

From the editors

In this issue,¹ we published a paper on sleep bruxism in children exposed to secondhand smoke (see page 392). After publication, we received a letter (below) raising questions about the ethics of the study. Normally, responses to papers are published electronically as Rapid Responses, because we simply do not have page space for extensive discussions between authors and readers. However, we take research ethics very seriously at

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Tobacco Control, and so we are making an exception in this case to share openly with readers our process in responding to the criticism. Because the senior editors felt some of the concerns raised were reasonable, we requested further clarification about the study procedures from the authors (see response below). We also sought an expert opinion from the Department of Bioethics at the US National Institutes of Health (see editorial, below). We invite our readers to review these materials in the interest of furthering reflection on the ethical implications of research on the effects of secondhand smoke, but also on the

research enterprise more generally. While standing behind our decision to publish the paper, we appreciate the thoughtful critiques and responses from our colleagues. We hope you will find the dialogue illuminating.

Contributors Ruth Malone, Andrew Hyland, Joaquin Barnoya, Joanna Cohen, Coral Gartner, Sally Haw, Lisa Henriksen.

Competing interests None.

Provenance and peer review Commissioned; internally peer reviewed.

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REFERENCES

1. **Montaldo L**, Montaldo P, Caredda E, *et al*. Association between exposure to secondhand smoke and sleep bruxism in children: a randomised control study. *Tob Control* 2012;**21**:392–5.

Meeting our ends by our means: protecting children from SHS in research

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We are concerned by the recent publication of a randomised clinical trial in your journal, in which smoking parents were asked to continue smoking in the presence of their children for 6 months to evaluate if secondhand smoke (SHS) exposure increased the risk of bruxism.¹ It is surprising that after acknowledging that SHS is “...a serious public health threat” with a large impact on children’s health,

ranging from respiratory affections to cardiovascular damage, authors conducted a study in which:

“The smoking members of the families in group 1 were asked not to smoke in the presence of the child for a period of 6 months, while those in group 2 were asked not to change their smoking habits.”

What would have happened if a parent in group 2 had decided to quit smoking during follow-up? Would the investigators have encouraged him/her not to, or to wait until the end of the study? The active involvement of researchers in the decision to expose children to SHS contravenes the Helsinki declaration, since “...the well-being of the individual research subject must take precedence over all other interests”.² Preventing family members from stopping smoking and actively seeking children to be exposed to a dangerous pollutant is reckless, as the benefits of knowing if SHS is a risk factor for bruxism cannot overcome

the dangers of exposing children to SHS or the benefits of quitting. A reasonable approach to address the research question posed by the authors would have been to take an observational stance, developing the most effective intervention possible to eliminate SHS exposure at home for all children, closely monitoring bruxism and SHS exposure levels at home over time, and using each child as its own control. The methodological disadvantages associated with this approach would have been clearly balanced by its adherence to the Helsinki declaration.

As we move forward in eliminating SHS exposure, it is imperative that researchers, ethical committees, reviewers and scientific journals remain aware of the ethical implications of research, so our ends are met by our means. Failing to do so undermines participants’ health and the global movement towards SHS elimination. Considering children’s high vulnerability and inherent risks from SHS, we

What this paper adds

- ▶ The scientific community must remain aware of the ethical implications of second-hand smoke (SHS) exposure research.
- ▶ A careful risk-benefit analysis should guide the ethical considerations of each specific study, but as a general rule experimental studies involving exposure to SHS should be discouraged.

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cannot think of a single research question that could justify actively seeking exposing children to SHS or preventing parents from stopping smoking to provide a healthier environment for themselves and their families. Although each study requires an individual assessment of the risk-benefit ratio, as a general rule, experimental studies involving exposure to SHS should be discouraged, preferring

observational designs built upon the premise that all efforts will be made to support smoking cessation and eliminate SHS.

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REFERENCES

1. **Montaldo L**, Montaldo P, Caredda E, *et al*. Association between exposure to secondhand smoke and sleep bruxism in children: a randomised control study. *Tob Control* 2012;**21**:392–5.
2. **Anon**. World Medical Association. Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA* 2000;**284**:3043–5.

Association between exposure to SHS and sleep bruxism in children: further details on the trial

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I am writing in response to the concerns raised about the randomised trial published by your journal and conducted by my team.¹ This research was part of a larger project focusing on the education of families and children about the risks of smoking and SHS. At the beginning of the trial, parents were all informed about the risks of SHS and after the end of the trial, they were all involved in lessons held by a psychologist and a doctor. SHS is indeed a “...serious public health threat” and during the research, smoking and exposure to SHS have never been encouraged.

As stated, the trial included as many as 27 families who refused to participate.

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Most families refused to be included in the trial after being randomly selected either in group 1 or in group 2. Data about these 27 families were not reported and they were all listed among those refusing to participate. Some of these families were part of group 1 and decided not to participate because, in spite of being informed about the risks of SHS, they reported that they would not have been able to reduce SHS exposure for their children. Other families were part of group 2 and, aware of the risks of SHS, decided to reduce it and therefore did not participate. Those families were just excluded from the study and were not encouraged to continue smoking. All the parents of group 2 remaining in the trial were those who reported not being able to reduce children's exposure to SHS. Therefore, in group 1, the trial was interventional, but in group 2, it was just observational.

What this paper adds

- ▶ The purpose of this letter is to reply to the concerns raised about the randomised trial ‘Association between exposure to secondhand smoke and sleep bruxism in children: a randomised control study’.
- ▶ In the trial, group 2 included those parents who reported not being able to reduce SHS children exposure. There was no action on this group.
- ▶ In group 1, the trial was interventional; in group 2, it was just observational.

I can understand that the above mentioned information is needed as it was not fully described in the paper and readers may misunderstand the instructions given during the trial. Under no circumstances should smoking be encouraged and every study should fulfil this requirement.

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REFERENCE

1. **Montaldo L**, Montaldo P, Caredda E, *et al*. Association between exposure to secondhand smoke and sleep bruxism in children: a randomised control study. *Tob Control* 2012;**21**:392–5.