Author's response to reviews

Title: Student Public Commitment in a School-Based Diabetes Prevention Project: Impact on Physical Health and Health Behavior

Authors:

Lynn L DeBar (lynn.debar@kpchr.org)
Margaret Schneider (margaret.schneider@uci.edu)
Kimberly L Drews (kdrews@bsc.gwu.edu)
Eileen G Ford (forde@email.chop.edu)
Diane D Stadler (stadlerd@ohsu.edu)
Esther L Moe (moe@ohsu.edu)
Mamie White (mawhite@bcm.edu)
Arthur E Hernandez (art.hernandez@tamucc.edu)
Sara Solomon (solo0058@gmail.com)
Ann Jessup (ajessup@email.unc.edu)
Elizabeth M Venditti (vendittiem@upmc.edu)

Version: 2 Date: 8 August 2011

Author's response to reviews: see over
Response to Reviewer’s Concerns (BMC Public Health MS: 7620736675431259)

BMC Public Health Associate Editor Comments

1. The clinical trial number is included at end of the abstract.

2. We have included a statement noting that “the study was approved by each participating university’s Institutional Review Board (IRB)” (page 10, lines 14-15). The list of participating institutions is included in the acknowledgements. Given the very large number of participating universities and institutions (at least 10) this was more feasible than listing the specific names of each ethics committee within the document.

3. The abstract format is consistent with author’s checklist instructions for BMC medicine journals.

BMC Public Health Reviewer 1 (Josef Mitas)

1. Reviewer 1 asked that we include “key words” for the study. It was not evident from the BMC Public Health instructions to authors nor the format of the submission site how to specify key words so we have included relevant key words here: obesity prevention; diabetes prevention; school research; communications; social-marketing; public commitment.

2. Reviewer 1 suggested that we consider expanding our analyses to examine additional factors that may influence the study outcomes as well as a repeated measures approach to the analyses. With regards to using a repeated measures analytic approach, while we did collect the anthropometric and health behavior information in a longitudinal fashion, we only have baseline and end of study measures. With only two time points measured, the use of repeated measures is not warranted. We did account for the baseline values when performing the end of study analysis by including the baseline value as an adjustment variable or covariate in the model. This does allow for an accounting of the first measure taken but not in a typical repeated measures way. If we had additional measurement times, we would certainly use the repeated measures mixed model approach to more appropriately fit the data available. With regard to this reviewer’s encouragement to examine a broader range of variables, we point to our response to Reviewer #2 (responses #4 and 5) in which we describe conducting analyses that considered the socioeconomic status of the students as well as their pubertal development status and have indicated within the manuscript (page 14, lines 15-18 and page 15, lines 2-6) our consideration of these variables and approach to model building. However, in attempting to balance this request for expanded analyses with Reviewer 3’s caution about interpretation of post-hoc analyses we thought it most appropriate to retain a focused target on key anthropometrics and health behaviors overall so have limited additional analyses accordingly.

3. In response to this reviewer’s request to include more information on the specific criteria for selection of respondents and consequent limitations, we have included additional narrative in the manuscript (page 10, lines 8-11) describing the results of comparison of consented study students to the larger group of students in the participating schools. Although
differences are statistically significant, examination of the absolute values together with the very large sample size for this study suggests that such differences are not clinically meaningful. We wish to emphasize that this study included all students from the schools who consented to participate so participants were not “selected” by the researchers in any manner.

4. At the suggestion of reviewer 1, we have thoroughly edited our references to ensure that full information is provided for each citation. PubMed citations reflect substantial heterogeneity in whether or not journal names are abbreviated and most journals including many we checked against in BMC journals also reflect this variability. However, we have attempted to fully write out all journal names in the reference section as requested by this reviewer.

**BMC Public Health Reviewer 2 (Gisela Nyberg)**

1. We added narrative to the abstract (page 4, lines 10-11) and in the background section (page 8, lines 14-15) to describe study outcomes more clearly as requested by Reviewer 2.

2. We have removed the two page references for quotes from the main body of the manuscript and placed them in the reference section as requested and ensured that the linkage between quote and specific reference was unambiguous.

3. In response to Reviewer 2’s request for more detail regarding the training process of the student peer communicators, we have added a more detailed description in this part of the methods section (page 11, lines 2-11).

4. Reviewer 2 asked the rationale for not adjusting for SES in the analyses and how low SES might bias some of the findings. The study only collected a proxy of the socioeconomic status of the student’s parent/guardian, namely the highest household education. The distribution of the highest household education was presented in Table 2 and is found to not differ statistically between the groups. The variable was also included during model building, both alone and as an interaction with group assignment, and was not found to make a significant contribution to the model. Hence, it was not included in the final models as a covariate or adjustment variable. Since half of our sample had parents with at most a high school degree, there is little indication that we could expect a bias in findings as a result of low household education. A clarification of this procedure for all characteristic variables has been added to the manuscript to make clear the statistical process (page 14, lines 15-18).

5. In response to Reviewer 2’s query, we have added information about our use of pubertal status in the analyses (page 15, lines 2-6). Sexual maturation or pubertal stage was determined using the gender-specific pubertal development scale from which Tanner score was determined at both baseline and end of study. These findings were not presented in this manuscript but can be found for the larger baseline sample in another study manuscript (HEALTHY Study Group. Risk factors for type 2 diabetes in a sixth-grade multiracial cohort: the HEALTHY study. Diabetes Care 2009; 32:953-5). In short, the majority of the females in the sample (82.2%) had already begun puberty in the 6th grade (baseline) while the majority of the males were still pre-pubertal and at the end of study the majority of the
males were still only at most Tanner stage 3. Of secondary note, the pubertal status was obtained by self report and not by physical exam which is a limitation. However, when the pubertal status at either time point was included in models related to fitness it was found to contribute very little (no difference in fitness results) and was removed.

