



## Response

## Rejoinder to Dennis Gorman's critique of: "Preventing alcohol harm: Early results from a cluster randomised, controlled trial in Victoria, Australia of comprehensive harm minimisation school drug education"



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As researchers seeking to contribute to better alcohol and other drug prevention we appreciate the need for critical reviews of intervention programs. Gorman's critique of our recent paper is therefore welcome. It does identify some weaknesses in specificity, which in hindsight could have been better addressed. It also provides an opportunity to explain why certain choices were made in terms of reporting findings (Gorman, 2015; Midford et al., 2014).

Gorman's (2015) primary criticism is that registering the study with the Australian and New Zealand Clinical Trials Registry (ANZCTR) and publishing a study protocol did not preserve the integrity of the study design because we did not adhere to the methodology and measures described (Midford, 2012; Midford et al., 2012). We do not agree with the implication of this critique, that our results are flawed, although we do acknowledge greater detail could have been provided in the ANZCTR description and study protocol (Midford, 2012; Midford et al., 2012). In these documents we used general descriptive terms to indicate that knowledge, patterns and context of use, attitudes and harms experienced in relation to alcohol, tobacco, cannabis and other illicit drug use would be collected. Subsequently, in the paper on findings in relation to alcohol from the first year of the study, we specified teaching dose and parent communication as contributing contextual factors. We also differentiated and specified each outcome measure in detail. Importantly, however, the methodology and core hypotheses of the

study, namely that intervention students would consume alcohol, tobacco and illicit drugs in a less risky manner and experience less harms associated with use, are articulated consistently in the ANZCTR description, the study protocol and the first year alcohol study paper (Midford, 2012; Midford et al., 2012, 2014).

Gorman (2015) considers that departure from the study design described in the ANZCTR registration and study protocol creates four particular problems in terms of the findings from the study. First, "the posttest contains only results pertaining to alcohol". This paper on early alcohol findings is the first in a series reporting the results from the study, as is usual in large complex studies of this sort. We have subsequently published findings on cannabis and are writing further papers on tobacco and the effect of the full two-year program on alcohol use (Lester et al., 2014). The merits of the study should be considered as a whole, based on the information presented across the series of papers, and not judged prematurely on the basis of one early paper.

Second, three of the five significant differences were for "measures that were not described in either the study protocol or the ANZCTR registration". These three significant measures were not considered hypothesised outcomes in their own right, but rather contributing factors. The intention to measure knowledge was included in the methodology sections of both documents, and measurement of teaching dose and parent communication should be considered as assessing "context of use", again mentioned in both documents.

Third, "one of these new measures 'Alcohol lessons remembered' is a very weak measure of program efficacy". We agree that

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number of lessons remembered does not well measure program efficacy, but that was not the intention. Control students received the drug education normally provided by their schools. We included this as a contributing factor in that it measures program implementation and impact, against what students would otherwise receive, and against a national comparator (White & Bariola, 2012).

Fourth, “the differences between the DEVS group and the control group on two of the measures are of dubious practical or clinical significance”. The differences on these two measures; knowledge, and communication with parents are relatively small, but the changes are important in that they are associated with the efficacy outcomes of lower alcohol consumption and fewer alcohol harms. This suggests that activities to increase these behaviours should be included in school drug education programs. It is also important to point out here, that with a significance threshold of  $p = .05$ , these differences were not likely to have occurred by chance because of multiple testing, as they were only among 9 measures tested.

While we have responded to each of Gorman’s points of criticism, we also wish to make the point that in a study such as ours, which evaluated the impact of a complex psychosocial intervention, it is the pattern and consistency of results across multiple hypothesised outcomes that are arguably more important than a single primary outcome. This is especially the case when the measures typically used are imperfect; a major problem and challenge in behavioural research. Graham made this point some time ago, in a well-written and robust response to an earlier critique by Gorman (Gorman, 2008; Graham, 2008a). We also suggest that (a) Gorman’s critique is premature because it comes before all the results from our study are published; and (b) the basis for his criticism is too narrow in that it does not consider the need, articulated by Graham (2008b), to balance rigour with creation of practical knowledge.

In summary, we accept that the study variables could have been specified in greater detail in the ANZCTR registration and study protocol, but we dispute Gorman’s (2015) proposition that the evaluation is “capitalizing on relatively small differences on outcome measures not described in its study protocol or the trial registration”. The specific hypothesised prevention outcomes described in the first year alcohol study paper clearly derive from those in the earlier documents, and where there are differences between the intervention and control student in terms of these prevention outcomes they are of meaningful public health benefit (Midford, 2012; Midford et al., 2012).

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