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Reducing tobacco smoke exposure in children aged below 4 years — A randomized controlled trial

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ABSTRACT

Objective: To explore the reach of a German population-based household sample using proactive recruitment and to test the efficacy of a behavioral change counseling intervention including feedback about children's urine cotinine level (CUCL).

Methods: A randomized controlled trial (2008–2010) was conducted in households with at least one child aged below 4 years and at least one current smoker. The study area comprised of 3570 households. A screening assessment was provided in 2641 households; 1282 included one current smoker and 852 completed the study protocol. The intervention group (IG; n = 428) received feedback about CUCL and up to two counseling sessions. The control group (CG; n = 424) received a leaflet. Assessments were provided at baseline and 12-month follow-up. Heckman's selection model analysis was used to consider the detection limit of cotinine in urine (10 ng/ml).

Results: CUCL below the detection limit in the IG was found in 43.2% at baseline and 44.6% at follow-up and in 44.8% of the CG at baseline and 47.2% at follow-up. The CUCL difference between follow-up and baseline was smaller in the CG than in the IG. The effect was not significant.

Conclusions: Data revealed a high reach of the target population but failed to identify an intervention effect. Clinical Trial Registration www.clinicaltrials.gov (NCT00647413).

Introduction

The adverse effects of environmental tobacco smoke (ETS) on children's health are well investigated (Boldo et al., 2010; Gehring et al., 2006; Hofhuis et al., 2003; Moshammer et al., 2006). To address the effects of ETS on children, the majority of studies have addressed families in health care settings (Baxi et al., 2014). However, this type of study may be insufficient to reach the majority of the target population of families, especially those from socioeconomically disadvantaged groups (Hovell et al., 2000).

Because interventions that prove efficacious in randomized controlled trials are much less effective in general population samples, progress in public health has been hampered by a lack of approaches that address whole populations (Glasgow et al., 1999). According to the RE-AIM model, five dimensions (reach, efficacy, adoption, implementation, maintenance) must be assessed to evaluate the public health impact of an intervention. The dimensions reach and efficacy will be addressed in this paper. Reach refers to the recruitment of a proportion of participants in an intervention among the population of eligible individuals (Glasgow et al., 1999). The reach of socioeconomically disadvantaged populations for interventions has been found to be more likely outside of health care settings and when proactive recruitment within the community setting is used (Harkins et al., 2010; Heinrichs et al., 2005). Given that the home environment has been found to be the primary source of ETS, there may be advantages to the recruitment and delivery of an intervention at the location where children are exposed (Öberga et al., 2010).

Evidence has not shown which interventions are most effective in reducing ETS exposure in childhood (Baxi et al., 2014). One promising aspect of behavioral change strategies to reduce children's ETS exposure is the provision of feedback based on child's urine cotinine level (CUCL) (Chilmonczyk et al., 1992; McIntosh et al., 1994; Wakefield et al., 2002; Wilson et al., 2001).

The two aims of this paper are 1) to explore the reach of households with children below the age of 4 years using proactive recruitment at

Abbreviations: CCR, cotinine–creatinine-ratio; CG, control group; CUCL, children's urine cotinine level; ETS, environmental tobacco smoke; HSBL, home smoking ban level; IG, intervention group.

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their homes and to 2) describe the efficacy of a brief intervention to reduce ETS exposure using CUCL feedback on ETS absorption in child and behavioral change counseling.

Methods

Study design

A randomized controlled trial was performed with two arms, an intervention group (IG) and a control group (CG). The follow-up was conducted 12 months after the baseline assessment. Data were collected between June 2008 and December 2010 in the German Federal State of Mecklenburg–West Pomerania.

Inclusion and exclusion criteria

The inclusion criteria were children below the age of 4 years and at least one parent, who was a current daily smoker, living in the household. Addresses for children in a defined region were provided by the residents' registration files (as of January 5, 2008). Each household found eligible for screening was assessed to determine whether at least one parent living in the household reported being a current daily smoker. Current daily smoking was defined as having smoked at least one cigarette per day in the four weeks prior to the screening assessment. The following households were defined as ineligible for study participation, those households that were intellectually handicapped and those in which the youngest child permanently resided outside the parents' home (e.g., the infant lived in an institution). Households were excluded if they did not plan to reside in the study area for the next 12 months.

Group assignment

Prior to the start of the study, all of the selected households ($n = 3750$) were randomly assigned to the IG or CG. This procedure was used prior to the concurrent provision of baseline assessments by study team members in the study region.

