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- Comments from the reviewers and editors (email to author requesting revisions)
- Response from the author (cover letter submitted with revised manuscript)*

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Date: Jul 29, 2022
To: "Meryl Megumi Sperling" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-22-1240

RE: Manuscript Number ONG-22-1240

Fasting versus fed: A randomized trial on oral intake prior to the 1 hour oral glucose tolerance test

Dear Dr. Sperling:

Thank you for sending us your work for consideration for publication in Obstetrics & Gynecology. Your manuscript has been reviewed by the Editorial Board and by special expert referees. The Editors would like to invite you to submit a revised version for further consideration.

If you wish to revise your manuscript, please read the following comments submitted by the reviewers and Editors. Each point raised requires a response, by either revising your manuscript or making a clear argument as to why no revision is needed in the cover letter.

To facilitate our review, we prefer that the cover letter you submit with your revised manuscript include each reviewer and Editor comment below, followed by your response. That is, a point-by-point response is required to each of the EDITOR COMMENTS (if applicable), REVIEWER COMMENTS, STATISTICAL EDITOR COMMENTS (if applicable), and EDITORIAL OFFICE COMMENTS below. Your manuscript will be returned to you if a point-by-point response to each of these sections is not included.

The revised manuscript should indicate the position of all changes made. Please use the "track changes" feature in your document (do not use strikethrough or underline formatting).

Your submission will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Aug 19, 2022, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: Thank you for the opportunity to review this manuscript entitled, "Fasting versus fed: A randomized trial on oral intake prior to the 1-hour oral glucose tolerance test." This is a randomized clinical trial that compares fasting for >=6 hours versus oral intake within 2 hours prior to the 1-hour GTT test and examines the impact on the frequency of GTT screen positivity. I was initially excited by the title and precis as this clinical question of timing of oral intake in relation to the 1-hour GTT has come up many times in my own clinical practice. This study has several strengths: mainly its randomized pragmatic study design and the stratification of randomization sequence based on "high" versus "average" risk for GDM, However, I have significant concerns about the study outcomes and the framing and presentation of study results.

On my first read of this manuscript, my initial summary of the findings was the following: fasting group had significantly higher rate of screen positivity and higher mean 1-hr GTT glucose value and therefore feeding before the 1-hr GTT is better because the false positive rate with fasting is higher. In fact, the conclusion of the manuscript is the following: "Based on the biologic plausibility of a prolonged fast creating an aberration in normal glucose metabolism in subjects without evidence of prior glucose intolerance, as well as there being no difference in maternal or neonatal outcomes in our study, it could suggest that fasting prior to the 1-hour OGTT leads to a higher false positive result, or potentially leads to a greater increase in the diagnosis of GDM in a subset of patients that is not clinically relevant to their pregnancy course and outcomes."

However, I believe this conclusion is misleading. This study merely shows that the fasting state resulted in higher 1-hr GTT screen positivity and higher mean GTT glucose value. Based on the study design, we do not know the "true" frequency of GDM in either group because the need for a 3-hour GTT was based on the result of the 1-hour GTT test which was impacted differentially by the study intervention. In fact, the frequency of GDM was much higher in the fasting group compared to the fed group (12.4% vs. 5.1% respectively). While the p-value was not significant (p=0.08), this is likely more of a reflection of the small sample size. There was no other 'check' performed in the study to see if the difference in the 1-hour GTT values was better or worse for diagnosing GDM. The authors use the absence of significant differences in

the maternal or neonatal outcomes as a proxy for good detection of GDM in both groups, however the sample size is small and would not be expected to detect significant differences in the more clinically important but less frequent outcomes. Looking at Table 3, most cells have less than 10 for the more clinically significant outcomes.

While some of the study findings are interesting, the follow-through to the next step of being able to determine what this all means clinically is lacking. The manuscript needs important re-framing to avoid misleading the reader of the study conclusions.

Methods
-Line 58: It would be helpful if the authors would elaborate on the recruitment site that they describe as "institution's outpatient obstetric clinic." Is this the only obstetric clinic at the institution, i.e., are all potentially eligible patients being captured at this one clinic site? This is important to describe to assess generalizability, potential impacts of other practice patterns, and potential for selection bias.

-Lines 62-67: It would be helpful if the authors would provide definitions for some of the eligibility criteria. For example, does "diabetes medication use" mean metformin for PCOS? How was "chronic steroid use" defined?

-Lines 95-96: The authors should specify the timing of when the electronic survey was sent after the completion of the 1-hr GTT. Was it immediate, within 24 hours, or just any time after the completion of the 1-hr GTT? Similarly, how soon after the completion of the 1-hr GTT did the subject have to complete the survey to be considered valid? These details are important given the risk of recall bias and ability to accurately assess adherence to protocol.

-Lines 114-115: Were all babies followed through 28 days of life? What if they were discharged at DOL 2-3 and their pediatrician was not in the EMR system? Details about how babies are typically followed up at this institution would be helpful.

-Lines 117-126: The only pre-specified study outcome (according to clinicaltrials.gov website) was the 1-hr GTT screen positive rate. Not sure why the authors chose to examine so many secondary outcomes: 11 maternal outcomes and 10 perinatal outcomes. Based on the study sample size, these would all be exploratory at best, and many are not directly related to the study interventions. For example, not sure why IAI, HDP, and Apgar scores would be related to whether a patient fasted or fed for their 1-hour GTT.

-Lines 128-129: It would be helpful to know what the authors based the baseline rates for the sample size calculation on? Existing literature? Institutional data?

-Line 136: Should include chi-square tests.

-Line 150: Clarify what "first-trimester screen" means. I think the authors mean whether first-trimester GDM screening was done. This wording could be confused with other screening such as genetic screening.

