Author's response to reviews

Title: Identifying acceptable postpartum intervention approaches to prevent type 2 diabetes in women with a history of gestational diabetes

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Author's response to reviews: see over
Dear Editors,

We appreciate the two helpful and thorough reviews to our manuscript, “Identifying acceptable postpartum intervention approaches to prevent type 2 diabetes in women with a history of gestational diabetes,” and we respond below.

Reviewer 1:
1. The unique features of the manuscript (i.e. having a denominator, preferences for lifestyle intervention, information that was not helpful) could be emphasized further in the abstract as well as the discussion. We have emphasized these unique features further in the abstract and in the background (last paragraph) and discussion section of the manuscript (paragraphs 1, 3, 4).

-There apparently were multiple women with recent histories of GDM who wanted to attend the focus group, but simply couldn't. The implications for a) group interventions and b) lifestyle interventions, in general, should be discussed further. If women can't attend a single focus group, what does that portend for any lifestyle intervention, particularly group interventions such as were conducted in the Diabetes Prevention Program? We have addressed this further in the first paragraph of the discussion section.

-“Lifestyle coach” was used by the women to mean an educator who would see them as an equal. However, this is a vague definition. How would a lifestyle coach differ from a nutritionist vs. a diabetes educator vs. a personal trainer vs. a guru? More detail or further characterization of what women desired would be helpful. Is it "optional?" rather than "compulsory?" Or perhaps the women themselves didn't know and couldn't say? If this is the case, it should be stated specifically. The lifestyle coach was described by our study team as someone to “help you stay on track, motivate you, answer your questions and help you to achieve your goals.” We have added this as a footnote to Table 1 and elaborated on the concept in the second and third paragraphs of the “Preferred design of a postpartum intervention” part of the results section. We did not define what type of training this person would have. Since we were just gathering preliminary data about the idea of a “lifestyle coach” we did not state that it would be optional or compulsory to work with a lifestyle coach, but all participants were interested in the idea of working with a lifestyle coach.

-Several of the women definitely did NOT want a physician who "didn't know them" counseling about lifestyle. What does this imply for physician advice about lifestyle change and risk in this population and others. Should physicians not be discussing this issue, or should be physicians not be part of future interventions? Or is it that the manner in which such counseling is given counter-productive? This should also be expanded upon.
We agree that this is an interesting and novel finding and we included this in the abstract and we have expanded upon its implications in the third paragraph of the discussion section.

2. The investigators note that lifestyle intervention was equally effective in women with and without GDM. In fact, lifestyle intervention was more effective in older adults, whereas younger women (who tended to have higher BMI) had relatively greater success with metformin. The investigators could expand on this. Given that their women had such a difficult time with lifestyle change, could a medication be more effective? The authors themselves note that sociocultural contexts may be more important than individual-level determinants. What does this imply for an intervention? It seems to suggest that medication might be a good alternative. Lifestyle is certainly more appealing from a holistic sense, but if it cannot be achieved, would medication make more sense? Did they solicit comments on this topic from their focus group participants? If not, it should be noted in the Discussion.

Since we were focusing upon lifestyle change for this study, we did not ask about willingness to take a medication to prevent type 2 DM in our focus groups or informant interviews and agree that this information is of interest and have added this to the conclusions section.

Reviewer 2:

1) Abstract – The abstract and the title are a bit confusing since not all women interviewed had a prior history of GDM and were actually currently pregnant with GDM at the time of the interview. These 8 women should have been excluded because being pregnant with GDM may have many different perspectives than women who had GDM and are currently in the postpartum period. This is important because the main objectives were to identify barriers and facilitators to lifestyle changes postpartum with a major focus on postpartum women. We have excluded the three women pregnant with GDM who never before experienced a GDM pregnancy from the analysis as suggested. Because we asked women to think about their postpartum experiences during the year after their most recent pregnancy complicated by GDM, we retained the five women who were currently pregnant with GDM but had previously experienced GDM pregnancies. We elaborated further on the potential for recall bias inherent in this methodology in the limitations section of the discussion.

