RESEARCH PAPER

Use of nicotine replacement therapy in socioeconomically deprived young smokers: a community-based pilot randomised controlled trial

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Background: Smoking is common in young people, particularly in disadvantaged groups, and continued smoking has a major impact on quality and quantity of life. Although many young smokers want to stop smoking, little is known about the design and effectiveness of cessation services for them.
Objective: To determine whether nicotine replacement therapy (NRT) when combined with counselling is effective in young smokers in a deprived area of Nottingham, UK
Methods and subjects: We surveyed smoking prevalence and attitudes to smoking and quitting in young people accessing an open access youth project in a deprived area of Nottingham, and used the information gained to design a community based smoking cessation service incorporating a randomised controlled trial of nicotine patches against placebo given in association with individual behavioural support. We resurveyed smoking prevalence among project attendees after completing the pilot study.
Results: Of 264 young people surveyed (median age 14 years, range 11–21), 49% were regular smokers. A total of 98 young people were recruited and randomised to receive either active nicotine patches on a six week reducing dose regimen (49 participants), or placebo (49 participants). Adherence to therapy was low, the median duration being one week, and 63 participants did not attend any follow up. At four weeks, five subjects receiving active NRT and two receiving placebo were abstinent, and at 13 weeks none were. Adverse effects were more common in the active group but none were serious. Smoking prevalence among 246 youth project attendees surveyed after the trial was 44%.
Conclusions: This study suggests that NRT in this context is unlikely to be effective in young smokers, not least because of low adherence to therapy. It also suggests that young smokers want help with smoking cessation, but that establishing the efficacy of smoking cessation services for young people who need them most will be very difficult.

Smoking is the biggest single preventable cause of mortality and morbidity in the United Kingdom,[1] and most smokers establish their addiction as teenagers.[2–4] Disadvantaged young people are more likely to become lifelong smokers[5–7] and to smoke more heavily.[8] Although self-reported motivation to quit is at least as high in socioeconomically deprived smokers,[9] smoking cessation rates have doubled in the most socially advantaged groups over the past two decades but have not changed in the most disadvantaged smokers.[10]

Despite the fact that most teenagers say that they want to stop smoking[11] and many have tried and failed, the prevalence of smoking among young people in Britain shows no sign of falling, particularly among young women.[12] Although adult smoking cessation services have become well established in the UK since the government White Paper,[13] there are still very few specialist cessation services for young people. Those that are available tend to be bolted on to adult cessation services, and as such are not perceived by many young people to be acceptable.[11 14] The effectiveness of nicotine replacement therapy (NRT) has not been established in young smokers; open label trials[15 16] and one recent placebo-controlled trial[17] have shown NRT to be well tolerated but with no significant effect on smoking cessation.

We have carried out a placebo-controlled trial of the acceptability and effectiveness of NRT, delivered in conjunction with individual or small group behavioural support, in disadvantaged young people using an open-access youth project in a deprived area of Nottingham.

SUBJECTS AND METHODS

The Zone Youth Project is a relational voluntary sector youth project based in a deprived area of inner city Nottingham and was originally established to provide a resource for local children who were not attending school. In cooperation with local secondary schools, the Zone Project has developed a rolling programme of issue-based work for local young people, many of whom struggle to attend, or are excluded from, full-time education. The project has an emphasis on arts-based activities and an open-access sexual health facility, provided in partnership with Nottingham Community NHS Health Trust. This attracts a core group of young people as well as a more transient group who are involved on the fringes of the project.

In 2001, in response to requests for help with smoking cessation from young smokers attending the Zone project, we carried out a questionnaire survey of smoking prevalence and smoking cessation service delivery preference in all young people who accessed the Zone project in the month of October. We also used the questionnaire responses to identify young people interested in participating in the trial. We then carried out qualitative work, comprising informal discussion groups, one-to-one interviews and brainstorming activities during group sessions, with young people and youth workers to determine optimum methods of service delivery. We established support services at the Zone based on the results of the process and publicised these and our intention to carry out a trial of NRT using flyers, posters and other novel methods including street outreach, schools outreach and

Table 1 Inclusion and exclusion criteria for trial of nicotine replacement therapy

Inclusion criteria	Exclusion criteria
Aged 14–20 years and able to consent	Age <12 or >20 years
Aged 12–14 and parental consent obtained	Aged 12–14, or aged 14 or over but not competent to consent, and parents unable or unwilling to give consent
Regular smoker: >1 cigarette per day (cpd) OR <1 cpd but past or anticipated withdrawal	Self-reported non-smoker
Carbon monoxide validation >5 ppm	Allergic to sticking plaster
No medical contraindications	Pregnant or risk of pregnancy

Theatre in Education workshops. Recruitment and follow up took place between March and December 2002 at an after school drop-in café run by the Zone youth project. We aimed to recruit all attendees who were daily smokers; inclusion and exclusion criteria are shown in table 1.

