

# Should smoking cessation cost a packet? A pilot randomized controlled trial of the cost-effectiveness of distributing nicotine therapy free of charge

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## SUMMARY

*This pilot study suggests that changes in prescribing policy for nicotine replacement patches should be made only when evidence of cost-effectiveness can be adduced from a randomized controlled trial.*

*Keywords: randomized controlled trials; transdermal nicotine replacement therapy; cost effectiveness.*

## Introduction

Transdermal nicotine replacement therapy (NRT) has been proved effective in helping smokers to quit.<sup>1</sup> Some observers believe that providing patches through the National Health Service (NHS) will lead to a further reduction in smoking.<sup>2</sup> This paper reports on a pilot evaluation to investigate whether a change in prescribing policy is warranted.

## Method

Eight general practices in East Lancashire agreed to participate. The study was approved by the local research ethics committee. Subjects aged 25 to 64 years who smoked more than 15 cigarettes a day and who expressed a desire to quit were recruited during 1996. Exclusion criteria included contraindications to NRT and the participation of another household member. All subjects received standardized brief counselling from the practice nurse and were then randomly allocated by an off-site randomization office to either the intervention or the control arm.

Subjects in the intervention arm were given prescriptions for Nicorette patches, which were dispensed free of charge at nominated pharmacies (these subjects constituted the 'free' group). Subjects in the control arm were given private prescriptions for Nicorette patches, which were dispensed at nominated pharmacies at slightly less than the retail charge (these subjects were the

'purchase' group).

Subjects were asked to reattend one, four, and eight weeks after randomization for further counselling and prescriptions. Final assessment of smoking status was undertaken after 14 weeks (two weeks after stopping NRT); subjects not attending were followed up by questionnaire. Salivary cotinine levels and expired air carbon monoxide (ECO) levels were measured on subjects reporting abstinence. Success was defined as self-reported abstinence between eight and 14 weeks, validated by a salivary cotinine level <14 ng/ml and ECO levels <10 ppm.

## Results

A total of 129 subjects were eligible and 122 agreed to participate; 64 were allocated to the free group and 58 to the purchase group. Those in the purchase group were more likely to report that other household members smoked, and members of the free group were more likely to be owner-occupiers. Other baseline characteristics were similarly distributed between study groups (Table 1). Sixty-two (97%) and 28 (48%) subjects in the free and purchase groups, respectively, exchanged at least one weekly prescription.

Information on self-reported smoking status at 14 weeks was available for 58 subjects (91%) in the free group and 39 (67%) in the purchase group. Fourteen (24.1%) of the subjects allocated 'free' patches and seven (17.9%) of those allocated 'purchase' patches reported abstaining between eight and 14 weeks — a difference between the groups of 6.2% (95% confidence interval = -10.1% to 22.5%).

Salivary cotinine levels were available for 16 of the 21 self-reported abstainers; one subject using nicotine gum at final follow-up had only ECO levels measured. Self-reported abstinence was validated in 11 of these 17 subjects. Excluding the four subjects for whom validation was not available, six (10.7%) of the subjects in the free group and five (13.5%) of those in the purchase group were validated abstainers — a difference between the groups of -2.8% (95% confidence interval = -16.5% to 10.9%).

## Discussion

This study found similar validated abstinence rates in the free and the purchase groups, despite higher self-reported abstinence in the free group. More subjects in the free group collected their patches from the pharmacy. A similar pilot trial of nicotine gum also indicated increased self-reported abstinence and use of patches among those receiving free NRT, but biochemical validation was not undertaken.<sup>3</sup>

The study was not designed to determine conclusively the effectiveness of providing free NRT. The sample size is small and only short-term outcomes are reported. However, the findings of this study cast doubt on the idea that providing NRT patches free of charge is more effective than suggesting purchase; a more substantial study is warranted.

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**Table 1.** Baseline characteristics of the 122 recruited subjects

Characteristics	'Free' group n = 64 (% in brackets) <sup>a</sup>	'Purchase' group n = 58 (% in brackets) <sup>a</sup>
Age: mean (sd)	44 years (11.7)	42 years (10.2)
Sex		
Male	28 (44%)	26 (45%)
Female	36 (56%)	32 (55%)
Marital status		
Married/cohabiting	38 (68%)	37 (70%)
Single/divorced/widowed	18 (32%)	16 (30%)
Unknown	8	5
Home owner	39 (70%)	31 (58%)
Unknown	8	5
Access to car	38 (68%)	37 (70%)
Unknown	8	5
Number of cigarettes smoked per day		
20 or fewer	28 (50%)	25 (46%)
21 or more	28 (50%)	28 (54%)
Unknown	8	6
Number of years smoked		
20 or less	23 (42%)	25 (47%)
21 or more	32 (58%)	28 (53%)
Unknown	9	5
Previous attempts to quit smoking		
Fewer than two	14 (25%)	14 (26%)
Two or more	41 (75%)	39 (74%)
Unknown	9	5
Used NRT before	16 (29%)	20 (38%)
Unknown	9	5
Others who smoke in house	24 (44%)	33 (62%)
Unknown	9	5
Time of first cigarette of the day		
Up to 15 mins after waking up	38 (69%)	35 (66%)
More than 15 mins after waking up	17 (31%)	18 (34%)
Unknown	9	5

<sup>a</sup>Percentages exclude unknowns.

The differential response rate is disappointing. We were reliant on practice nurses to follow up non-attenders. More rigorous assessment of non-attenders by an independent research assistant might have increased the response rate. The possible impact of the non-responders was explored further by assuming, as other studies have done, that all non-responders were still smoking.<sup>1,3</sup> On this assumption, 9.4% in the free group and 8.6% in the purchase group were validated quitters.

Some health authorities already invest in schemes to distribute 'free' NRT. The recent White Paper on tobacco promises that the NHS will provide one week of NRT free of charge to the 'worse off'.<sup>4</sup> Randomized controlled trials of the cost-effectiveness of such policies are both feasible and acceptable, and should be undertaken before they become widespread practice.

## References

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