Discussion:
-Lines 192-209: This paragraph is the most problematic in misleading the reader in the conclusion of the study. This reasoning sets the tone that all the patients who did not get diagnosed with GDM were correctly not diagnosed with GDM, and therefore the fasting state increased the false positive rate. However, this study did not actually confirm that subjects who tested negative on the 1-hr GTT (particularly in the fed group) correctly were not given the 3-hour GTT and truly did not have GDM. Although the difference in GDM diagnosis did not reach statistical significance, I am concerned that the frequency of GDM in the fasting group was double that of the fed group. If randomization was done correctly, the actual "real" frequency of GDM should be similar between groups. The fasting vs. fed state should only be impacting the screen test value. Further, if the screen positive rate is higher in the fasting state but it picks up more patients with GDM, that would be a good thing.

-Lines 214-215: The authors highlight their high survey completion rates in several sections. However, they also write the word "partially." What part of the survey completion was partial? And is the partial completion highlight an important omission?

Reviewer #2:

1. This is a prospective randomized trial to evaluate the effect of fasting prior to the gestational diabetes screening test. This question has been answered in previous publications. Although this is a well-executed study, it does not give information for inform unanswered questions; and it was not powered to inform the hypothesis.

2. Overall, it was well written.

3. Line 88: This part about the "high" versus "average" risk groups is confusing. I think they excluded patients that had an abnormal early GLT (glucose loading test), but did they include those who had the test as deemed by their risk

factors and it was normal? This is not clear from the text.

4. Line 102: Why did the authors use the Carpenter and Coustan criteria for diagnosing GDM, but did not use their cut off for the GLT (I believe their cut off was 130 mg/dL)

5. Line 161: Not sure the value of asking the patient what they thought would happen (did they think that fasting or fed would affect the test outcome). Why did they do this?

6. Line 163: Not sure why they asked patients whether they would prefer to be fasted or fed, I think the answer would be intuitive. Did they think to ask why 30% of the patients preferred to be fasted? Is it correlated with the patient's belief on whether fasting or fed state would affect the test?

7. Did the authors consider analyzing the type of food intake prior to the test, to see if there is a correlation between food type (CHO content or ratio) to test outcome.

8. Table 1: The demographics of the patients the preponderance of Asian and White race/ethnicity, low percentage of obesity as well as an extremely well resourced (94% privately insured) very much limits the generalizability of the findings.

STATISTICAL EDITOR COMMENTS:

Need to reconcile lines 12-17 and lines 127-132 to a consistent narrative re: the assumed (+) rates.

Abstract and Table 2: Since the primary outcome was defined as the 1-hr OGTT screen (+) rate and the sample size was based on a ≥ 20% difference in the rates for the two cohorts, then should cite the primary as the first outcome reported in Table 2 and formatted in terms of (1) the two rates and then (2) the difference in %s, along with its CIs. The other outcomes in Table 2, while of interest, were not the primary outcome and should be clearly separated from the primary. The differences in GDM diagnosis based on 1-hr OGTT ≥ 180 mg/dL or in Total GDM diagnoses each have small counts, so the NS comparisons cannot be generalized.

Table 1: Since the groups were randomized, there is no need to provide stats tests to compare them. Any difference is due to random chance.

Tables 3, 4: Same issue as in Table 2 in terms of stats power. Many of the counts are small and the NS findings cannot be generalized.

EDITORIAL OFFICE COMMENTS:

1. If your article is accepted, the journal will publish a copy of this revision letter and your point-by-point responses as supplemental digital content to the published article online. You may opt out by writing separately to the Editorial Office at em@greenjournal.org, and only the revision letter will be posted.

2. When you submit your revised manuscript, please make the following edits to ensure your submission contains the required information that was previously omitted for the initial double-blind peer review:
* Funding information (ie, grant numbers or industry support statements) should be disclosed on the title page and at the end of the abstract. For industry-sponsored studies, describe on the title page how the funder was or was not involved in the study.
* Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).
* Name the IRB or Ethics Committee institution in the Methods section (if applicable).
* Add any information about the specific location of the study (ie, city, state, or country), if necessary for context.

3. Obstetrics & Gynecology's Copyright Transfer Agreement (CTA) must be completed by all authors. When you uploaded your manuscript, each coauthor received an email with the subject, "Please verify your authorship for a submission to Obstetrics & Gynecology." Please ask your coauthor(s) to complete this form, and confirm the disclosures listed in their CTA are included on the manuscript's title page. If they did not receive the email, they should check their spam/junk folder. Requests to resend the CTA may be sent to em@greenjournal.org.

4. For studies that report on the topic of race or include it as a variable, authors must provide an explanation in the

manuscript of who classified individuals' race, ethnicity, or both, the classifications used, and whether the options were defined by the investigator or the participant. In addition, describe the reasons that race and ethnicity were assessed in the Methods section and/or in table footnotes. Race and ethnicity must have been collected in a formal or validated way. If it was not, it should be omitted. Authors must enumerate all missing data regarding race and ethnicity as in some cases missing data may comprise a high enough proportion that it compromises statistical precision and bias of analyses by race.

Use "Black" and "White" (capitalized) when used to refer to racial categories.

List racial and ethnic categories in tables in alphabetic order. Do not use "Other" as a category; use "None of the above" instead.

Please refer to "Reporting Race and Ethnicity in Obstetrics & Gynecology" at https://edmgr.ovid.com/ong/accounts/Race_and_Ethnicity.pdf.

5. ACOG uses person-first language. Please review your submission to make sure to center the person before anything else. Examples include: "People with disabilities" or "women with disabilities" instead of "disabled people" or "disabled women"; "patients with HIV" or "women with HIV" instead of "HIV-positive patients" or "HIV-positive women"; and "people who are blind" or "women who are blind" instead of "blind people" or "blind women."

