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Abstinence from smoking eight years after participation in randomised controlled trial of nicotine patch

Patricia Yudkin, Kate Hey, Sarah Roberts, Sarah Welch, Michael Murphy, Robert Walton

Department of Primary Health Care, University of Oxford, Institute of Health Sciences, Oxford OX3 7LF
Patricia Yudkin
reader in medical statistics

Cancer Research UK General Practice Research Group, Institute of Health Sciences, Oxford OX3 7LF
Kate Hey
research officer
Michael Murphy
director
Sarah Roberts
research nurse
Sarah Welch
research nurse

Department of Clinical Pharmacology, University of Oxford, Radcliffe Infirmary, Oxford OX2 6HE
Robert Walton
senior research fellow

Correspondence to: P Yudkin
pat.yudkin@dpipc.ox.ac.uk

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Few studies have investigated abstinence beyond three years among participants who stop smoking during trials of nicotine replacement therapy,¹⁻³ and even fewer have followed up smokers who failed to quit during such trials. We carried out an eight year follow up of people who had participated in a randomised controlled trial of the nicotine patch.

Participants, methods, and results

Participants were the 1686 patients from general practices in Oxfordshire who took part in a double blind randomised controlled trial of the patch in 1991-2.^{4,5} At entry they smoked ≥ 15 cigarettes a day and were aged 25-64 years. Participants wore the patches for 12 weeks. The main outcome was abstinence from smoking for one year, confirmed at 12, 24, and 52 weeks by a salivary cotinine concentration ≤ 20 ng/ml (89% of cases) or expired carbon monoxide ≤ 10 ppm (11%).

In 1999-2000, we contacted 1532 of the 1625 living participants. We sent two follow up letters and phoned non-responders. In total 840 participants completed a questionnaire giving demographic details and information about smoking. The mean time from enrolment in the trial to follow up was 8.3 (SD 0.35) years, with a range of 7.4-9.3 years. Responders were more likely to be women (59.0% v 51.7%; $P=0.005$) and were more likely to have stopped smoking during the trial than non-responders (13.2% v 5.5% quit for one year; $P < 0.0001$). Reported abstinence at follow up was confirmed by a plasma cotinine concentration ≤ 20 ng/ml. Responders reported for how long they had been abstinent. We assumed that all those lost to follow up were still smoking.

Of the 153 participants who had stopped smoking for a year in the original trial, 83 were still not smoking at follow up, giving an eight year abstinence rate of

83/1625 (5%; 95% confidence interval 4% to 6%) and a relapse rate of 70/153 (46%; 38% to 54%) (table). Relapse was similar in active and placebo groups: the active/placebo odds ratio (OR) for continuous abstinence up to follow up was 1.39 (0.89 to 2.17; $P=0.19$) compared with 1.45 (1.04 to 2.03; $P=0.03$) for quitting for a year in the trial.

Of the 1472 who did not quit for a year in the trial, 116 (8%; 7% to 9%) were abstinent at follow up. Of these, 89 (6%; 5% to 7%) had abstained for a year or more, and 27 for less than a year (median 4 months). Overall at follow up therefore, 172 (11%; 9% to 12%) of trial participants had been abstinent for a year or more, 29 (2%) had been abstinent for less than a year, and 1424 (88%) were smoking.

Comment

Eight years after taking part in a randomised trial of the nicotine patch, just under half of the 9% who had stopped smoking for a year had relapsed, leaving 5% of all trial participants continuously abstinent for eight years. Previous studies have reported that a third to a half of all those who stop during a trial relapse by three or four years.¹⁻³ Use of the nicotine patch conferred a 39% increase in the odds of continuous abstinence compared with placebo. The increase was not significant, but our original trial was not powered to detect the small difference observed in eight year abstinence rates (5.9% v 4.3%). Of the majority who did not quit in the trial, only 8% had given up smoking at follow up, leaving 88% of trial participants still smoking. Our estimates were based on the conservative but well accepted assumption that those lost to follow up were still smoking. Finding more effective ways to help people to give up smoking remains an ongoing challenge.

