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Short communication

Long-term efficacy of nicotine replacement therapy for smoking cessation in adolescents: A randomized controlled trial

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ABSTRACT

Background: A double-blind RCT on the short-term efficacy of nicotine patches compared to placebo patches among Dutch adolescents was conducted. The findings demonstrated that nicotine patches are efficacious for smoking cessation at end-of-treatment; however, only in highly compliant participants. We tested whether the effects of NRT also held in 6- (T7) and 12-month (T8) follow-up assessments.
Methods: Adolescents aged 12–18 years, who smoked at least seven cigarettes a day and who were motivated to quit smoking were recruited at school yards and randomly assigned to either a nicotine patch ($n = 182$) or a placebo patch ($n = 180$) condition according to a computer generated list. Participants ($N = 257$, age: 16.7 ± 1.13 years) attended an information meeting followed by a 6- or 9-week treatment. Smoking cessation, compliance, and potential covariates were measured by means of online questionnaires. Smoking cessation at T8 was biochemically validated by saliva cotinine.
Results: At T7, 8.1% and 5.7% of participants were abstinent in the nicotine and placebo patch groups, respectively. At T8, abstinence was 4.4% and 6.6%, respectively. Intention-to-treat analyses showed no significant effects of NRT on abstinence rates at T7 (OR = 1.54, 95% CI = 0.57, 4.16) and validated abstinence rates at T8 (OR = 0.64, 95% CI = 0.21, 1.93) neither after considering compliance nor after adjusting for covariates.
Conclusions: NRT fails in helping adolescents quit smoking at 6- and 12-month follow-ups. This finding suggests that a more intensive approach is needed to assist youngsters in their quit attempts.
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1. Introduction

Considering the negative health consequences (NHS, 1998), the high prevalence of adolescent smoking (11% daily smokers aged 11–19; STIVORO, 2012), and the low success rates of (self-aided) quitting among adolescent smokers (12.2%; Centers for Disease Control and Preventions [CDC], 2009), a strong need exists for evidence-based intervention programs to help young people quit smoking. Because research has found that nicotine dependence is an important factor that hampers smoking cessation among youngsters (e.g., Kleinjan et al., 2009; Prokhorov et al., 2001), nicotine replacement therapy (NRT) may help. Nicotine replacement therapy acts mainly by reducing withdrawal symptoms in regular smokers who quit (Molyneux et al., 2006).

While NRT has been shown to facilitate smoking cessation in adults (Lemmens et al., 2008; Stead et al., 2012; Willemsen et al., 2003), evidence for the efficacy of NRT among adolescents is not as straightforward. Recently a meta-analysis (Kim et al., 2011) and a review (Bailey et al., 2012) focused on the effectiveness of pharmacotherapy (NRT + bupropion) in adolescents. These studies showed some evidence for short-term efficacy (≤12 weeks; Bailey et al., 2012); however, no mid-term (26 weeks) efficacy was found (Kim et al., 2011).

Recently, the short-term efficacy of nicotine patches, compared to placebo patches, was tested among Dutch adolescents (Scherphof et al., 2014). The results indicated that nicotine patches were efficacious in predicting abstinence 2 weeks after participants' quit dates. At end-of-treatment (after 6 or 9 weeks), nicotine patches increased abstinence rates significantly, but only in high-compliant, compared to low-compliant, participants (22.4% versus 7.4%, respectively). The percentages of quitters in the placebo patch group were quite similar among high- and low-compliant participants (14.5% and 11.7% respectively). The current study was

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conducted as a continuation of the study by Scherphof et al. (2014) on the short-term efficacy of NRT and the same sample was used. We examined whether NRT enhances adolescents' mid-term (6-month follow-up) and long-term (12-month follow-up) quit rates, thereby including the possible moderating role of compliance.

2. Methods

2.1. Procedure

The recruitment of participants was conducted by visiting schools. Individuals interested in participating were required to fill out an online screening questionnaire to define eligibility (12–18 years old, not having major physical health problems, smoking ≥7 cigarettes per day, parent awareness of smoking behaviors, and motivated to quit smoking). Excluded from participation were those (1) who were using nicotine replacement therapy or other smoking cessation medication at the time of participant recruiting, (2) who were pregnant or lactating, and (3) who reported being allergic to patches in general or any ingredients in the patches. Both participants and parents (if participants were 17 years or younger) were required to sign informed consent. Participants began the intervention with a 75-min information meeting that consisted of a pre-treatment questionnaire (T0), information about the study, a short behavioral intervention aimed at quitting smoking (e.g., preparations and expectations), and instructions on using NRT that emphasized the relevance of using the patch during the whole treatment period as described.

The treatment period with the patches started the Monday after the meeting (Day 1), and participants were asked to quit smoking from that day on. The duration of treatment with nicotine (or placebo) patches was 6 or 9 weeks, depending on the number of cigarettes participants smoked at T0. Participants were asked to fill out eight online questionnaires; six were administered during treatment and the other two were administered 6 months (T7) and 12 months (T8) after the start of treatment.