2) Background – Par. 1, line 2 the incidence of GDM is 3-5% from ref. 1 (from 2006) and on line 7 the incidence is reported as 26-95% from refs. 3-6, these are all from 2004-2005? Are these refs outdated and what is the true incidence of GDM in the US?
   We have removed the percentages from this sentence. We have included the Hunt reference in the first paragraph of the Background section to reflect more current knowledge (2007).
3) Is ref. 7 the correct reference for this statement in par. 1?
*We have changed the reference to the correct Ratner reference at the end of the first paragraph of the discussion section.*

4) Pg. 4 – line 7-8. Refs. 17-19 examined women with a history of GDM, so what is the difference between these studies and yours? What new information are you adding to this literature?
*We clarified in the last paragraph of the background and the first paragraph of the discussion section what from our study reinforces what has been found in previous studies, and what from our findings is novel.*

5) Pg. 4 – If the authors are seeking the perspectives of women with a history of GDM that may be unique to women that had this disease, why did they not have a comparison group of women who did not have the disease in focus groups as well?
*As we were exploring barriers to a lifestyle intervention for women with prior GDM as this population is at high risk for Type 2 DM, we did not study women without a history of GDM. We have removed the “unique” terminology from the last paragraph of the introduction, and state that we are trying to describe the postpartum experience for the post-GDM population.*

6) Pg. 4 – how can retention be predicted? Retention is extremely unpredictable as life happens and may not work out with the best of intentions?
*We agree retention is difficult to predict. We have removed “retention” from this sentence on page 4 and from the abstract.*

7) Methods – Page 4, For recruitment, women saw posters etc, and contacted the authors, then the authors contacted potential participants to set up an interview at their convenience? Did the authors ask the women when they would be able to participate? If the focus group methodology was too difficult to organize why did the authors not conduct all informant interviews, instead of completely different methodologies (focus vs informant interview)? How comparable are these methods?
*All subjects responded to recruitment materials asking if they were interested in participating in a focus group. They were offered three possible times for focus group meetings. If they could not attend any of the three times offered they were then asked if they would complete an informant interview by phone. Since focus groups provide an important way to obtain descriptive findings that allow the identification of important themes, focus groups were our preferred method for data collection. However, given the small number of women able to participate in a focus group, the decision was made to supplement the focus groups with data from informant interviews. The informant interviews allowed us to get more information on focus group topics, and also to address some topics that were not covered in focus groups due to the natural flow of focus group conversation.*
8) Methods, pg. 4, Postpartum women that had GDM within the last 7 years are not really postpartum? There are many different aspects of life regarding infant care (postpartum is defined as up to one year post delivery), vs toddler, vs child care vs. school age children. How did the authors account for all of these different issues in these women's lives? 
The average length of time since last GDM episode was 1.7 years. We asked women to recall their experiences during the most recent postpartum year following their most recent pregnancy complicated by GDM. We have discussed the potential of recall bias resulting from this in the limitations section.

9) Methods, pg. 4, How did the authors know that these women did not have type 2 diabetes? Were they screened? 
We did not validate that they did not have type 2 diabetes. We used self report that they were never told that they had type 2 diabetes. We have clarified this in the methods section.

10) Pg. 5, line 2. Did the authors ask the women who could not attend the focus groups why they could not attend? Could this be a part of the barriers and should this important information be captured regarding this population group? 
We agree that this would be important data to present but we did not ask this question. Some women spontaneously provided information about why they were unable to attend, other women just said that they could not and were willing to do the informant interview.

11) Pg. 5 – two different methods – focus group vs informant interview. The informant women did not have the group interaction like the focus group methodology. The informant women received a gift while the focus group received compensation for childcare and transportation costs? The telephone interview lasted 20-45 minutes – how long did the focus groups last? Was the telephone interview audiotaped or digitally recorded as well? What other differences were there between these 2 methods and how did the authors account for these differences? Data analyses also appear to be different? Over the phone is anonymous while in a focus group people are identified? 
We agree that focus groups are a different method for collecting data and should be analyzed separately. Consequently the focus groups are analyzed according to themes while the informant interviews are analyzed quantitatively. Our goal was not to contrast the responses obtained by the two methods but instead to use a mixed method approach to obtain complementary information. In the methods section (paragraphs 1-5 of study design, data analysis) we have clarified how the data were collected and analyzed.

Because the focus group participants had to travel to Brigham and Women’s Hospital and leave their child or children at home they received more
compensation ($50). The informant interviews required only time on the telephone so they were given a $10 gift card to thank them for their participation. The focus groups lasted 70 minutes on average. The phone interview was not recorded – we clarified this in the methods section. The informant interviewees were consented orally before the interview and their personal information was collected; these interviews were not anonymous.

12) Results – Par. 1 – the numbers do not add up? Out of 38 women, 10 attended the focus groups, which leaves 28 women. Why does Table 2 have 29 women listed?
In the original paper, 10 focus group participants + 19 informants = 29 participants.

If 18 women completed the interviews, why are 19 listed and what happened to the one woman?
With regards to the difference between the 18 and 19 women, 19 women did informant interviews but one woman did complete her informant interview. We have now removed her from all of the analyses.