Estimated smoking cessation at eight year follow up among trial participants (n=1625). Values are numbers (percentage) of participants in each trial group*

	Nicotine	Placebo	Total
Followed up			
No in group	412	428	840
Quit for 1 year in trial†:	66 (16.0)	45 (10.5)	111 (13.2)
Abstinent from trial to 8 years	48	35	83
Abstinent at 8 years for <1 year	1	1	2
Smoking at 8 years	17	9	26
Did not quit for 1 year in trial:	346 (84.0)	383 (89.5)	729 (86.8)
Abstinent at 8 years for ≥1 year	36	53	89
Abstinent at 8 years for <1 year	12	15	27
Smoking at 8 years	298	315	613
Not followed up			
No in group	403	382	785
Quit for 1 year in trial†	25 (6.2)	17 (4.5)	42 (5.4)
Did not quit for 1 year in trial	378 (93.8)	365 (95.5)	743 (94.6)
Assumed smoking at 8 years	403	382	785
Total			
No in group	815	810	1625
Quit for 1 year in trial†:	91 (11.2)	62 (7.7)	153 (9.4)
Abstinent from trial to 8 years	48 (5.9)	35 (4.3)	83 (5.1)
Abstinent at 8 years for <1 year	1 (0.1)	1 (0.1)	2 (0.1)
Assumed smoking at 8 years	42 (5.1)	26 (3.2)	68 (4.2)
Did not quit for 1 year in trial:	724 (88.8)	748 (92.3)	1472 (90.6)
Abstinent at 8 years for ≥1 year	36 (4.4)	53 (6.5)	89 (5.5)
Abstinent at 8 years for <1 year	12 (1.5)	15 (1.9)	27 (1.7)
Assumed smoking at 8 years	676 (82.9)	680 (84.0)	1356 (83.4)
Total abstinent at 8 years for ≥1 year	84 (10.3)	88 (10.9)	172 (10.6)
Total abstinent at 8 years for <1 year	13 (1.6)	16 (2.0)	29 (1.8)
Total assumed smoking at 8 years	718 (88.1)	706 (87.2)	1424 (87.6)

*Table excludes the 61 trial participants known to have died since trial. All participants who were not followed up were assumed to be smoking.

†Biochemically confirmed quitting at 12, 24, and 52 weeks.

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Smoking cessation dilemmas in prison

Helping prisoners to stop smoking can be a real conundrum. A delicate balance has to be struck between the equality of health care that prisoners deserve and the intricacies of running a secure prison. This year I had the opportunity to view this phenomenon in one of Britain's maximum security jails.

The implementation of a workable smoking cessation programme was an uphill battle for the staff involved. Even the simplest of leaflets on giving up, kindly designed by the Health Education Board for Scotland, were unsuitable. Their suggestions to "eat more fruit" or "take a walk" in the park to beat off a craving isn't really feasible when your scenery extends only to a prison cell and your meals are what you get given, not what you request.

There were further obstacles, including the devious personalities that can be found in prisons. Nicotine replacement gum was banned because it could be used to block locks or form key impressions. Opaque patches were also disallowed for fear that they could be used to conceal small items. The influx of illicit

drugs into prison excluded the use of inhalers as these could be modified for transporting other substances into the body.

There was a multitude of hurdles and unique aspects of the prison environment that had to be considered in the delivering of the smoking cessation programme. I hope that this account gives you some insight into the barriers that our colleagues in the prison health service have to contend with in the struggle to provide equality in health care for Britain's prisons.

Julie Ann Colclough *University of Dundee*

We welcome articles up to 600 words on topics such as *A memorable patient*, *A paper that changed my practice*, *My most unfortunate mistake*, or any other piece conveying instruction, pathos, or humour. If possible the article should be supplied on a disk. Permission is needed from the patient or a relative if an identifiable patient is referred to.