Author's response to reviews

Title: Pilot Evaluation of the text4baby mobile health program

Authors:

William D Evans (wdevans@gwu.edu)
Jasmine L Wallace (jwallace@gwu.edu)
Jeremy Snider (jeremy.snider@gmail.com)

Version: 6 Date: 9 October 2012

Author's response to reviews: see over
9 October 2012

BMC Public Health

Dear Editor:

Thank you for your email of 1 October. This letter is in response to reviewer comments on the manuscript entitled “Pilot evaluation of the text4baby mobile health program.” In the following, we respond to each reviewer comment. The manuscript reflects these revisions, which have been highlighted in yellow.

We look forward to the journal’s review and final decision on this manuscript. If I may answer any questions, please contact me directly at wdevans@gwu.edu or +12029943632.

Sincerely,

W. Douglas Evans Ph.D.
Professor
RESPONSE TO REVIEW COMMENTS

REVIEWER: STEVEN CHAPMAN
Since this reviewer accepted the manuscript as is, we have no responses. Thank you.

REVIEWER: LORRAINE WALLACE
Major Compulsory Revisions

Abstract

1. The abstract seems too long. Is it within the journal word limit?
RESPONSE: THANK YOU, WE CHECKED THE JOURNAL REQUIREMENTS AND THE ABSTRACT FOLLOWS THE REQUIRED FORMAT AND IS WITHIN THE WORD LIMIT.

2. The Background section should include a strong and focused purpose statement.
RESPONSE: WE HAVE ADDED A STATEMENT OF PURPOSE AS THE REVIEWER REQUESTED.

3. In the conclusion section, you note that this was a “pilot” study. This should be acknowledged in the purpose statement.
RESPONSE: DONE

Introduction

4. The third and fourth paragraph would be better suited to include within the Methods section.
RESPONSE: WE HAVE MADE THIS AND OTHER RELATED REVISIONS TO THE INTRODUCTION AND METHODS.

5. As noted in the comment above, the Figure 1 should be presented in the Methods section.
RESPONSE: DONE.

6. The purpose statement should acknowledge that this was a pilot study.
RESPONSE: DONE

Methods

7. At nearly five pages, the Methods section is too long. Much of the information presented is duplicated; much important information is not discussed.
RESPONSE: AS REQUESTED, WE HAVE SHORTENED THE METHODS SECTION BASED ON THE PREVIOUS CONTENT. HOWEVER, PREVIOUS COMMENTS BY THE REVIEWER CALL FOR ADDING MATERIAL TO THIS SECTION AND SO IT MAY IN THE END BE SOMETHOUGH LONGER GIVEN THE MATERIAL THAT THE AUTHORS WERE ASKED TO ADD.
8. Where the women provided incentives to participate? What was the response rate? How many women were approached to participate? What was the drop-out rate? Do you have any information on drop-outs?
RESPONSE: NO INCENTIVES WERE PROVIDED. WE HAVE CLARIFIED THE POINTS REGARDING RESPONSE RATES AND ATTRITION.

9. A large proportion of the women were Spanish-speaking. I am assuming that study personnel were fluent in Spanish and/or bilingual. Please elaborate on the training study personnel underwent.
RESPONSE: THE NURSES WHO SAW PATIENTS WERE FLUENT OR HAD A TRANSLATOR PRESENT. THE INTERVIEWER WHO CALLED WOMEN RECRUITED INTO THE STUDENT WAS FLUENT. WE HAVE CLARIFIED THE TRAINING PROVIDED.

10. Was the 24-item valid and reliable? Please provide these data. Was the survey administered in both Spanish and English?
RESPONSE: ITEMS WERE DERIVED FROM NATIONAL SURVEY INSTRUMENTS INCLUDING THE BRFSS OR WERE CREATED FOR THIS STUDY. THE LATTER WERE BASED ON VALIDATED MEASURES FROM PREVIOUS STUDIES BY THE INVESTIGATORS.

