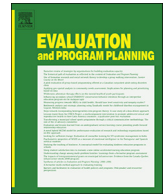




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Implementation fidelity and adolescent smoking: The X:IT study—A school randomized smoking prevention trial

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ABSTRACT

Background: Assessing the actual implementation of multi-component interventions can provide important knowledge for future interventions. Intervention components may be implemented differently, knowledge about this can provide an understanding of which components are essential and therefore must be included. The aim of this study was to examine the implementation of one, two, or all three main intervention components at the individual level and to assess the association to current smoking among 13 year-olds in the X:IT study.

Methods: Data stems from a cluster-randomized controlled trial in 94 Danish elementary schools (51 intervention; 43 control schools). Implementation was measured by aspects of adherence, dose, quality of delivery, and participant responsiveness based on questionnaire data from 4161 pupils at baseline (mean-age: 12.5 years) and 3764 pupils at first follow-up eight months later. Coordinator responses from 49 intervention schools were also included. Associations between individual level implementation of the three main components and pupil smoking were examined through a 3-level logistic regression model.

Results: Although implementation fidelity for the three main intervention components was good, only one third (38.8%) of pupils in intervention schools were exposed to full implementation of the intervention. Among these pupils odds ratio for smoking was 0.25 (95% CI: 0.15 – 0.42).

Conclusions: School-based programs can be very effective if carefully implemented. Future school-based smoking preventive initiatives should include multiple components, and seek to enhance implementation quality of all components.

1. Introduction

Careful measurement of implementation fidelity is crucial in the examination of whether an intervention is applied as intended or not (Durlak & DuPre, 2008). However, knowledge about implementation of school-based smoking preventive initiatives are limited (Wolfenden, Carruthers, Wyse, & Yoong, 2014). Without knowledge about how well an intervention is implemented, there is a risk of concluding that the intervention is ineffective, when in reality implementation is lacking. Even interventions with positive results will benefit from this knowledge. Firstly, the effect could potentially be due to other factors than the intervention itself (Bellg et al., 2004), secondly, if implementation is low the intervention may have additional potential, not explicated by this specific level of implementation. Further, the positive effect can stem from some of the main intervention components being implemented well, while others are not.

Schools are regarded suitable settings for preventive initiatives for children and adolescents, as the school setting offers the possibility to

reach almost all children within the relevant age group (Kaftarian, Robertson, Compton, Davis, & Volkow, 2004; Mihalic, Altman-Bettridge, & Turk, 2004). Implementation of school-based preventive initiatives often relies on teachers as implementers along with the many other tasks of teaching (Reinke, Herman, Stormont, Newcomer, & David, 2013), and the implementation therefore compete with many other responsibilities (Domitrovich et al., 2008; Han & Weiss, 2005). At the same time, the demands on the schools have been rising during the past years (Domitrovich, Gest, Jones, Gill, & Sanford Drouis, 2010; Greenberg, 2004; Hung, Chiang, Dawson, & Lee, 2014; Wick, 2015), and implementation of a new intervention in an already challenged school setting may be difficult and induce a higher stress load on the teachers (Ballet & Kelchtermans, 2009).

Within school-based smoking prevention, comprehensive strategies using multiple components have generally been more effective compared to single component initiatives (Backinger, Fagan, Matthews, & Grana, 2003; Thomas & Perera, 2006). However, multi-component interventions are often more costly than single component initiatives, and

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implementing multi-component interventions in the school setting is challenging (Domitrovich et al., 2008). The implementation of these initiatives is seldom thoroughly assessed, and it can be difficult to draw conclusions on what worked. Was it only one of the components, or the combination of all components which was effective? (Domitrovich et al., 2008).

There is no overall consensus on how to best report on implementation and relation to effect of multiple component interventions. Often percentages of different aspects of implementation, i.e. adherence or dose, are reported for various intervention components, without associations to effect. Few studies within the field have reported on an overall implementation measure, i.e. Trigwell et al. (2015) who examined implementation of a school-based smoking prevention intervention by assessing reach, dose of intervention delivered, fidelity (whether the intervention was delivered as intended), acceptability and sustainability. Total scores for implementation was reported and calculated into an overall implementation measure: low (0–33%), medium (34–66%) and high (67–100%) implementation. The overall average fidelity score for sessions was 57.8%, while 28% of sessions were scored with high fidelity (Trigwell et al., 2015). In 2001, Rhode et al. assessed implementation in a similar manner; also dividing schools into three groups of implementation (< 33.3%; 33.4–66.6%; > 66.7%) based on six predefined implementation criteria (tobacco-free school policies, family involvement, community involvement, tobacco prevention curriculum instruction, teacher/staff training, and pupil tobacco use cessation support). Here 14 schools were categorized as low implementers, 15 schools as medium and 9 schools as high implementers. Within the group of schools with low implementation there was no smoking preventive effect, whereas the odds for smoking in the medium implementation group was 0.8 (95% CI: 0.6–1.0), and in the high implementation group 0.7 (95% CI: 0.5–0.9) (Rohde et al., 2001). These studies combined different aspects of implementation fidelity into overall implementation measures at the school level. Studies reporting at the individual level most commonly report percentages of the different aspects of implementation fidelity (i.e. adherence or dose) for the main intervention components, and some also relate to effect (Ennett et al., 2011, Ferrer-Wreder et al., 2010, Sloboda et al., 2009; Stead, Stradling, MacNeil, MacKintosh, & Minty, 2007).

