Author's response to reviews

Title: Evaluation of HbA1c Screening during Outreach Events for Prediabetes Subject Recruitment for Clinical Research

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Author's response to reviews:

Dear Dr Mader, Trials Editor

Upon revision, we would like to resubmit our manuscript entitled: “Evaluation of HbA1c Screening during Outreach Events for Prediabetes Subject Recruitment for Clinical Research” (TRLS-D-17-00428).

We would like to thank the editorial office and reviewers for their comments and recommendations. We were very pleased that they found our manuscript “interesting” and “well written”. We have made the suggested changes to address the reviewers’ concerns. Specifically, we have provided details on the statistical analysis, updated the statistical analysis description in figure and table legends, as well as revised Figure 1 to improve the quality of the graph. In addition, we addressed a number of study limitations in the Discussion and made minor editorial changes throughout the manuscript for ease of reading. Changes to the text are highlighted in grey.

We hope that with these revisions, the manuscript will be considered suitable for publication in the journal of Trials. Please find a point-by-point response to the comments outlined below.

Reviewer reports:

Reviewer #1: The article of Paglialunga and co-workers addresses an important aspect of medical research methodology. The article is well structured and the written English does not need major revisions.
On the other hand, the authors should provide further details about the statistical methods used. In fact, these are described superficially and the related figures are difficult to interpret. The authors are invited to share their data and expand the explanations of the statistical tests used. Also, improvement in the quality/presentation of the related figures is suggested.

Response - Thank you for your comments and recommendations. A detailed statistical description of the analyses is now included in the Methods sections (page 5, line 96): “Age and HbA1c results are presented as mean and standard deviations (SD), with ranges and sample size (n) given. Statistically significant differences were analyzed by unpaired Student’s t-test or one-way ANOVA followed by Tukey’s post-hoc test as indicated in the figure or table legend. Categorical data such as gender, ethnicity and diabetes status are presented as sample size (n) and percentage (%) with statistical significance determined by Chi-squared test with degrees of freedom (df) shown. Statistical significance set at p<0.05.” In addition, the figure and table legends clearly indicate which statistical test was used for analysis. The scatter plots in Figure 1 have also been revised to highlight the group mean and standard deviation. Lastly, we have indicated our dataset is available to interested parties upon request (page 10, line 203).

Reviewer #2:

The study provides an underrepresented community recruitment and awareness tool for future studies with pre-diabetes and type 2 diabetes mellitus (DM2). HbA1C collection was performed with a hand-held monitor and finger-stick blood sample. The study seems an early phase of a clinical trial, where enrollment of participants was translated as a study. The findings of this study do not present concrete results, only demonstrate prevalence of pre-diabetes and DM2 in the studied population, gender, HbA1C mean, data more consistent with a Table 1 of a clinical trial. While interesting to know that places are more likely to recruit people for clinical trials, I believe that the manuscript is not consistent with the scope of this journal.

Response – We thank you for your comments. The aim of our study was to evaluate the utility of HbA1c screening as a recruitment tool, and agree a main limitation to this study is the lack of clinical results. This has been acknowledged in our limitations sections in the Discussion (page 9, line 185). Nonetheless, participant recruitment can be one of the most challenging aspects of a clinical trial. To our knowledge this is the first report to describe how a community-based HbA1c screening event can promote clinical research education and gain insight into subjects’ willingness to participate in clinical trials. As subject enrollment is essential for clinical study success, we feel this manuscript is consistent with the scope of the journal as we describe a successful method for prediabetes and type 2 diabetes patient recruitment.