11. Please provide specific examples of the behavioral outcome variables.
RESPONSE: DONE

12. The target sample size for the study was 260 participants. The actual number of participants enrolled was much smaller than this (n=123). Please explain why you were unable to recruit less than half of the needed participants for this study.
RESPONSE: WE HAVE ADDED DETAILS ON THIS POINT.

13. Was the sample size adequate to allow for multivariate logistic analyses? Please confirm with a statistician.
RESPONSE: YES AND WE HAVE CONFIRMED.

Results
14. How many interviews were conducted in English and Spanish separately?
RESPONSE: WE HAVE ADDED THIS DETAIL.

Discussion
15. Much of the information presented in the limitations section is not presented in the Methods or Results section. Many of these issues should be addressed prior to being acknowledged in the limitations section.
RESPONSE: WE HAVE REVISED ACCORDING TO THE REVIEWERS COMMENTS.

Table 1
16. It would be helpful to the reader to provide sociodemographic data as a
function of language as well.
RESPONSE: WE CONDUCTED BI-VARIATE ANALYSIS TO EXAMINE WHETHER THERE WERE DIFFERENCES IN SOCIO-DEMOGRAPHICS BASED ON LANGUAGE AND HAVE PROVIDED THE RESULTS.

Table 2
17. I am assuming that the p-value presented represents the difference between the baseline and follow-up samples. Is this correct? If so, this information should be provided at the bottom of the table.
RESPONSE: DONE

Table 3
18. Many of the confidence intervals are significant, but very wide. These findings are a result of the small sample size. This should be listed an additional study limitation.
RESPONSE: DONE.

REVIEWER: GREGORY NORMAN

Major Revisions
The strengths of this study include the evaluation of an intervention targeted at healthcare needs of an underserved population segment. The intervention is theory-based and scalable. Unfortunately, the study was significantly underpowered and there are many methodological concerns about the analysis and presentation of results (see below). The authors need to follow the CONSORT guidelines for RCTs. For example, a study flow diagram of the trial is not included in the paper. The conclusions that the program is “promising” are not supported by the study results.
RESPONSE: THANK YOU, WE CONSULTED WITH THE JOURNAL EDITORIAL OFFICE UPON INITIAL SUBMISSION AND DETERMINED THAT BECAUSE THIS STUDY IS A RANDOMIZED PILOT, IT DID NOT REQUIRE A FLOW DIAGRAM.

Any information on reliability and validity on the developed questionnaire for attitudes and behaviors?
RESPONSE: WE HAVE ADDED DETAILS ON THIS POINT.

Target sample size was 260 but only 123 participants were recruited. The study was significantly underpowered.
RESPONSE: WE AGREE WITH THE REVIEWER THAT THE STUDY DID NOT ACHIEVE ITS TARGETED STATISTICAL POWER. HOWEVER, IT IS A PILOT AND VALID STATISTICAL TESTS RUN ON THE DATA DEMONSTRATE INTERVENTION EFFECTS. WITH LIMITATIONS NOTED, THESE RESULTS ARE VALID AND USEFUL TO THE FIELD.

The missing completely at random assumption is not verifiable. Why was a
missing data imputation procedure used?
RESPONSE: THANK YOU. IF THERE IS COVARIATE-DEPENDENT NON-RESPONSE (A SUBSET OF MCAR), AS APPEARS TO BE THE CASE FROM THE ANALYSIS OF MISSING DATA, THEN ACCOUNTING FOR THIS BY CONDITIONING ANALYSES ON THESE COVARIATES WOULD BE APPROPRIATE. THUS, THE ANALYSIS CONSIDERATIONS ARE AKIN TO THOSE OF MCAR. WE HAVE ADDED MORE INFORMATION ABOUT THE RESPONSE LEVELS OF STUDY COVARIATES AND TREATMENT GROUPS. ALSO WE ONLY USED COMPLETE CASES IN THE ANALYSES, AND DID NOT HAVE ITEM NON-RESPONSE TO DEAL WITH. FROM THE REVIEWER'S COMMENT WE WONDERED IF ITEM NON-RESPONSE WAS BEING RAISED.