Should the data in Table 1 reflect only 28 women?
Regarding the question that Table 1 should reflect 28 women, as we indicated above under comment 1, we have now removed the three women who had not experience a prior postpartum period after a pregnancy complicated by GDM. Table 1 now reflects 25 participants with complete data, including 10 focus group participants and 15 informant interviews.

13) Did the authors try visiting the women at home and providing child care as they did for the focus groups? This may have solved the problem of 6 women participating in the phone interview while caring for their children. The interview setting over the phone appears to have several different factors involved and may have been extremely stressful for these women (while driving?) and also bed rest in hospital (was this one pregnant?) These are compared to a relaxed setting of a focus group where the kids are looked after? Differences between the 2 groups regarding those that have time vs those who do not? What about the age of the children between the 2 groups?
We did not visit the women at home for the informant interviews. We removed the data about the multitasking during the informant interviews from the results section because the reviewers correctly noted that these data do not systematically reflect the experience of the actual postpartum year for all study participants. We agree that the context for the informant interviews may have affected the quality of the data and we have added information about the multitasking during the informant interviews to the limitations section.

For the focus groups we did not provide childcare, but we did provide compensation to cover childcare costs. For this reason and the other reasons identified above, we present the data for the focus groups and informant
interviews separately, and we do not attempt to do a comparison of the focus group versus informant data.

We have added the requested data on the ages of the children to Table 2 and the first paragraph of the results section.

14) Results, pg. 7, par. 2. The 8 women who were currently pregnant should have been excluded as they did not meet your inclusion criteria of history of GDM (this does not mean currently having GDM?) These women’s perspectives would be quite different?
We have excluded the three women with a current GDM pregnancy but no prior GDM pregnancy. We did however retain five women who were pregnant at the time of the interview but who had experienced a prior pregnancy complicated by GDM. We have addressed the potential for recall bias in the limitations section.

15) Results – Why did the authors only present information regarding the focus groups and not the informant results for “reaction to the diagnosis”? The result section is extremely confusing as the authors jump between focus group information and interview information without cohesion between the themes or results. This should be rewritten. Were the questions different between the groups and that is why there were no consistent themes? What were the themes in the interview group? Can the results be condensed into common themes using two different methods? The results appear to be reporting verbatim what was said without capturing the overall themes?
Reaction to diagnosis was not asked in the informant interview. We have modified the manuscript to include: a) those questions which were asked of both the focus groups and informant interviews, and b) those questions asked solely in the informant interviews. The reason we have included the questions only asked in informant interviews is that these questions were part of the original focus group interview guide but they were not able to be captured in the limited time frame of the focus group.
In response to the reviewer’s comment and the comments above we have attempted to amplify upon themes that are common across the two different data collection methods. We do report verbatim comments in the results section organized by theme (as subheadings in tables and themes in text) and as indicated above we have attempted to expand upon the major themes in the discussion section (paragraphs 1, 2, 5).

16) Pg. 14, par. 2, one of the themes that appear in this paragraph is the importance of family. Why was this not captured as a theme?
We now emphasize this as a theme in the discussion section (paragraph 5).

17) Discussion – pg. 14, first par. With the inclusion criteria of within 7 years after diagnoses of GDM, the authors cannot claim that the women provided information regarding the year postpartum. Eight of these women were also currently pregnant and again did not fit these criteria.
As indicated above, we now emphasize in the methods and limitations that we asked women to recall their postpartum year after their most recent GDM pregnancy. As stated above, we removed 3 of the pregnant women who had not experienced a prior pregnancy complicated by GDM from the analysis.

18) Pg. 16, par. 1, line 9, if 4 out of the 19 women said that they decided to follow the principles of a GDM diet after delivery, how can this be a major theme? We agree that this should not be a major theme and we have rewritten this section so that it does not read as a major theme.

19) Pg. 17, line 2. Again these numbers do not add up? As described above, we have rewritten the paper so that the numbers add up clearly.

20) Pg. 17, par. 2, line 1. Focus group or interview participants? It would be interesting to compare the 2 groups with same or different themes emerging from the analyses? Financial barriers were mentioned by both focus group participants as well as women who participated in informant interviews. We have clarified this in the discussion section, paragraph 5. We have attempted to identify specific themes that occur in one or both data collection methods (e.g. comments regarding feeling judged by clinicians appeared only in the focus group).

21) There are many confounding factors between the 2 methods that were not accounted or reported. We agree that there are many confounding methods between the two methods. We include information about potentially confounding factors in the limitations section (e.g. multitasking during informant interviews).

Sincerely,
Jacinda Nicklas, MD, MA