Author's response to reviews

Title: A cluster randomised controlled trial of the Climate Schools: Ecstasy and Emerging Drugs Module in Australian secondary schools: study protocol

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Author's response to reviews: see over
2nd September, 2013
Victorino Silvestre
Journal Editorial Office
BioMed Central

Dear Mr. Victorino Silvestre,

Re: A cluster randomised controlled trial of the Climate Schools: Ecstasy and Emerging Drugs Module in Australian secondary schools: study protocol

Thank you for your email regarding the submission of the above manuscript to BMC Public Health. Please find responses to your comments below:

• **Could you please clarify whether you have ethical approval and external funding for your study, and if so, could you send evidence of your approvals via email.**
  This study is funded by the National Health and Medical Research Council through a competitive Postgraduate Research Scholarship (APP1056432; approval letter attached) and an Australian Government Department of Health and Ageing grant (approval letter attached). This study has been approved by the University of New South Wales Human Research and Ethics committee (HREC HC13075 – approval letter attached)

• **Could you please provide a list of any manuscripts that are under submission with other journals based on this study protocol?**
  The protocol for this research project has not been published or submitted for publication elsewhere.

• **BioMed Central requires all controlled clinical trials to be registered in a suitable publicly accessible registry prior to consideration for publication.**
  This trial has been registered with the Australian and New Zealand Clinical Trials registry (ACTRN12613000708752).

• **Could you please explain why you have chosen to obtain passive consent methodology and not active consent and whether an ethics committee has approved this?**
  Ethics approval to employ passive parental consent in this study has been obtained from the University of NSW HREC (HREC HC13075). This methodology has been used previously by the investigators in a recent NHMRC-funded school-based prevention trial called the CAP Study (UNSW HREC 11274). In this study, Independent and Catholic school students were able to obtain passive parental consent, while the NSW Department of Education specified that public school students required active parental consent. Of the 1300 public school students that were invited to participate in the CAP Study, only 45% received active consent, with the vast majority of the other 55% not returning their forms and therefore being unable to take part. Less than 5% of students were
actively “not given” consent to participate. This is in comparison to more than 98% of private school students (n=2013) that received passive consent to participate. These statistics clearly demonstrate that active parental consent procedures dramatically reduce participation rates and can be detrimental for data collection. Furthermore, research indicates that active consent procedures can result in the exclusion of certain demographic and high risk groups, and has the potential to introduce a degree of selection bias into studies of adolescents’ substance use (White et al., 2004; Chartier et al., 2008). Teacher feedback from the CAP Study also indicates that passive parental consent is the preferred procedure by many schools, and that active consent can exclude certain types of students. For example, the Deputy Principal at a participating public school stated that “a number of students who would benefit...did not participate - some didn’t bother to return the sheet, others’ parents said no”. Taking this all into account, we believe that it is more appropriate to employ passive consent in the proposed study.

- **Please format the Authors' Contributions section of your manuscript according to the following guidelines (please use initials to refer to each author's contribution):**

  We have updated the Authors Contribution section so it now reads: “KC, NN and MT were involved in the study design and are responsible for the ethics and clinical trial submission, recruitment of schools and data collection. KC, NN and MT contributed to the manuscript preparation and read and approved the final manuscript”. Please see an amended copy of the manuscript attached.

Please contact me should you have any questions regarding the manuscript. We look forward to your response.

Best wishes,

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