6. The journal follows ACOG's Statement of Policy on Inclusive Language (https://www.acog.org/clinical-information/policy-and-position-statements/statements-of-policy/2022/inclusive-language). When possible, please avoid using gendered descriptors in your manuscript. Instead of "women" and "females," consider using the following: "individuals;" "patients;" "participants;" "people" (not "persons"); "women and transgender men;" "women and gender-expansive patients;" or "women and all those seeking gynecologic care."

7. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions and the gynecology data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

8. Make sure your manuscript meets the following word limit. The word limit includes the manuscript body text only (for example, the Introduction through the Discussion in Original Research manuscripts), and excludes the title page, précis, abstract, tables, boxes, and figure legends, reference list, and supplemental digital content. Figures are not included in the word count.

Original Research: 3,000 words

9. For your title, please note the following style points and make edits as needed:
* Do not structure the title as a declarative statement or a question.
* Introductory phrases such as "A study of..." or "Comprehensive investigations into..." or "A discussion of..." should be avoided in titles.
* Abbreviations, jargon, trade names, formulas, and obsolete terminology should not be used.
* Titles should include "A Randomized Controlled Trial," "A Meta-Analysis," "A Systematic Review," or "A Cost-Effectiveness Analysis" as appropriate, in the subtitle. If your manuscript is not one of these four types, do not specify the type of manuscript in the title.

10. Specific rules govern the use of acknowledgments in the journal. Please review the following guidelines and edit your title page as needed:

* All financial support of the study must be acknowledged.
* Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.
* All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form verifies that permission has been obtained from all named persons.
* If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting or indicate whether the meeting was held virtually).
* If your manuscript was uploaded to a preprint server prior to submitting your manuscript to Obstetrics & Gynecology, add the following statement to your title page: "Before submission to Obstetrics & Gynecology, this article was posted to a preprint server at: [URL]."
* Do not use only authors' initials in the acknowledgement or Financial Disclosure; spell out their names the way they appear in the byline.

11. Be sure that each statement and any data in the abstract are also stated in the body of your manuscript, tables, or figures. Statements and data that appear in the abstract must also appear in the body text for consistency. Make sure there are no inconsistencies between the abstract and the manuscript, and that the abstract has a clear conclusion statement based on the results found in the manuscript.

In addition, the abstract length should follow journal guidelines. Please provide a word count.

Original Research: 300 words

12. Abstracts for clinical trials should be structured according to the journal's standard format. The Methods section should include the primary outcome and sample size justification. The Results section should begin with the dates of enrollment to the study, a description of demographics, and the primary outcome analysis. Please review the sample abstract that is located online at http://edmgr.ovid.com/ong/accounts/sampleabstract_RCT.pdf and edit your abstract as needed.

13. Only standard abbreviations and acronyms are allowed. A selected list is available online at http://edmgr.ovid.com /ong/accounts/abbreviations.pdf. Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.

14. The journal does not use the virgule symbol (/) in sentences with words, except with ratios. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

15. ACOG avoids using "provider." Please replace "provider" throughout your paper with either a specific term that defines the group to which are referring (for example, "physicians," "nurses," etc.), or use "health care professional" if a specific term is not applicable.

16. In your abstract, manuscript Results sections, and tables, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001").

Express all percentages to one decimal place (for example, 11.1%"). Do not use whole numbers for percentages.

17. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available at http://edmgr.ovid.com/ong/accounts/table_checklist.pdf.

18. Please review examples of our current reference style at https://edmgr.ovid.com/ong/accounts/ifa_suppl_refstyle.pdf. Include the digital object identifier (DOI) with any journal article references and an accessed date with website references.

Unpublished data, in-press items, personal communications, letters to the editor, theses, package inserts, submissions, meeting presentations, and abstracts may be included in the text but not in the formal reference list. Please cite them on the line in parentheses.

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Please make sure your references are numbered in order of appearance in the text.

19. Figures 1-3: Please upload as figure files on Editorial Manager.

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If you choose to revise your manuscript, please submit your revision through Editorial Manager at

http://ong.editorialmanager.com. Your manuscript should be uploaded as a Microsoft Word document. Your revision's cover letter should include a point-by-point response to each of the received comments in this letter. Do not omit your responses to the EDITOR COMMENTS (if applicable), the REVIEWER COMMENTS, the STATISTICAL EDITOR COMMENTS (if applicable), or the EDITORIAL OFFICE COMMENTS.

If you submit a revision, we will assume that it has been developed in consultation with your coauthors and that each author has given approval to the final form of the revision.

Again, your manuscript will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Aug 19, 2022, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Jason D. Wright, MD
Editor-in-Chief

_____

September 19, 2022

Dear *Obstetrics & Gynecology* Editors-in-Chief:

On behalf of our investigators, I am writing to resubmit our manuscript entitled *Fasting versus fed: A randomized trial on oral intake prior to the 1 hour oral glucose tolerance test* for consideration as an *Obstetrics & Gynecology* research article.

There is limited evidence regarding the effect of oral intake prior to the 1 hour oral glucose tolerance test (OGTT) on screening results for gestational diabetes mellitus. We conducted a prospective randomized trial that randomized participants to either fast for 6 or more hours or to eat within 2 hours of the 1 hour OGTT to assess the screen positive rate, using a cutoff of 140 mg/dL. This trial was registered on clinicaltrials.gov, NCT04547023 and was approved by the Stanford Research Compliance Office Institutional Review Board (IRB-57772). We enrolled 200 patients between 11/2/2020 – 4/29/2021 through the Stanford University outpatient obstetrics clinic and found that fasting for at least 6 hours prior to the 1-hour OGTT more than doubled the incidence of a positive screen when compared with eating within 2 hours of the test (32.0% vs. 13.3%, respectively, P=.002). Mean glucose values were also significantly higher in the fasting group (127.7 mg/dL vs. 113.3 mg/dL, *P*=.002).

We are extremely appreciative of the reviewers' comments and feel they have strengthened our manuscript. Please see below for comments to each reviewer. We appreciate the continued consideration of our manuscript to your journal.

