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# Long-term effects of a home-based smoking prevention program on smoking initiation: A cluster randomized controlled trial ☆

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ABSTRACT

*Objective.* The aims of the study were to evaluate the long-term effects of a home-based smoking prevention program 'Smoke-free Kids' during preadolescence on smoking initiation during adolescence and to test the potential moderating role of parental smoking, socioeconomic status, and asthma.

*Method.* In 2008, 1478 9–11 year old children and their mothers were recruited from 418 elementary schools in the Netherlands. An independent statistician randomly allocated schools to one of the two conditions using a 1:1 ratio (single blind): 728 children in the intervention and 750 in the control condition. The intervention condition received five activity modules, including a communication sheet for mothers, by mail at four-week intervals and one booster module one year after baseline. The control condition received a fact-based intervention only. Intention-to-treat analysis was performed on 1398 non-smoking children at baseline.

*Results.* In the intervention 10.8% of the children started smoking compared to 12% in the control condition. This difference was non-significant (odds ratio = 0.90, 95% confidence interval = 0.63–1.27). No moderating effects were found.

*Conclusion.* No effects on smoking initiation after 36 months were found. Perhaps, the program was implemented with children that were too young. Programs closer to the age of smoking onset should be tested.


## Introduction

Smoking is the leading cause of preventable death, killing more than six million people each year (WHO, 2012). A major increase in smoking rates can be observed during adolescence. Therefore, preventing tobacco use among children is important, particularly because delaying the age of the first puff decreases risk of developing long, enduring smoking patterns (Chassin et al., 2000).

Most smoking prevention programs take place at school. The majority of these programs show positive short-term effects while evidence on the long-term effects is not yet convincing (Flay, 2009; Thomas and Perera, 2006). A possible explanation is that most programs take place during secondary school years. Previous research showed that particularly children who are transitioning from primary to secondary school (in the Netherlands children at age 12) are vulnerable to factors leading to smoking (Côté et al., 2004). Therefore, it is important to intervene with children before they form attitudes and beliefs about smoking and before they have to deal with smoking-related situations with peers.

Another explanation could be that school programs generally disregard the role of parents (Glyn, 1989). Involving parents in smoking prevention may be crucial, as parents can affect their children's risk of smoking through parenting practices specifically aimed at smoking (Chassin et al., 2005; Cohen et al., 1994). Parental anti-smoking socialization consists of discussing smoking-related topics, setting rules not to smoke at home, establishing a non-smoking agreement, limiting the availability of cigarettes at home, and providing appropriate reactions regarding their child's smoking (Engels and Willemsen, 2004).

The 'Smoke-free Kids' program developed in the U.S. is a successful smoking prevention program targeting parenting practices (Jackson and Dickinson, 2003, 2006). This home-based smoking intervention program for parents and elementary school-aged children deals with anti-smoking socialization strategies to assist parents in preventing their children from smoking (Jackson and Dickinson, 2003). After 36 months, 12% of children in the intervention condition tried smoking compared to 19% in the control condition (OR = 2.16, 95% CI = 1.39–3.37) (Jackson and Dickinson, 2006). In a later trial for children of non-smoking parents, no program effects were found (Jackson and Dickinson, 2011).

☆ Clinical Trial Registration: Dutch Trial Register NTR1465.

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It is important to replicate the U.S. trial (Jackson and Dickinson, 2003, 2006, 2011) in other Western countries before implementing the Smoke-free Kids intervention program. The aim of the present study was to evaluate the long-term effectiveness of the Smoke-free Kids program (i.e., 36 months) on smoking initiation of adolescents using a cluster randomized controlled trial. We also tested whether the program effects would differ by parental smoking and socio-economic status (SES) as well as for children with asthmatic symptoms. Previous research showed that children of smoking parents are more likely to start smoking compared to children of non-smoking parents (Gilman et al., 2009; Leonardi-Bee et al., 2011). Children from low SES families are more likely to start smoking compared to children from higher SES (Hanson and Chen, 2007), and children with asthmatic symptoms are more likely to start smoking compared to their non-asthmatic peers (Mcleish and Zvolensky, 2010).

## Methods

### *Procedure and participants*

Families were recruited predominantly via primary schools in the Netherlands (i.e., via active informed consent). Specifically, a total of 1347 school boards were requested to distribute letters to parents via their children. In total 630 school boards were willing to provide letters to the children in order to pass them to their parents. Parents could decide to participate by providing contact information by mail or register online via a secured webpage.

Participants had to meet the following inclusion criteria: children had to be 9 to 11 years old, adults had to be mothers or female guardians, both mother and child had to be able to read and speak Dutch, and only one child per household was eligible to participate. For a sub-aim, approximately 200 children with asthmatic symptoms were recruited. Therefore several strategies were used (i.e., media) and health professionals (i.e., general practitioners) were contacted (see Hiemstra et al., 2009). Eventually, a total of 1478 mothers and children were eligible, including the subsample of children with asthmatic symptoms.