6. Reviewer 2 suggested that we provide further discussion about the sustainability of the student public commitment in the HEALTHY intervention. In many ways the public commitment activities described here are a very sustainable portion of a multi-component behavioral intervention as they are cheap to implement and are largely student led suggesting that the relevance for the particular time and place in which they are implemented should be high. However, we are skeptical that such activities would be sustained after the conclusion of a clinical trial such as HEALTHY without a motivated teacher or administrator within the school to continue to structure the opportunities for participation perhaps through a club or other after school program – we have added additional narrative in the discussion noting this (page 21, lines 13-19). Further, we emphasize in the discussion that this was not a stand alone component but one built upon the core intervention elements (nutrition and physical activity offerings as well as behavioral change campaigns).

BMC Public Health Reviewer 3 (Ralph Maddison)

1. We appreciate Reviewer 3’s cautionary note about reporting subgroup analyses. Accordingly, we have added narrative to the discussion further emphasizing the exploratory intent of these analyses and the hypothesis generating rather than hypothesis testing nature of the analyses presented in this manuscript (page 20, lines 21-23). We acknowledge that the communications activities described in the report evolved as a result of early formative research in this project and, as such, were not and could not have been pre-specified secondary analyses in the initial study protocol. This reviewer pointed towards a Lancet review on subgroup analyses in RCTs in presenting his concern yet we wish to point out that this review as well as other similar reports (e.g., Wang et al, NEJM 2007; Kent et al, Trials, 2010) largely focus on trials of medications, devices, and surgical interventions. We suggest for community trials of behavioral interventions carried out among maturing adolescents over a lengthy period of time (3 year intervention) – although the primary study targets (improving dietary and physical activity patterns) are invariant and specified before beginning the trial – the means of motivating such youth to continue to participate in these healthy behaviors necessarily evolve as such youth mature emotionally and cognitively through these early adolescent years. This study purposefully included a strong process evaluation component to assess participants’ reactions to our means of promoting these behavioral changes thereby allowing us to adjust strategies in an attempt to increase and maintain participants’ motivation throughout this very lengthy intervention. As such, rather than identifying important secondary analyses after the onset of the study as a methodological flaw, we respectfully suggest that analyses such as those in this report are important products of such long term behavioral trials with youth. In addition, we wish to emphasize that the analyses reported here were guided by a theoretical framework (as specified in the introduction to the paper) and that study variables were judiciously chosen and limited to those appropriate for exploring hypotheses consistent with such a conceptual framework. Further, the analyses presented here were guided by an a priori defined process, research questions, and analysis plan. The only review of the data conducted prior
to developing this plan was that needed to make sure that we had sufficient numbers of observations in each category to ensure that we could conduct the appropriate analyses. Accordingly, we believe that the analyses presented meet the spirit of the standards specified by this reviewer, namely: a pre-specified plan, careful justification, and restriction to a limited number of substantive clinical questions. Importantly, while we agree that results of post hoc analyses should not carry the same weight as those from primary analyses, many important studies have emanated from what began as post hoc analyses and, in fact, the scientific community depends on such exploratory research to speed the cycle of innovation and science.

2. We have condensed the methods section somewhat in response to Reviewer 3’s suggestion (page 12, lines 11-23 and page 13, lines 1-22). We have tried to balance brevity with retaining elements we thought important to providing sufficient details to readers so that they need not consult previous articles for key elements of the study and approach.

3. We have included an additional sentence in the abstract to clarify the inclusion of control school participants in the current report (page 4, lines 19-20).

4. Our measure of school commitment – participation in any study public commitment activities - was chosen as the most unequivocal as well as conservative threshold of participation in the relevant discretionary study activities that are the focus of this report. We believe this represents the most unambiguous measure of participation and one we could identify prior to undertaking study analyses rather than being guided by the patterns of these activities seen among our sample. We believe making this a priori decision is consistent with minimizing the data fishing that can be a danger in secondary analyses and a clear concern raised by this reviewer. Further, the more inclusive categorization of commitment ensures a larger subgroup to proceed with the analyses conducted (see concern #5 below).

5. This reviewer raised the concern that the numbers in the subgroups are quite small and that we did not indicate whether there was sufficient power to detect the effects presented in the manuscript. The smallest analyzed subgroup is comprised of 392 students (those students with baseline BMI’s greater than or equal to the 85th percentile for their age and gender as displayed in Tables 2 and 3). This sample size is much larger than the group size for the vast majority of behavioral trials; accordingly, we respectfully suggest that the numbers in the subgroups are not small. Although there are smaller numbers presented in Table 1, these numbers describe the particulars of students’ public commitment activity and do not in themselves indicate cell sizes used in subsequent analyses. Similar to the vast majority of clinical trials that routinely examine moderators of outcomes, we did not power these analyses. Accordingly, we state explicitly in the discussion that as a post-hoc exploratory analysis the study was not powered to test the effects presented underscoring the importance of replicating these findings (page 20, lines 21-23).