked but not currently trying to stop”; “Whether they are using products to help cut down the amount smoked” and “Whether they use products to cut down, stop smoking or for any other reason.” All smokers were also asked

various questions about their beliefs regarding smoking which were based on PRIME theory (West, 2006). Age, gender and social grade (classified as non-manual (ABC1) and manual (C2DE) using the NRS classification scale, see <http://www.nrs.co.uk/lifestyle-data/>) were measured, as was nicotine dependence (Heaviness of smoking index, Heatherton, Kozlowski, Frecker, Rickert, & Robinson, 1989), previous attempts to quit smoking, and attempts to cut down cigarette consumption. See <http://www.smokinginengland.info> for further details of the survey design and methodology.

Participants

Between August 2010 and April 2012, 9,328 smokers were recruited of whom 7% (n=104) were excluded due to missing data on NRT use. This resulted in a final sample of 9,224 smokers: 70% (n=6,505) were in manual occupation, the mean age was 42 (SD±16.9) and 48% (n=4,552) were women.

Data Analysis

Analysis was carried out using SPSS 20.0. Associations between the long-term use of NRT and socio-demographic, and smoking characteristics and beliefs, were assessed by logistic regression analyses, controlling for potential confounding variables age, gender, social grade, and time to first cigarette of the day, as appropriate. The 14 questions on beliefs about smoking were factorised following assessment for factorability: several of the items were corrected at 0.3 or above; the Kaiser-Meyer-Olkin was 0.69 (above the commonly recommended value of 0.6); Bartlett's test of sphericity was significant ($X^2(91)=15173$, $p<0.001$); and the diagonals of the anti-image correlation matrix were all over 0.5. Thus factor analysis was deemed suitable. Principle components analysis was used with oblique rotation as there was reason to believe that factors would be related to each other. A four

factors solution was identified, which explained 47.7% of the variance (Factor 1: 20.5%; Factor 2: 11.5%; Factor 3: 8.1%; and Factor 4: 7.6%). The four factors and factor loadings of the variables are given in Table 1. One of the variables “I have had enough of being a smoker” although loading better onto Factor 1 was moved to Factor 2 as this made greater theoretical sense. It loaded with -0.22 which is considered significant for the sample size. These factors were labelled using the constructs identified by PRIME theory (West, 2006): Factor 1 - Biopsychosocial prompts to stop (motives); Factor 2 - Positive smoker identity (identity); Factor 3 - Individual addiction (evaluations); and Factor 4 - Plans to stop (plans). Composite scores were created for each of the four factors with “I want to quit smoking”, “I have had enough of being a smoker”, “I am confident I could stop smoking if I tried” to and “I ought to stop smoking” being recoded so that higher scores were associated with more biopsychosocial prompts, a stronger smoker identity, greater perceived addiction and greater plans to stop.

RESULTS

Nearly 16% (95%CI 15.0-16.5) of smokers (n=1,453) were concurrently using NRT: 5.0% (95%CI 4.6-5.4, n=460) had used NRT for at least 3 months (longer-term users) and 10.8% (95%CI 10.1-11.4, n=993) had used NRT for less than three months (short-term users).

NRT users were a heterogeneous group and their characteristics differed as a function of length of use (see Table 2). Longer-term NRT users were older and more likely to be in a non-manual occupation compared with short-term NRT users and less likely to have made a recent quit attempt or to try cutting down. Whilst there were no differences in terms of biopsychosocial prompts to stop and plans to stop between longer and short-term users, smokers who used NRT for longer were generally more likely to harbour a positive smoker identity and to evaluate themselves as more addicted.

As was the case when compared with short-term users, longer-term users were older and less likely to be in manual occupations than smokers who did not use NRT at all for harm reduction purposes. They were also more likely to be female and to exhibit higher dependence (Table 2). However, contrary to the comparison with short-term users, longer-term users were more likely to have made a quit attempt and to try to cut down than smokers who did not use NRT and less likely to exhibit a positive smoker identity. They were more likely to report biopsychosocial prompts to stop and to evaluate themselves as more addicted. They were also more likely to have plans to stop smoking than smokers who did not use NRT at all (Table 2).

DISCUSSION

This study aimed to develop a typology of long-term and short-term NRT users in order to inform interventions aimed at encouraging smokers who are unwilling to quit smoking to substitute their cigarettes with safer medicinal products.

The analyses revealed that those using NRT longer-term were more likely to be being female, older and from non-manual occupations compared with smokers not using NRT. Despite appearing to be more nicotine dependent, NRT users had higher odds of having tried to change their smoking behaviour, i.e. to have made a quit attempt and/or cut down their cigarette consumption. In addition, longer-term users relative to non-users reported more environmental prompts to motivate them to change their behaviour and were less likely to exhibit a positive smoker identity. The findings demonstrate that concurrent NRT and cigarette users are a rather heterogeneous group. In particular, longer-term users were from higher socio-economic grades, were of an older age, were less likely to have tried to modify their smoking behaviour either through quitting or harm reduction and generally endorsed a more positive smoker identity.