All consenting study participants were offered regular behavioural counselling and were randomised using computer generated randomisation codes in batches of 10 to either active or placebo nicotine patches. Participants were reviewed weekly by the study doctor for side effect monitoring; patch dispensing and counselling was delivered weekly on a one-to-one basis or in small friendship groups by a Zone project youth worker trained in smoking cessation, or a smoking cessation counsellor from the adult smoking cessation service, in 10–15 minute sessions which were offered at flexible times to suit the young people involved. It was felt that 15 minutes was the optimum length for sessions because of concentration span, although this is less time than offered to adults receiving intensive counselling. A behavioural counselling model was used[18] and then refined to incorporate some motivational interviewing techniques.[19] NRT was custom made (Stowic Resources Ltd, Oxford, UK) to ensure identical active and placebo patches, the active dose schedule being 15 mg/10 mg/5 mg for two weeks each for a maximum of six weeks. Other forms of NRT were not offered because of the lack of identical placebos available. The researchers delivering NRT and counselling were blind to the allocation of subjects. The study code was broken for each individual at three months, and up to six weeks of NRT offered to all continuing smokers who received placebo. Primary outcome measures were carbon monoxide validated quit rates at four and 13 weeks; secondary outcomes included reported adverse effects and follow up rates.

Qualitative assessments of the acceptability of the intervention were conducted by the study doctor and counsellor in one-to-one and friendship group settings using a variety of techniques including flip chart listing and pile-sorting exercises. In October 2002, we repeated the initial questionnaire survey to assess any change in smoking prevalence, knowledge of smoking and quitting, and awareness of the intervention among all the young people attending the project, some but not all of whom had been surveyed in the initial questionnaire. The original power calculation for the NRT trial was based on recruiting 550 of the 1080 presumed young smokers in contact with the youth project in to the trial, providing 90% power to detect an increase from 15% cessation rates in the placebo group to 22% in the active group. These estimates proved to be unrealistic because of difficulties in recruitment and retention of study participants.

RESULTS

Initial questionnaire survey

In October 2001, we obtained valid questionnaires from 264 participants, recruited opportunistically from all available Zone project attendees. Very few attendees declined to participate, and 198 (75%) of respondents consented to exhaled carbon monoxide (CO) measurement. The median age (range) of respondents was 14.0 (11–21) years, 111 (42%) were male, and 129 (49%) were self-reported current, regular smokers. Among the smokers the median CO reading was 8 ppm (1–32), median Fagerstrom score 3.0 (0–7), and the median number of cigarettes smoked per day was 10. Most smokers (248; 94%) came from households with at least one smoking adult; 84 (65%) of smokers reported that they would like to quit smoking and 110 (85%) had made previous unsuccessful attempts, giving up for an average of two weeks. A total of 108 (84%) said that they would like the chance to use some kind of NRT, with a preference for gum among the girls and cutaneous patches among boys. Family support and willpower rated highest among non-pharmacological aids perceived to be helpful, with one-to-one support from a counsellor also scoring highly. Young people indicated in questionnaire responses and subsequent discussion groups that they would prefer cessation support to be regular but with flexible timings, held in a community setting and offering counselling in one-to-one or small friendship groups.

Trial of NRT

A total of 145 young people volunteered for screening for the NRT trial and 98 proved eligible and were randomised to receive active or placebo patch. Inclusion criteria are shown in table 1. There were no statistically significant differences in baseline characteristics between subjects randomised to active or placebo patches. Most attended as a result of word-of-mouth publicity rather than direct advertisement of the trial. All participants received behavioural counselling. The median number of weeks of patch therapy with counselling in those who attended following baseline was one week, and eight young people (three active *v* five placebo) completed the full six weeks of patch treatment. Most young people who dropped out did so within the first two weeks of the study, and over half of those who dropped out did so by not attending follow up after initial screening and recruitment. Of the 90 who did not complete patch therapy, two withdrew because of adverse effects, two because they had quit smoking, one because of a perception that the patches were ineffective, and 22 because they changed their mind about quitting. The remaining 63 did not attend further follow up, so were presumed to be still smoking. At four weeks, five subjects using active NRT and two subjects using placebo achieved point abstinence (table 2). These subjects were similar in age and addiction measures to those who were not abstinent, but were more likely to be girls, to have been initially ''very interested'' in quitting, and to have strong parental and peer support to quit. At 13 weeks, no smokers were abstinent. The nicotine patches were associated with itching but there were few other adverse events (table 2).

Acceptability of intervention: qualitative assessments

A core group of young people, already involved with the work of the youth project, attended all counselling sessions and gave positive feedback. Other young people who were more peripheral within the host project and who were recruited opportunistically were more difficult to follow up.