Information in table 2 should be presented stratified by treatment and control group.
RESPONSE: WE HAVE REVISED THE TABLE.

It is not clear what the row headings mean in table 3.
RESPONSE: WE HAVE REVISED THE TABLE.

Eight outcomes are tested without any adjustment to the type 1 error rate.
RESPONSE: WE INTERPRET THE REVIEWER'S COMMENTS TO REFER TO THE ISSUE OF MULTIPLE COMPARISONS (I.E. THAT BY MAKING 8 COMPARISONS, WE RISK DRAWING INCORRECT CONCLUSIONS AT THE A=0.5 LEVELS). THERE ARE SEVERAL REASONS WHY MAKING STRONG ADJUSTMENTS (E.G. BONFERRONNI CORRECTIONS) FOR MULTIPLE COMPARISONS MAY NOT BE ADVISED. FIRSTLY, THE COMPARISONS IN THE REGRESSION ANALYSIS WERE BASED ON SOUND A PRIORI ASSUMPTIONS BASED ON A RESEARCHED CONCEPTUAL MODEL (AS DESCRIBED IN THE INTRODUCTION, TEXT4BABY IS BASED ON AN EVALUATION CONCEPTUAL MODEL BASED ON MULTIPLE BEHAVIORAL THEORIES). THUS, IT WAS A THEORY-BASED ANALYSIS PLAN, NOT A 'FISHING EXPEDITION' FOR SIGNIFICANT RESULTS. SECONDLY, THE MAGNITUDE OF THE ASSOCIATIONS FOUND ARE GENERALLY STRONG, BUT ARE SURROUNDED BY LARGE CONFIDENCE INTERVALS DUE TO LOW POWER. THIRDLY, THE STRONG FACE VALIDITY (E.G., DIFFERENCES IN EFFECTS BY EDUCATION IS FACE VALID IN THAT ONE WOULD EXPECT HEALTH EDUCATION MESSAGES TO HAVE DIFFERENT EFFECTS FOR LOWER V. HIGHER LEVELS OF LITERACY BASED IN PART ON EDUCATION) OF THE FINDINGS WOULD SEEM TO REDUCE THE CHANCE OF THESE RESULTS BEING ATTRIBUTED TO RANDOM VARIABILITY OR STATISTICAL ABERRANCE. FINALLY, AS AN EXPLORATORY STUDY WITH A SMALL POPULATION SIZE, IT IS IMPORTANT TO IDENTIFY POTENTIAL FACTORS FOR FUTURE STUDY, EVEN IF THEY MAY BE OF MARGINAL SIGNIFICANCE UNDER NULL-HYPOTHESIS TESTING.

TO FULLY RESPOND TO THE REVIEWER'S IMPORTANT COMMENTS, WE CHANGED THE WORDING TO EMPHASIZE THE MAGNITUDE OF THE INFERRED EFFECTS, AND ADDED A SENTENCE IN THE LIMITATIONS SECTION OF THE PAPER ON CAUTIONING ABOUT DIRECT INTERPRETATION OF THE P-VALUES TO REJECT OUR NULL HYPOTHESES.

Minor Revisions:
What was the rational for including education status an effect modifier of the
intervention? Was this an a priori decision?
RESPONSE: EDUCATION STATUS IS AN IMPORTANT SOCIO-DEMOGRAPHIC VARIABLE THAT HAS BEEN SHOWN TO MODERATE EFFECTS OF HEALTH COMMUNICATION INTERVENTIONS SUCH AS THE ONE TESTED IN THIS STUDY. IT WAS CONCEPTUALIZED AS A POTENTIAL CO-VARIATE IN THE EVALUATION CONCEPTUAL MODEL NOTED IN THE INTRODUCTION. THE INVESTIGATORS HAVE ROUTINELY USED IT IN PREVIOUS STUDIES AND THUS INCLUDED IT FROM THE OUTSET.