REVIEWER COMMENTS:

Reviewer #1: Thank you for the opportunity to review this manuscript entitled, "Fasting versus fed: A randomized trial on oral intake prior to the 1-hour oral glucose tolerance test." This is a randomized clinical trial that compares fasting for >=6 hours versus oral intake within 2 hours prior to the 1-hour GTT test and examines the impact on the frequency of GTT screen positivity. I was initially excited by the title and precis as this clinical question of timing of oral intake in relation to the 1-hour GTT has come up many times in my own clinical practice. This study has several strengths: mainly its randomized pragmatic study design and the stratification of randomization sequence based on "high" versus "average" risk for GDM, However, I have significant concerns about the study outcomes and the framing and presentation of study results.

On my first read of this manuscript, my initial summary of the findings was the following: fasting group had significantly higher rate of screen positivity and higher mean 1-hr GTT glucose value and therefore feeding before the 1-hr GTT is better because the false positive rate with fasting is higher. In fact, the conclusion of the manuscript is the following: "Based on the biologic plausibility of a prolonged fast creating an aberration in normal glucose metabolism in subjects without evidence of prior glucose intolerance, as well as there being no difference in maternal or neonatal outcomes in our study, it could suggest that fasting prior to the 1-hour OGTT leads to a higher false positive result, or potentially leads to a greater increase in the diagnosis of GDM in a subset of patients that is not clinically relevant to their pregnancy course and outcomes."

However, I believe this conclusion is misleading. This study merely shows that the fasting state resulted in higher 1-hr GTT screen positivity and higher mean GTT glucose value. Based on the study design, we do not know the "true" frequency of GDM in either group because the need for a 3-hour GTT was based on the result of the 1-hour GTT test which was impacted differentially

by the study intervention. In fact, the frequency of GDM was much higher in the fasting group compared to the fed group (12.4% vs. 5.1% respectively). While the p-value was not significant (p=0.08), this is likely more of a reflection of the small sample size. There was no other 'check' performed in the study to see if the difference in the 1-hour GTT values was better or worse for diagnosing GDM. The authors use the absence of significant differences in the maternal or neonatal outcomes as a proxy for good detection of GDM in both groups, however the sample size is small and would not be expected to detect significant differences in the more clinically important but less frequent outcomes. Looking at Table 3, most cells have less than 10 for the more clinically significant outcomes.

While some of the study findings are interesting, the follow-through to the next step of being able to determine what this all means clinically is lacking. The manuscript needs important re-framing to avoid misleading the reader of the study conclusions.

Response: Thank you for your thorough read of our manuscript and insightful comments. We agree that our study is only powered to assess the GDM screen positive rate and the mean glucose values. However, we are underpowered to detect a difference in GDM diagnosis or various maternal and neonatal outcomes. We have edited the manuscript to clarify these issues. We agree with the reviewer that larger studies are needed in order to inform the impact of oral intake on final GDM diagnosis. We reformatted Table 2 in order to show the difference between the 2 groups along with their 95% CIs as per the astute request of the statistical editor. When analyzing the final GDM diagnosis, the difference between the fasting and fed groups was 7.3% [95% CI -1.2%-16.2%] and P=.08. This finding could be a reflection of the small sample size, but we are unable to firmly make a conclusion without a larger study. We reframed our discussion section to address these issues as well.

Methods
-Line 58: It would be helpful if the authors would elaborate on the recruitment site that they describe as "institution's outpatient obstetric clinic." Is this the only obstetric clinic at the institution, i.e., are all potentially eligible patients being captured at this one clinic site? This is important to describe to assess generalizability, potential impacts of other practice patterns, and potential for selection bias.

Response: We thank the reviewer for this constructive comment. Yes, we recruited from our outpatient obstetrics clinic which is based out of a single site and encompasses general obstetrics and maternal-fetal medicine practices. We have added these details to the manuscript:
“Participants were recruited from Stanford’s outpatient obstetrics clinic in Palo Alto, CA which is a single site that encompasses both general obstetrics and maternal-fetal medicine practices.”

-Lines 62-67: It would be helpful if the authors would provide definitions for some of the eligibility criteria. For example, does "diabetes medication use" mean metformin for PCOS? How was "chronic steroid use" defined?

Response: Thank you for this comment. Yes, we excluded patients who have taken metformin or any medication for glycemic control prior to pregnancy. We have clarified this in the manuscript and listed examples (insulin, metformin, glyburide) and have also clarified that chronic steroid use was defined as a daily oral steroid use over 4 weeks in the past year by stating the following:
“We excluded patients with pre-gestational diabetes, gestational diabetes diagnosed in the first trimester during early screening per ACOG guidelines, patients with an elevated 1-hour OGTT prior to 24 weeks, those with diabetes medication use prior to pregnancy such as insulin, metformin, or glyburide, those receiving an oral steroid daily for over 4 weeks in the past year, a

history of bariatric surgery, and those less than 24 weeks of gestation at the time of the 1-hour OGTT."

-Lines 95-96: The authors should specify the timing of when the electronic survey was sent after the completion of the 1-hr GTT. Was it immediate, within 24 hours, or just any time after the completion of the 1-hr GTT? Similarly, how soon after the completion of the 1-hr GTT did the subject have to complete the survey to be considered valid? These details are important given the risk of recall bias and ability to accurately assess adherence to protocol.

Response: We thank the reviewer for this important comment. The survey was sent on the day the patient was to complete the 1-hr OGTT. We would call patients to confirm the date and time of their blood draw and then scheduled REDCap to send out a survey at the time of their scheduled draw. There was no time limitation in order to complete the survey. However, we would call patients the following day if their survey was not completed. We have added this information to the manuscript: "On the day participants were scheduled to complete the 1-hour OGTT, they were sent an electronic survey inquiring about the time of last oral intake and the type of oral intake prior to the test. In addition, participants were surveyed about their perception of the effect of fasting compared to eating on the screen result, and if given a choice, to which group would they have preferred to have been randomized. If a patient did not complete the survey on the day of their blood draw, they were called the following day to encourage completion."