The finding that long-term NRT users tend to be of higher social-grade is unsurprising, since NRT use for harm reduction is generally obtained over the counter, rather than on prescription or free of charge (Hammond et al., 2008). This also likely explains the finding that longer-term NRT users were of higher social-grades than short-term users; with longer use equating to higher costs. Although this association with social-grade is consistent with previous studies (Beard et al., 2013b), it is of concern given that harm reduction approaches have been mooted as a means of reducing inequalities in smoking cessation. The recent NICE guidance on harm reduction acknowledged the issue of affordability, stating that “people may

be put off by the cost of some licensed nicotine-containing products” and that “people may be at risk of relapse after their prescriptions for licensed nicotine-containing products run out if they find cigarettes are cheaper” (pp. 30-31). Therefore, consideration is required as to how costs may be driven down in addition to ensuring smokers are aware that in the long term, NRT use can be cheaper than continued smoking. A 7-day course of patches costs around £15, whilst on average £35 is spent on cigarettes by smokers each week. Thus even if smokers substitute only half their cigarettes for a full course of NRT, they would save on average 10 pounds a month (Davis, 2007).

In line with previous studies (Moore et al., 2009; Beard et al., 2013b), we found that smokers using NRT concurrently are more motivated to quit smoking than non-NRT users. These findings are also consistent with the PRIME theory (West, 2006) as the constructs identified in the factor analysis (motives, identity, evaluations and plans) are related to this model, and revealed that NRT users were not only more motivated to quit, but they were also more likely to have plans to stop, and less likely to have a positive smoker identity. Accordingly, NRT users were more likely to have made more recent quit attempts than non-NRT users. Whilst the cross-sectional nature of this study means that causal inferences cannot be made, this finding is consistent with the view that NRT use may increase smokers’ propensity to quit by reducing withdrawal and craving symptoms which can lead smokers to believe that giving-up may not be uncomfortable (Fagerstrom, Schneider & Lunell, 1993). This may also increase smoker’s self-efficacy by helping them to learn that it is possible to cope without tobacco for several hours without undue discomfort. Yet, this finding may also reflect the possibility that smokers who go on to use NRT concurrently are already more confident and motivated to stop at baseline.

However, on the basis of previous survey and clinical trial data, the former appears a more plausible argument as it has been shown that the concurrent use of NRT and cigarettes is associated with increased desire to quit smoking over time. For example, a recent prospective population study which matched participants on prior motivational levels using propensity score matching procedures reported that NRT use for harm reduction was associated with increased odds of attempting to quit smoking at 6 months (Beard et al., 2012b). Thus it might be argued that smokers who are unwilling or unable to quit smoking should be encouraged to use NRT in the hope that this will, at some point, induce an attempt to quit smoking.

At the same time, our findings also point to the possibility that benefits are largest for short-term users. The fact that longer-term NRT users were less motivated to quit smoking than short-term users could reflect dissipation of motivation to quit over time. Alternatively, selection bias may play a role, with less motivated smokers opting to use NRT long-term. Of course, the cross-sectional nature of the data complicates the picture as short-term users are likely to include both those using NRT short-term but will also consist of those who will go onto long-term use, resulting in a group that is overall less addicted and more likely to have plans to stop compared with longer-term users. As previously shown (Beard et al., 2013a), concurrent NRT use is associated with similar cigarette consumption compared with those not using NRT. However, if it is the case that long-term NRT users are slightly more nicotine dependent, then cross-sectional analyses may preclude any reduction in cigarette consumption, if smokers started at a higher cigarette level prior to reduction.

Finally, the finding of greater NRT use among women and those of an older age gives some indication as to those who may be most receptive to a harm reduction approach and is perhaps unsurprising: men are generally less likely to seek preventative healthcare

(Courtenay, 2000), whilst older smokers hold greater positive beliefs about medications (Horne & Weinman, 1999). However, the fact that these findings largely coincide with studies on the characteristics of those using NRT for smoking cessation (Botello-Harbaum et al., 2010; Emmons et al., 2000; Kotz et al., 2009), raises the concern that harm reduction approaches are targeting those willing to quit smoking, as opposed to those unable or unwilling to do so.

This study has a number of limitations. Firstly, being carried out in England where NRT is liberally licensed, the findings in this study cannot be generalised to other countries where NRT is not licensed for harm reduction. However it should be noted that the STS appears to be representative of the population as it has obtained similar demographic and smoking data to other large national surveys (Fidler et al., 2011). Secondly, as indicated above, data were cross-sectional in nature, which limits the conclusions that can be drawn in relation to the causal association between NRT use and motivation to quit smoking. Thirdly, despite careful wording of questions, the reliance on retrospective reports means that the current reasons for NRT use may differ from the reasons that first initiated NRT use, and may further differ from reasons for future NRT use. A longitudinal study following use of NRT over time may be better able to identify causality and associated changes in cognitions. A strength of this study is the fact that the analysis was theory-driven and findings are consistent with PRIME theory as the concepts that arose from the factor analysis were based on this model.