Sample size

We determined the sample size using a power of .80 and an intervention effect of 10% resulting in a number of 472 households per group in order to secure a statistical difference using a two-sided chi-square test ($\alpha = 0.01$). Adjusting for 25% potential losses to follow-up, the study estimated the sample size to be equal to 1260.

Data collection

Data were collected by two trained study teams: a screening team and an intervention team. The screening team contacted the household, conducted the screening assessment to check for eligibility, provided information about the study, and requested participation. The parent (index parent) who participated in the screening assessment provided the information on behalf of the household. This was the mother in 82.2% ($n = 392$) of the IG and 85.9% ($n = 378$) of the CG. The staff members on this team were blind to the group assignment. Households that agreed to participate in the study were referred to the intervention team.

The staff members on this team conducted one visit per household in both study groups. During the visit, written informed consent was obtained, and baseline data and the first urine sample of the youngest child (index child) were collected. The intervention team was not blind to the group assignment.

The 12-month follow-up data were collected by team members from both study teams via phone call. Assessors were not blind to the group assignment. The second urine sample of the index child at household's homes was collected by team members from both teams.

Incentives

Participating households received 5 Euro for completing the baseline assessment. Participation in a lottery with the possibility to win 25 Euro was offered to all participants who completed the follow-up assessment.

Recruitment and retention

The study area comprised of 3570 households including one child aged below 4 years. All households were invited by letter to participate in a screening assessment. A personal visit by a screening team member was announced within 2–3 weeks following receipt of the letter. Invited households were encouraged to use a free phone number to participate in the screening assessment or to receive more information about the study by phone. Contact ($n = 3293$) was defined as successful if at least one parent (mother, father, or partner) living in the household responded personally or by phone. Screening assessment was provided in 2641 households (80.2%). Of these, 48.5% were current daily smoker households. Thus, a total of 1282 households were eligible. Among these households, 917 (71.5%) consented to participate (Kastirke et al., 2013). At baseline, the laboratory analyses failed in 2 cases due to

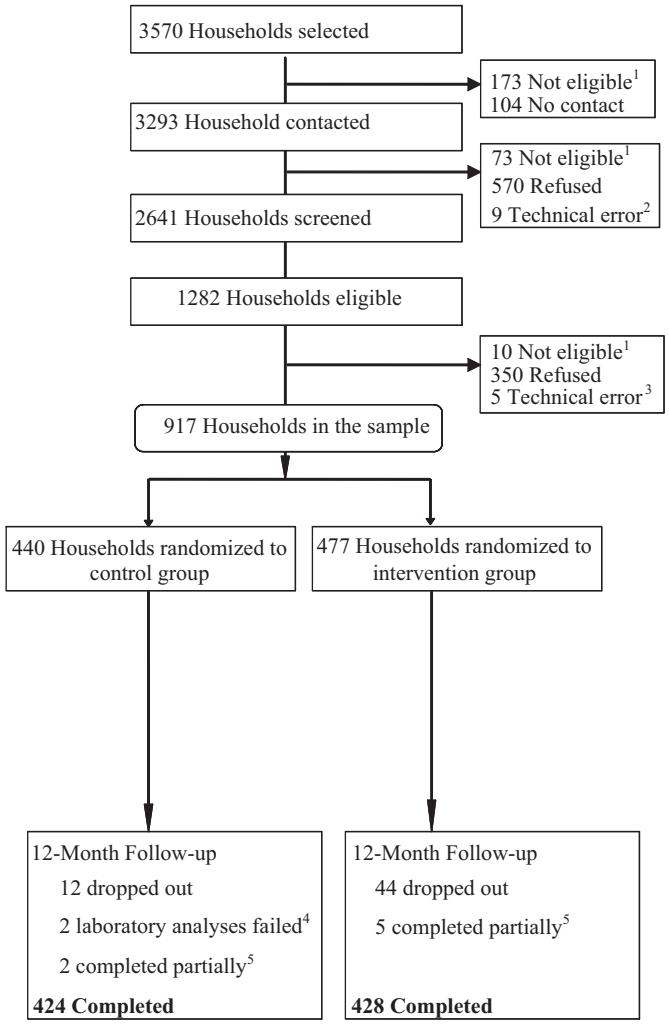

Fig. 1. Flow chart of participants in the home intervention trial, Germany, 2008–2010. [1]Ineligibility (insufficient German language, intellectually handicapped, permanent placement of the children outside the parent's home, fixed planned move to outside the study area during the study period). [2]Missing document of having been asked for screening. [3]Missing document of having been asked for study participation. [4]Repeated collection of urine samples but insufficient material. [5]Follow-up assessment or urine sample provided.