In addition, we added the following text to clarify when patients completed the survey and the number of participants that only partially completed it: "All 195 participants, in addition to 1 participant who could not tolerate the 1-hour OGTT, partially (n=9, 4.6%) or fully (n=187, 95.4%) completed the post-test survey. 148 (75.5%) participants completed the survey on the same day as their blood draw and 176 (89.7%) completed the survey within 7 days of their blood draw (Appendix 1)."

We also created a supplementary table showing the completion rates for further clarification:

Appendix 1: Timing of survey response rate

Completion of survey from 1-hour OGTT	**Number of respondents (Total of n=196) n (%)**
Same day	148 (75.5)
1 day	8 (4.1)
2 days	8 (4.1)
3 days	3 (1.5)
4-7 days	9 (4.6)
8-14 days	8 (4.1)
< 4 weeks	3 (1.5)
4-8 weeks	6 (3.1)
>8 weeks	2 (1.0)

-Lines 114-115: Were all babies followed through 28 days of life? What if they were discharged at DOL 2-3 and their pediatrician was not in the EMR system? Details about how babies are typically followed up at this institution would be helpful.

Response: Thank you for this clarifying comment. We collected only inpatient neonatal data until 28 days of life. We revised the manuscript as follows: "Inpatient neonatal data were collected up to 28 days of life during the delivery hospitalization as long as the baby remained hospitalized or was readmitted within that time frame. Outpatient data were not collected."

-Lines 117-126: The only pre-specified study outcome (according to clinicaltrials.gov website) was the 1-hr GTT screen positive rate. Not sure why the authors chose to examine so many secondary outcomes: 11 maternal outcomes and 10 perinatal outcomes. Based on the study sample size, these would all be exploratory at best, and many are not directly related to the study interventions. For example, not sure why IAI, HDP, and Apgar scores would be related to whether a patient fasted or fed for their 1-hour GTT.

Response: Thank you for this constructive comment. Yes, we recognize that many of the secondary study outcomes are infrequent, but we analyzed them in order to see if there were any discernable differences that could be seen in one group or another. We analyzed hypertensive disorders of pregnancy because of the increased risk of HDP with GDM. We agree that IAI and Apgar scores are more of a stretch, and these have been removed from Tables 3, Table 4, and the manuscript.

-Lines 128-129: It would be helpful to know what the authors based the baseline rates for the sample size calculation on? Existing literature? Institutional data?

Response: We thank the reviewer for this clarifying comment. We calculated our sample size based on institutional data from the previous year the study was conducted which was an approximately a 35% screen positive rate on the 1-hr OGTT. In regards to the absolute difference in the screen positive rate, we extrapolated at least a 20% absolute difference in diagnosis based on an observational study by Hancerliogullari et al (2018) that showed an approximate 30% absolute difference in the screen positive rate in those who fasted for more than 6.5 hours versus those who fasted for less than this amount of time. Given that this was an observational study without any delineation on when patients fasted or ate, as well as > 50% of their population screening positive (much higher than our screen positive rates), we felt that a more conservative measure of a 20% difference would still be meaningful and practical. We edited the manuscript to reflect this: "To detect a difference of at least 20 absolute percentage points in the percent screen positive rate between the fasting and fed groups (presumed overall GDM positive screen incidence of 35% based on past institutional data, with an estimated screen positive rate of 45% in the fasting and 25% in the fed), we calculated the study would require 88 participants per group (total N=176), assuming two-sided α=0.05, power=0.8. A sample size of 100 participants per group (total n = 200) was then chosen in order to account for an approximate 10% attrition after initial enrollment."

-Line 136: Should include chi-square tests.

Response: Thank you for this comment. In consultation with our biostatistician, we used Fisher's exact test due to the small sample size and to be consistent for all categorical outcomes. As requested by the Statistical Editor, we added calculations for the mean difference in the screen positive rate with a 95% confidence interval. We therefore revised this section of the Methods: "For the primary outcome, we calculated the mean difference between the fasting and fed groups in the percentage of participants who screened positive, with a 95% confidence interval, and calculated the p-value using Fisher's exact test. We calculated p-values for differences in secondary outcomes using Fisher's exact test for categorical outcomes and the Mann-Whitney-Wilcoxon test for continuous outcomes."

-Line 150: Clarify what "first-trimester screen" means. I think the authors mean whether first-trimester GDM screening was done. This wording could be confused with other screening such as genetic screening.

Response: Thank you for this comment and its potential to confuse readers. We clarified the text in this section: “Baseline participant characteristics including age, pre-pregnancy body mass index (BMI), race/ethnicity, insurance status, first trimester GDM screening, family history of diabetes mellitus, and multiparity were similar between the two groups (Table 1).”

Discussion:
-Lines 192-209: This paragraph is the most problematic in misleading the reader in the conclusion of the study. This reasoning sets the tone that all the patients who did not get diagnosed with GDM were correctly not diagnosed with GDM, and therefore the fasting state increased the false positive rate. However, this study did not actually confirm that subjects who tested negative on the 1-hr GTT (particularly in the fed group) correctly were not given the 3-hour GTT and truly did not have GDM. Although the difference in GDM diagnosis did not reach statistical significance, I am concerned that the frequency of GDM in the fasting group was double that of the fed group. If randomization was done correctly, the actual "real" frequency of GDM should be similar between groups. The fasting vs. fed state should only be impacting the screen test value. Further, if the screen positive rate is higher in the fasting state but it picks up more patients with GDM, that would be a good thing.