Implementation fidelity is the degree to which a program is implemented as intended by the program developers (Dane & Schneider, 1998; Dusenbury, Brannigan, Falco, & Hansen, 2003). In order to gain a comprehensive picture of the implementation of a particular intervention, it is recommended to measure several aspects of implementation fidelity; adherence, dose, quality of delivery, and participant responsiveness (Dane & Schneider, 1998; Dusenbury et al., 2003). Here we rely on the definitions from Dusenbury et al. (2003), and we define the aspects of implementation fidelity as follows: **Adherence** refers to the extent to which core intervention components are delivered in accordance with how the program was designed. **Dose** is the amount of the intervention components received by participants, i.e. the number of lessons received. **Quality of delivery** is how the program content is delivered; it is not directly related to prescribed content and delivery strategies, but rather to aspects such as teachers' enthusiasm, preparedness and attitudes towards the program. **Participant responsiveness** reflects the extent to which participants are engaged by and involved in the activities of the program (Dusenbury et al., 2003).

In 2010, the Danish Cancer Society launched a large smoking prevention program for 13- to 15-year olds - the X:IT study, which is based on the Theory of Triadic Influences. The three main components are 1) smoke-free school grounds, 2) curricular activities on smoking related issues, and 3) parental involvement, comprising smoke-free contracts and dialogues (Andersen et al., 2014). The program was evaluated in a cluster-randomized controlled trial involving schools from all over Denmark. Intention to treat analyses showed an overall significant effect after one year; odds ratio for smoking among pupils in intervention schools compared to the control group was 0.61 (95% CI: 0.45 - 0.81)

(Andersen, Krølner, Bast, Thygesen, & Due, 2015). Examination of the overall school-wise implementation showed that about one fourth of the schools succeeded in implementing all three intervention components as prescribed in the program (high implementers). Further, there was an association between high implementation and reduced odds ratio for smoking at the school level: 0.44 (95% CI: 0.32 – 0.68) (Bast et al., 2016). X:IT was implemented at multiple levels in schools; the smoke-free school grounds at the school level, the curricular activities at the class level, whereas the parental component, comprising smoke-free contracts and dialogues, were implemented at the individual level (Andersen et al., 2014), and we still do not know how implementation of the three components was associated to individual level smoking, i.e. how implementation of one, two or all three components affected smoking among individual participants of the intervention.

The aim of the present study was therefore: 1) to examine the individual level implementation fidelity of each of the three main components after the first year of intervention; and 2) to examine how implementation of one, two or all three components was associated to current smoking at individual level.

2. Methods

2.1. Evaluation design

The invitation to participate in the X:IT study was sent to all municipalities in Denmark (N = 98). Within the 17 municipalities that agreed to participate, 302 schools were eligible for trial and 97 of them were enrolled in the study (32.1%). Schools were randomized by drawing lots and after randomization three schools withdrew; leaving 51 intervention and 43 control schools. Semi-structured interviews were then conducted with six schools and ten municipalities, participants and non-participants, to access possible bias of participation.

All grade 7 pupils (mean age 12.5 years) in participating schools were invited to participate. Power calculations for the X:IT study were conducted according to Donner and Klar (1996). Based on an ICC of 0.053, a class size of 20 pupils and a power of 80%, it was estimated that in order to detect a 25% reduction in smoking prevalence 46 schools should be included in each study arm (intervention and control). Numbers of participating schools (coordinators) and pupils at baseline and first follow-up are shown in Fig. 1.

2.2. Data collections

Data was collected through the means of electronic questionnaires responded by pupils and one school coordinator at each school (Andersen et al., 2014). Baseline data were collected in the beginning of grade 7 (fall 2010) and first follow-up eight months later, at the end of grade 7 (spring 2011).

At baseline there were 2538 eligible pupils in the 51 intervention schools (response rate = 93.8%) and 1930 in the 43 control schools (response rate = 92.5%).

At first follow-up 2526 pupils were eligible from the 51 intervention schools (response rate = 87.2%). Pupils not attending school on the day of survey were encouraged to answer the questionnaire another day. One control school dropped out between baseline and first follow-up, leaving 42 schools with 1908 pupils eligible (response rate = 81.9%). Coordinators from 50 intervention schools responded to the follow-up questionnaire, unfortunately pupils from one of these schools did not respond, and data from this school was therefore not included in the analysis, see Fig. 1.

In this study, we included pupils who responded to the baseline and the follow-up questionnaire with available school coordinator responses: 2146 pupils at 49 intervention schools and 1528 from 40 control schools were included. Pupils were followed over time by information on their name, school class and school.

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