Data were collected using telephone interviews (60.2%) or questionnaires (39.8%) at all waves. Trained Master students administered the telephone interviews with mother and child. Prior to the interview, mothers and children were assured privacy and confidentiality. Questionnaires were sent to mothers and children by mail and returned in enclosed envelopes. The baseline assessment of mother and child was conducted between December 2008 and June 2009. From February 2008 to September 2009, the intervention was mailed to participants in both conditions at four-week intervals. The follow-up measures with children were conducted at 6, 12, 24, and 36 months after baseline via telephone or mail. The 36 month assessment was conducted between December 2011 and June 2012. Each family received €10 for completing all measurements. In addition, five travelers' checks of €1000 were raffled among these families. This study was approved by the ethics committee of the Faculty of Social Sciences at the Radboud University Nijmegen. The trial is registered at the Dutch Trial Register: NTR1465.

### *Sample size*

A power calculation indicated that 428 children were needed per condition to detect a 10% absolute difference between the control and intervention conditions in increase of smoking initiation among 12 to 14 year old adolescents (i.e., 36-month follow-up) using a two-tailed test with $\alpha = 0.05$ and power $(1\text{-}\beta) = 0.80$. We accounted for data clustering and imputations in case of missing data. Therefore, a minimum of 856 children and mothers were needed to detect significant differences in smoking initiation.

### *Randomization and masking*

An independent statistician randomly allocated schools to the intervention or control condition (allocation ratio (1:1)). SPSS was used to generate the allocation sequence. To avoid contamination between the two conditions, all children from one school were allocated to the same condition. Based on the baseline assessment, children were stratified by the number of asthmatic children. Participants were blind to randomization (i.e., single-blind trial).

### *Intervention program*

The intervention program is based on the U.S. version of Smoke-free Kids (Jackson and Dickinson, 2003, 2006). The Smoke-free Kids program concentrates on stimulating antismoking socialization within families in order to prevent children from smoking. All the materials were translated into Dutch and adapted to the Dutch situation. More specifically, some of the assignments were not suitable for the Dutch intervention because they were too culturally specific or they concerned issues that had changed since the U.S. program started (i.e., tobacco advertising). In addition, the layout of the modules was modernized and adapted (i.e., cartoons).

Families received five printed activity modules by mail at four-week intervals. Each module dealt with different socialization constructs 1) general communication about smoking; 2) influence of smoking messages; 3) rule setting and a non-smoking agreement; 4) creating a smoke-free house and -environment related to secondhand smoking; and 5) the influence of peers. Each module included different assignments, such as games and scripted role-plays, to gradually increase parental skills and comfort in communicating with children about smoking, addictions and expectations regarding abstinence. Each of the five activity modules also included a communication sheet for mothers, providing background information about the subjects discussed in the modules and communication tips for mothers. Finally, a booster module was delivered 12-months post-baseline (for more details: Hiemstra et al., 2009).

The control condition received a fact-based program. This alternative program was provided in order to minimize drop-out and to be able to follow families over time. The program was intended to function as 'care as usual'. The factsheets provided information on youth smoking and directed parents' attention towards macro-level variables relevant to youth smoking, but that were not targeted by the intervention version. The information in the factsheets was also available in local, state, or national media. The mothers received the program along with the intervention condition but did not receive a booster.

### *Outcome measures*

*Smoking initiation* of children was assessed at each wave using a well-established measure (Kremers et al., 2001). Children were asked to report, on a nine-point scale, which stage of smoking applied to them. Response categories ranged from 1 = *I have never smoked, not even one puff* to 9 = *I smoke at least once a day*. This was recoded to 0 = never smoker and 1 = smoker (i.e., any experience with lifetime smoking) (Harakeh et al., 2005). If children reported irregular smoking behavior over time and tried smoking at one of the different time points, we indicated them as smoker. The percentage of children with irregular smoking responses was 0% at 6 months, 0.4% at 12 months, 1.2% at 24 months, and 2.3% at 36 months.

*Parental smoking* was assessed on an eight-point scale ranging from 1 = *never smoked, not even a puff* to 8 = *I smoked at least once a day* by asking mothers about their and their partners' smoking at baseline (Harakeh et al., 2005). Based on their lifetime smoking status, both parents were classified to three groups, never, former, and current smoker. Six levels were constructed by combining responses of both parents.

*SES* was measured using the educational level of the parents at baseline. Educational level was assessed on a 9-point scale ranging from 1 = *primary school* to 9 = *university*. Parents were allocated to lower, middle, or higher education. The educational level of parents was combined to 0 = both parents follow lower education or one lower and one middle education; 1 = both parents followed middle education or one followed lower and one followed higher education; 2 = both parents followed higher education or one followed middle and one followed higher education (Ringlever et al., 2011).

*Asthma*. Children were categorized as having asthma if mothers responded 'yes' to the two following questions at baseline: '*Does your child ever have had asthma?*' and '*Did a physician confirm that your child has asthma*' (Ringlever et al., 2011).

### *Statistical analysis*

To examine whether randomization was successful the differences between the intervention and control conditions in covariates (i.e., gender, age, ethnicity child and mother, smoking behavior parents, SES, and asthma) and smoking initiation were examined using logistic regression analyses.

Program effects were analyzed (SPSS version 19) according to the intention-to-treat principle ($n = 1398$) and the completers-only framework ($n = 1238$). For the intention-to-treat analysis, missing data were handled using multiple