Response: We thank the reviewer for this insightful critique. It is correct that this study is unable to confirm that subjects who tested negative on the 1-hour OGTT did not truly have GDM, and administering the 3-hour OGTT to all patients would really be the only way to deduce this. We had discussed that this would be an interesting next step to our study. In response to the additional comments, we agree that the original conclusion we made regarding GDM diagnosis was a bit far reaching, and we tempered this in the latest draft.

We think it is difficult to draw conclusions on the diagnosis of GDM in the fasting versus the fed state as we were not powered to assess that outcome, and drawing conclusions from a small number of patients in both groups is difficult (12 in the fasting and 5 in the fed arm), which has also been stated as a comment by the statistical reviewer. We edited table 2 in order to show the difference between the 2 groups with 95% CIs. For GDM diagnosis, the 95% CI spans from -1.2% - 16.2%.

-Lines 214-215: The authors highlight their high survey completion rates in several sections. However, they also write the word "partially." What part of the survey completion was partial? And is the partial completion highlight an important omission?

Response: Thank you for this comment requesting additional information. There were 196 patients who completed the survey. We had 195 patients total who completed the GDM screen. There was one patient who was unable to tolerate the 1-hour OGTT and took the survey. This has been added to our manuscript for greater clarity. We do not believe that the partial completion was an important omission as only 2 patients did not report the duration of their fast prior to the 1-hour OGTT.

For 196 surveys, 187 (95.4%) were fully completed. The surveys were missing the following information from 9 participants (each number reflects a different participant and the question(s) not answered):

- 1: How many meals do you typically eat in a day, including snacks?
- 2: How do you think fasting will affect the glucose testing results?
- 3: How many hours has it been since you ate or drank anything prior to the 1 hour oral glucose tolerance test? What did you last eat or drink?
- 4: Are you vegan?
- 5: If you had a choice to fast or eat prior to the test, which would you choose?
- 6: How many hours has it been since you ate or drank anything prior to the 1 hour oral glucose tolerance test?
- 7: What did you last eat or drink prior to the 1 hour oral glucose tolerance test?
- 8: What did you last eat or drink prior to the 1 hour oral glucose tolerance test? How do you think fasting will affect the glucose testing results?
- 9: If you had a choice to fast or eat prior to the test, which would you choose?

We also added a significant figure after the decimal point to the tens place per the editorial guidelines.

"All 195 participants, in addition to 1 participant who could not tolerate the 1-hour OGTT, partially (n=9, 4.6%) or fully (n=187, 95.4%) completed the post-test survey. 148 (75.5%) participants completed the survey on the same day as their blood draw and 176 (89.7%) completed the survey within 7 days of their blood draw (Appendix 1). Among participants, 19.6% (n= 38) thought fasting would increase the glucose level, 49.0% (n=95) thought fasting would decrease the glucose level, and 31.4% (n=61) thought fasting would not affect the glucose level. Given a choice between fasting or eating before the screen, 71.1% (n=138) of participants indicated a preference to eat without restriction prior to the OGTT and 28.9% (n= 56) indicated a preference to fast for 6 or more hours prior. (Figure 2). In addition, 42.9% (n=84) of respondents completed the 1-hour OGTT in a prior pregnancy, with 19.0% (n=16) reporting that a health care professional gave recommendations about oral intake before the test. Among these 16 participants, 43.8% (n=7) were instructed to fast or not eat for 8 hours or longer prior to the 1-hour OGTT in a prior pregnancy, 18.8% (n=3) were told to not eat for 1-2 hours prior, 18.8% (n=3) were instructed to limit oral carbohydrate intake, and 25.0% (n=4) did not specify the recommendation given (Figure 3)."

Reviewer #2:

1. This is a prospective randomized trial to evaluate the effect of fasting prior to the gestational diabetes screening test. This question has been answered in previous publications. Although this is a well-executed study, it does not give information for inform unanswered questions; and it was not powered to inform the hypothesis.

Response: We thank the reviewer for this comment. In regards to previous publications that have assessed the effect of oral intake prior to the 1-hour oral glucose tolerance test, the most well-known is the Coustan crossover study that we referenced in our manuscript (Coustan DR, Widness JA, Carpenter MW, Rotondo L, Pratt DC, Oh W. Should the fifty-gram, one-hour plasma glucose screening test for gestational diabetes be administered in the fasting or fed state? *American Journal of Obstetrics and Gynecology*. 1986;154(5):1031-1035. doi:10.1016/0002-9378(86)90744-1). In that study, patients with known gestational diabetes were compared to patients who were presumed to not have gestational diabetes. The authors found that those who fasted had a significantly higher mean glucose value in only those with known gestational diabetes and not in the group who was presumed to not have gestational diabetes. Our

prospective randomized trial showed that mean glucose values were higher in both those with gestational diabetes and those without.

Our hypothesis was that there would be a higher screen positive rate in participants who fasted rather than in those who ate within 2 hours of the 1-hour oral glucose tolerance test which we found to be true. We were powered to answer the primary aim of our study. Our secondary outcome, the diagnosis of gestational diabetes, we were not powered to answer this question.

2. Overall, it was well written.

Response: We thank the reviewer for this comment.

3. Line 88: This part about the "high" versus "average" risk groups is confusing. I think they excluded patients that had an abnormal early GLT (glucose loading test), but did they include those who had the test as deemed by their risk factors and it was normal? This is not clear from the text.

Response: Thank you for this clarifying comment. Please see line 84 that references our definitions of high and average risk groups:

"The high-risk group was defined as those who were identified by their primary obstetrician as warranting early GDM screening based on ACOG guidelines and completed a first trimester 1-hour OGTT but did not screen positive and, therefore, would be recommended to undergo repeat 1-hour screening after 24 weeks of gestation as part of routine screening. The average-risk group was defined as those who did not complete a first trimester 1-hour OGTT (because their primary obstetrician did not feel they met criteria for early screening) and were scheduled to complete the test after 24 weeks' gestation."