Young people liked the fact that they could attend autonomously without parental involvement, could talk with a doctor in their own environment, and felt valued because someone was concerned about their health and because of the chance to use ''adult'' therapy, although many would

Table 2 Results of randomised controlled trial of nicotine versus placebo patches

	Randomised to active treatment	Randomised to placebo treatment
Total numbers	49	49
Mean age in years	14.9	14.7
Percentage female	64	56
Median exhaled CO (ppm)	12.9	11.8
CO validated point abstinence at 4 weeks	5	4
CO validated point abstinence at 13 weeks	0	0
Completed full six week treatment course	3	5
Withdrew because of adverse event	1	1
Other non-severe adverse events*		
Itching	16	7
Rash	6	3
Pain or paraesthesia at patch site	6	4
Dizziness, nausea or headache	2	3

*Some participants experienced more than one adverse effect.
CO, carbon monoxide.

have liked the chance to use other forms of NRT. Young people preferred to talk to a youth worker trained in smoking cessation counselling than an adult smoking cessation counsellor. Many young people did not realise how hard it would be for them to quit and felt that it was unfair that half of the study participants were given a ''fake'' patch.

Youth project staff found the intervention acceptable and easy to publicise, and felt that it had increased their confidence in raising smoking with young people and had encouraged several of them to think about their own smoking behaviour, and to quit smoking. We did not approach parents directly for their views, but those who we encountered gave positive feedback and several attended the sessions in the hope of obtaining advice and NRT for themselves.

Follow up questionnaire

Similar numbers of questionnaires were returned in the October 2002 survey (264 *v* 246) and there was similar gender distribution, age (mean age 13.7 *v* 13.8 years) and mean CO (5.46 *v* 5.3 ppm). Of those replying to the second survey, 64% were aware of the smoking cessation project. There were small but not significant differences in overall smoking prevalence (49% *v* 44%) and plans for future quit attempts (42% *v* 52%) regardless of whether individuals had accessed the service.

DISCUSSION

This study was intended to assess the effectiveness of NRT in young, disadvantaged smokers delivered in conjunction with a customised cessation service designed in accordance with their preferences. However, despite providing a service tailored to the views of young people involved, the service had low uptake and high dropout rates. Even though recruitment to the study was lower than anticipated and only small numbers were involved, there was little evidence that NRT might be effective. The only potential positive outcomes of the study were that NRT seemed safe in this group, and overall prevalence of smoking in the targeted community of young people decreased and stated intention to quit smoking increased over the course of the study period, suggesting that background increased awareness of smoking as a health issue arising from the conduct of the study may have had a positive impact.

This is the first published randomised controlled trial of NRT in young people in the UK and the first in this socioeconomic group. It is also the first published study to have used a smoking cessation intervention designed according to the views of young people for whom the service was intended. Recruitment to the study was low for a number of reasons: an overestimate on our part of the initial smoking prevalence in this population, unwillingness of young people to participate in a trial where half of participants would get ''nothing'' (placebo), difficulty gaining face-to-face consent from parents of 12–14 year olds, and problems with non-attendance after a visit for initial screening. Dropout rates were high partly because of the general characteristics of the young people taking part in the study, but also because of difficulty in maintaining enthusiasm in those who felt that they had placebo patches. Initial interest was high but when a quit attempt failed young people were not keen to come back and admit failure. Many were surprised at how difficult they found it to abstain from cigarettes.

What this paper adds

Young smokers want to quit smoking and are keen to be able to use NRT. Even with tailored, community based interventions, adherence to patch therapy is low. Although patch therapy was safe, it was not shown to be effective. Proving the efficacy of smoking cessation interventions in young people who need them most is difficult.

The low quit rates we achieved can be partly explained by fluctuating motivation to quit in this group of young people, low compliance with patch therapy, the strong influence of peer and family smoking in this socioeconomic group, and the easy availability to young people of cheap, smuggled cigarettes.

Compared with previous studies in the United States[15–17] showing small but non-significant effects of NRT on increasing quit rates in young smokers, our subjects were younger, lighter smokers, with lower CO levels and addiction measures, meaning that other influences may be more important than nicotine addiction in continued smoking in this group of young people. Because of the placebo nature of the trial, we were not able to offer young people a choice of nicotine preparations, and short-acting preparations such as gum and inhalator may have fitted in well with patterns of smoking in this group. In contrast to other studies, parental involvement in the study was minimal, we did not offer any form of financial incentive, and the project was entirely community based. There were fewer adverse effects of NRT when compared with previous studies.

In the event, our study was too small to detect an effect of NRT on smoking cessation rates with appropriate power, though if cessation had been as high as achievable in best practice in adult smokers, we would have expected nine in active and five in placebo to quit at one month. The fact that only seven in total achieved this suggests that NRT and counselling may be much less effective in younger age groups. This may be because the young people we studied were less addicted but had more social pressure to smoke, which was not specifically addressed by this study. Young people in this group may have found it more difficult than adult smokers to stay motivated to quit smoking, and there may be many other factors which we have not been able to explore in this study.

The outcome of this and other studies indicates, however, that the routine use of NRT in the form of patches for underage smokers in this demographic is probably not effective. Ideally, this issue needs to be addressed in larger trials but our experience suggests that these will be difficult to carry out, particularly against placebo, because of recruitment and retention problems inherent in working with

disadvantaged young people. We may therefore never know whether NRT is effective in young people, but this study suggests not. In the absence of conclusive evidence, a pragmatic approach offering a variety of nicotine replacement preparations to young people who smoke more heavily could be considered.

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The Lighter Side