Overall, this study has taken a first step in describing the attitudes, beliefs and characteristics of smokers with and without concurrent NRT use. We find that NRT users for harm reduction purposes are a heterogeneous group. However, irrespective of length of use, it appears they are more critical of smoking than never users, having greater awareness of various prompts to

stop, and hold a less positive smoker identity, resulting in greater modulation of their smoking behaviour with regards to quit attempts and cigarette consumption. Consequently, although NRT use may not necessarily lead to complete substitution, it helps to develop motivation and change perception about smoking towards a cessation trajectory. Crucially, however, the financial implications of NRT use may prevent those most in need of support from accessing it. Future interventions should aim to target specific characteristics to motivate and encourage smokers to use NRT, including provision of subsidised NRT for harm reduction purposes, provide them with support to maintain their motivation, and encourage quit attempts in order to achieve complete substitution. Lastly, given the limitations of cross-sectional analyses, further longitudinal research is warranted to confirm these findings.

DECLARATION OF INTERESTS

KS has nothing to declare in relation to this paper. E.B has received conference funding from Pfizer. LS has received honoraria for talks and travel expenses to attend meetings and workshops from pharmaceutical companies that make smoking cessation products.

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TABLES

Table 1: The four identified factors from the principle components analysis with factor loadings

Factor 1: Biopsychosocial prompts to stop

I am worried that smoking is harming my health right now (0.65)

I am worried about the effect of smoking on my family and loved ones (0.62)

I am worried smoking will harm my health in the future (0.61)

It is getting too difficult to smoke these days (0.56)

People I care about want me to stop smoking (0.53)

Smoking is costing me too much money (0.44)

I have had enough of being a smoker (0.61)

Factor 2: Positive smoker identity

I enjoy smoking (0.68)

I like being a smoker (0.63)

I want to stop smoking (0.56)

Factor 3: Individual addiction

I am confident I could stop smoking if I tried (0.68)

I am addicted to smoking (-0.58)

Factor 4: Plans to stop

I ought to stop smoking (0.68)

I intend to stop smoking soon (-0.86)

Table 2: Socio-demographic and smoking characteristics and beliefs of participants as a function of NRT use

	Overall (n=9224)	Smokers LT NRT (n=460)	Smokers ST NRT (n=993)	Smokers no NRT (n=7771)	LT NRT versus NRT^	ST	LT NRT versus no NRT^	
	% (N) [#]				Odds ratio (95% CI)			
Socio-demographic characteristics								
Age M(SD)	42.4 (16.9)	46.4 (16.1)	40.7 (15.0)	42.3 (17.1)	1.02***	1.02-1.03	1.04***	1.01-1.02
Female %(n)	48.7 (4496)	53.0 (244)	52.0 (516)	48.1 (3736)	1.00	0.80-1.25	1.24*	1.00-1.46
Manual%(n)	69.7 (6428)	60.4 (278)	68.5 (680)	70.4 (5470)	0.71**	0.56-0.90	0.60***	0.49-0.73
Smoking characteristics								
HSi M(SD)	2.0 (1.5)	2.2 (1.5)	2.1 (1.5)	2.0 (1.6)	1.07	0.99-1.16	1.11***	1.04-1.18
Strength of urges M(SD)	2.1 (1.1)	2.3 (1.0)	2.2 (1.0)	2.1 (1.1)	1.10	0.98-1.23	1.30***	1.19-1.42
Quit attempt in last year %(n)	30.3 (2793)	57.2 (263)	69.1 (684)	23.8 (1846)	0.62***	0.49-0.79	4.66***	3.83-5.67
Trying to cut down cigarettes %(n)	50.6 (4669)	72.4 (333)	87.4 (867)	44.7 (3469)	0.37***	0.28-0.49	3.33***	2.70-4.12
Biopsychosocial prompts to stop (Motives) (max score 6) M(SD)	1.6 (1.56)	2.2 (1.72)	2.2 (1.71)	1.5 (1.50)	1.00	0.94-1.07	1.28***	1.21-1.35
Positive smoker identity (identity) (max score 4) M(SD)	2.2 (1.03)	2.0 (1.03)	1.6 (0.98)	2.3 (1.00)	1.47 ***	1.31-1.65	0.74***	0.67-0.81
Individual addiction (Evaluations) (max score 2) M(SD)	1.1 (0.71)	1.3 (0.74)	1.1 (0.75)	1.1 (0.71)	1.26 ***	1.08-1.47	1.50***	1.31-1.73
Plans to stop (Plans) (max score 2) M(SD)	0.6 (0.57)	0.7 (0.56)	0.7 (0.63)	0.6 (0.56)	1.05	0.87-1.26	1.27**	1.08-1.50

[#]Unless otherwise indicated; ^ Controlling for age, sex, occupation and time to first cigarette where appropriate; Note: LT = Long-term (NRT use ≥ 3 months); ST = Short-term (NRT use < 3 months); *** significant difference $p < 0.001$; ** significant difference $p < 0.01$; * significant difference $p < 0.05$.