We excluded patients who had an abnormal early 1-hour OGTT, but we did include patients who had risk factors and had an early 1-hr OGTT that had a normal screen. We added the cutoff value in the paragraph of early 1 hour screening for further clarification as well as a statement that we excluded patients who screened positive on their early 1-hour OGTT. "Patients who completed a first trimester 1-hour OGTT and screened positive were excluded."

4. Line 102: Why did the authors use the Carpenter and Coustan criteria for diagnosing GDM, but did not use their cut off for the GLT (I believe their cut off was 130 mg/dL)

Response: We thank the reviewer for this comment. We used a cutoff of 140 mg/dL as this is what is used at our institution. In following with ACOG recommendations from Practice Bulletin 190 that states, "…in the absence of clear evidence that supports one cutoff value over another (ie, 130 mg/dL, 135 mg/dL, or 140 mg/dL) for the 1-hour glucose screening test, obstetricians and obstetric care providers may select one of these as a single consistent cutoff for their practice, using factors such as community prevalence rates of GDM when making their decision."

When designing the trial, we discussed potentially creating another study that would utilize the 130 mg/dL cutoff in order to identify an optimal cutoff for the 1-hour OGTT in the fasting or the fed state. However, given that our main objective was to analyze the screen positive rate in the fasting or the fed state, we felt that it was more feasible to use existing institutional cutoffs and felt comfortable with our current cutoff being supported by ACOG guidelines.

We clarified this as follows: “A screen positive result was defined as a glucose value ≥140 mg/dL which is the standard cutoff used for our institution.”

5. Line 161: Not sure the value of asking the patient what they thought would happen (did they think that fasting or fed would affect the test outcome). Why did they do this?

Response: Thank you for this question. We were interested in knowing how patients felt about oral intake prior to the test as it may affect how they would prepare for taking the test. There were patients who declined participation in the study because they felt that fasting or eating would change their results and were unwilling to be randomized because they only wanted to prepare in a particular manner (Figure 1). As most OGTTs outside of pregnancy are administered after a prolonged fast, we were also interested in gaining the patients’ perspective. In addition, it is valuable from the provider side to know that the majority of patients believe that fasting prior to the 1-hour OGTT will make no difference or decrease the glucose levels compared to those who eat within 2 hours of the test when our study shows the opposite result and is an opportunity for patient education (Figure 2).

6. Line 163: Not sure why they asked patients whether they would prefer to be fasted or fed, I think the answer would be intuitive. Did they think to ask why 30% of the patients preferred to be fasted? Is it correlated with the patient's belief on whether fasting or fed state would affect the test?

Response: Thank you for this comment. We did not think it was intuitive that patients would prefer to fast or eat prior to the test. Given that approximately 50% of patients believed that fasting would lead to lower glucose values, we were actually surprised that more people would still prefer to eat without restriction. We did not ask why the 30% of patients preferred to fast over eat prior to the test.

7. Did the authors consider analyzing the type of food intake prior to the test, to see if there is a correlation between food type (CHO content or ratio) to test outcome.

Response: Thank you for this comment. We did ask patients what they ate prior to the test. However, as patients ate at home and self reported on the survey, we did not collect reliable data on CHO or carb ratios and did not know the different serving sizes. Therefore, this was not a standardized food intake collection. The survey regarding timing from oral intake and last meal was primarily designed as an adherence tool to analyze whether participants were compliant with their randomization group.

8. Table 1: The demographics of the patients the preponderance of Asian and White race/ethnicity, low percentage of obesity as well as an extremely well resourced (94% privately insured) very much limits the generalizability of the findings.

Response: Thank you for your constructive comment. We acknowledge that generalizability due to differences in demographic makeup, as well as being from a single center, is a limitation of our study (Line 332). We added more specifics regarding ethnic and racial makeup as well as rates of private insurance coverage in the manuscript. “Furthermore, this was a single-center study and the demographic data of our cohort may be different than those seen among other centers, particularly centers who care for patients with different BMI levels, differing rates of private insurance coverage or racial and ethnic diversity, or absolute GDM rates.”

STATISTICAL EDITOR COMMENTS:

- Need to reconcile lines 12-17 and lines 127-132 to a consistent narrative re: the assumed (+) rates.

Response: Thank you for bringing this to our attention and we corrected this error. It was meant to be 45% in the fasting group and 25% in the fed for a total assumed incidence of 35% in the entire cohort as was discussed in lines 12-17. We reflected this in the manuscript. “To detect a difference of at least 20 absolute percentage points in the percent screen positive rate between the fasting and fed groups (presumed overall GDM positive screen incidence of 35% based on past institutional data, with an estimated screen positive rate of 45% in the fasting and 25% in the fed, we calculated the study would require 88 participants per group (total N=176), assuming two-sided α=0.05, power=0.8.”

- Abstract and Table 2: Since the primary outcome was defined as the 1-hr OGTT screen (+) rate and the sample size was based on a $\geq$ 20% difference in the rates for the two cohorts, then should cite the primary as the first outcome reported in Table 2 and formatted in terms of (1) the two rates and then (2) the difference in %s, along with its CIs. The other outcomes in Table 2, while of interest, were not the primary outcome and should be clearly separated from the primary. The differences in GDM diagnosis based on 1-hr OGTT $\geq$ 180 mg/dL or in Total GDM diagnoses each have small counts, so the NS comparisons cannot be generalized.

Response: Thank you for this constructive critique and suggestion. The table has been separated into the primary and secondary outcomes with the differences in % and 95% CIs reported. We also reported the percentage differences with the confidence intervals in the results section. “Using an intention-to-treat analysis, the screen positive rate in the fasting group was 32.0% (n=31) compared to 13.3% (n=13) in the fed group (*P*=.002) with a total absolute difference of 18.7% [95% CI 7.2%-30.1%].”