To assess the validity of smoking cessation, participants who self-reported being abstinent at T8 were contacted for biochemical analyses. Research assistants visited participants at their homes to collect salivary samples for a cotinine assay. Study participants were compensated a maximum of €90 for participating in all study phases. This study is registered at TrialRegister.nl (NTR3031), and was approved in September 2010 by the Medical Ethical Committee of the Utrecht Medical Center. For a detailed description of the procedures, we refer to our short-term efficacy article (Scherphof et al., 2014).

2.2. Measures

At T7, the 30-day point prevalence abstinence rate was measured using two items. Participants were asked to report which of the following statements suited them best: "In the period between the previous questionnaire until now (1) I have not smoked at all; (2) I have smoked, but now I quit; (3) I quit for a while, but now I smoke again; or (4) I have smoked the whole period." Respondents who answered (1) or (2) were presented with the following question: "How long ago did you smoke your last cigarette?" Participants who answered "4 weeks ago or longer" to the latter question were considered to be abstinent.

At T8, the same self-report measure was used and included biochemical verification of smoking cessation using the NicAlert saliva strip (Nymox). The NicAlert test yields a semi-quantitative measure of cotinine based on a colorimetric immunoassay reaction. The test strip displays seven zones that represent saliva cotinine levels ranging from 0 (0–10 ng/ml) to 6 (>1000 ng/ml). Results were recorded as values from 0 to 6; the cutoff for smoker versus nonsmoker was 1; however, a level of 1 could also indicate passive exposure to tobacco. Preceding the cotinine test, participants filled out a short paper questionnaire that examined smoking behaviors in the period between T8 and the cotinine test.

Thus, at T7 and T8, self-reported smoking cessation was measured using a 30-day point prevalence abstinence based on the answers given in the questionnaire. At T8, we used the additional criterion of a self-reported 30-day point prevalence abstinence validated by a cotinine level ≤1 to determine smoking cessation.

Compliance was measured with the first six online questionnaires. Respondents were asked how many days since the previous online questionnaire they had used the patches. The total number of days a participant used the patches was calculated by summing the answers from T1 to T6. Therefore, the compliance score for all participants ranged from 0 to 42 days.

2.3. Data analyses

Data were analyzed (SPSS version 20) in accordance with the intention-to-treat principle and with the completers-only framework. Missing data on all other variables were handled by the Expectation–Maximization algorithm (Schafer, 1999). Logistic regression analyses were used to explore the effect of NRT (1) versus placebo (0) on smoking cessation (0 = abstinence after 6 or 12 months; 1 = smoking). We followed the same procedure as in our previous article (Scherphof et al., 2014). In the first step, the sole effect of NRT was examined; the interaction between treatment condition and compliance was added in the second step. Both steps were tested in two models, one in which we adjusted for gender (Model 1) as this variable was associated with treatment group assignment, and one in which we adjusted for other variables that that were correlated significantly with the outcome measure of smoking cessation (Model 2).

3. Results

3.1. Loss to follow-up

The final sample consisted of 257 participants (for a flow diagram and participant characteristics we refer to our previous study: Scherphof et al., 2014). Participants who did not complete the seventh ($n = 19$, 7.4%) or eighth ($n = 26$, 10.1%) online questionnaire were slightly younger when they started smoking on a daily basis (T8: $t = -1.98$, $p = .049$) and more likely to have a lower educational level (T7: $\chi^2_{(1)} = 4.72$, $p = .049$; T8: $\chi^2_{(1)} = 10.55$, $p = .002$). No significant differences were found for treatment condition, gender, age, self-efficacy to quit smoking, motivation, alcohol consumption, or drug use as assessed at baseline.

3.2. Smoking cessation

In total, 18 adolescents self-reported to be abstinent at T7 and 21 at T8. The biochemically validated smoking cessation rate at T8 resulted in 14 abstinent adolescents (see Table 1). Reasons for these differences were (1) participants resumed smoking between the online questionnaire and the cotinine measurement ($n = 5$), (2) participants could not be contacted for the cotinine test ($n = 1$), and (3) the cotinine test was not valid ($n = 1$). Point prevalence validated abstinence results were discordant between outcome time points; only seven adolescents were abstinent after 6 and 12 months.

Table 2 showed no significant effects for both the main effect of NRT and the interaction between NRT and compliance regardless of the inclusion of covariates.

The analyses using self-reported abstinence yielded similar results except for the significant effect of alcohol consumption in Step 1 of Model 2 (see Supplementary Table S1). Additionally, the intention-to-treat analyses and completers-only analyses showed similar results for both self-reported abstinence and validated abstinence measures (statistics available upon request from the corresponding author).

Table 1
30-day point prevalence abstinence rates after 6 and 12 months.

	No./total no. (%) of subjects abstinent			
	Self-report		Validated self-report[a]	
	Nicotine patch	*Placebo patch*	*Nicotine patch*	*Placebo patch*
6 Months	11/135 (8.1)	7/122 (5.7)	–	–
12 Months	11/135 (8.1)	10/122 (8.2)	6/135 (4.4)	8/122 (6.6)

Note: Numbers are based on intent-to-treat analyses.
[a] Biochemically verified in participants who self-reported to be abstinent at T8, using the NicAlert saliva strip.

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