We agree that the total GDM diagnosis and those with $\geq$180 are small and therefore cannot be generalized and have also reflected the difference in GDM diagnosis between the 2 groups with the 95% CI to help reflect this. “The incidence of GDM in the fasting group was 12.4% (n=12) and in the fed group was 5.1% (n=5) (*P*=.08) with a total absolute difference of 7.3% [95% CI -1.2%-16.2%](Table 2).”

- Table 1: Since the groups were randomized, there is no need to provide stats tests to compare them. Any difference is due to random chance.

Response: Thank you for this comment. We deleted the p-values and mention of statistical testing

- Tables 3, 4: Same issue as in Table 2 in terms of stats power. Many of the counts are small and the NS findings cannot be generalized.

Response: Thank you for this comment. We agree that the counts are small and that these non significant findings are unable to be generalized. We were interested in seeing if there was a difference in outcomes based on the fasting and fed states that could potentially be attributed to a missed diagnosis of GDM in the fed group with complications that could arise because of untreated GDM. We agree that no steadfast conclusions can be drawn from such a small sample of participants. We are willing to place these tables into a supplemental section if desired.

EDITORIAL OFFICE COMMENTS:

1. If your article is accepted, the journal will publish a copy of this revision letter and your point-by-point responses as supplemental digital content to the published article online. You may opt out by writing separately to the Editorial Office at em@greenjournal.org, and only the revision letter will be posted.

Response: Thank you for this information. We agree to publishing a copy of this revision letter and our point-by-point responses as supplemental digital content.

2. When you submit your revised manuscript, please make the following edits to ensure your submission contains the required information that was previously omitted for the initial double-blind peer review:
* Funding information (ie, grant numbers or industry support statements) should be disclosed on the title page and at the end of the abstract. For industry-sponsored studies, describe on the title page how the funder was or was not involved in the study.
* Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).
* Name the IRB or Ethics Committee institution in the Methods section (if applicable).
* Add any information about the specific location of the study (ie, city, state, or country), if necessary for context.

Response: Thank you for this information.

- We added the funding information to the end of the abstract. It was already present on the title page.
- The clinical trial registration number is at the end of the abstract.
- The institution of "Stanford University" was added to the IRB content in the methods section.
- Palo Alto, CA was added for context.

"Participants were recruited from Stanford's outpatient obstetrics clinic in Palo Alto, CA, which is a single site that encompasses both general obstetrics and maternal-fetal medicine practices."

3. Obstetrics & Gynecology's Copyright Transfer Agreement (CTA) must be completed by all authors. When you uploaded your manuscript, each coauthor received an email with the subject, "Please verify your authorship for a submission to Obstetrics & Gynecology." Please ask your coauthor(s) to complete this form, and confirm the disclosures listed in their CTA are included on the manuscript's title page. If they did not receive the email, they should check their spam/junk folder. Requests to resend the CTA may be sent to em@greenjournal.org.

Response: Thank you for this information. All authors have now completed the CTA.

4. For studies that report on the topic of race or include it as a variable, authors must provide an explanation in the manuscript of who classified individuals' race, ethnicity, or both, the classifications used, and whether the options were defined by the investigator or the participant. In addition, describe the reasons that race and ethnicity were assessed in the Methods section and/or in table footnotes. Race and ethnicity must have been collected in a formal or validated way. If it was not, it should be omitted. Authors must enumerate all missing data regarding race and ethnicity as in some cases missing data may comprise a high enough proportion that it compromises statistical precision and bias of analyses by race.

Use "Black" and "White" (capitalized) when used to refer to racial categories.

List racial and ethnic categories in tables in alphabetic order. Do not use "Other" as a category; use "None of the above" instead.

Please refer to "Reporting Race and Ethnicity in Obstetrics & Gynecology" at https://edmgr.ovid.com/ong/accounts/Race_and_Ethnicity.pdf

Response: Thank you for this comment. "Black" and "White" are capitalized and "none of the above" is used. We also added the reason for collecting race and ethnicity data:

"Race and ethnicity were collected to determine if there were differences between the two study groups as ACOG has identified certain races and ethnicities as being more high risk for GDM[2]."

5. ACOG uses person-first language. Please review your submission to make sure to center the person before anything else. Examples include: "People with disabilities" or "women with disabilities" instead of "disabled people" or "disabled women"; "patients with HIV" or "women with HIV" instead of "HIV-positive patients" or "HIV-positive women"; and "people who are blind" or "women who are blind" instead of "blind people" or "blind women."

Response: Thank you for this comment. We have reread the manuscript and have ensure that person-first language has been used throughout the manuscript.

6. The journal follows ACOG's Statement of Policy on Inclusive Language (https://www.acog.org/clinical-information/policy-and-position-statements/statements-of-policy/2022/inclusive-language). When possible, please avoid using gendered descriptors in your manuscript. Instead of "women" and "females," consider using the following: "individuals;" "patients;" "participants;" "people" (not "persons"); "women and transgender men;" "women and gender-expansive patients;" or "women and all those seeking gynecologic care."

Response: Thank you for your comment. We have reread the manuscript to ensure that only inclusive language is used. We have used the word participants to describe our study population throughout the manuscript.

7. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions and the gynecology data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

Response: Thank you for this comment. We have reviewed the reVITALize definitions and are in agreement with the terms.

8. Make sure your manuscript meets the following word limit. The word limit includes the manuscript body text only (for example, the Introduction through the Discussion in Original Research manuscripts), and excludes the title page, précis, abstract, tables, boxes, and figure

legends, reference list, and supplemental digital content. Figures are not included in the word count.

Original Research: 3,000 words

Response: Thank you for this comment. We have ensured that the manuscript is within the 3,000 word limit.

9. For your title, please note the following style points and make edits as needed:
* Do not structure the title as a declarative statement or a question.
* Introductory phrases such as "A study of..." or "Comprehensive investigations into..." or "A discussion of..." should be avoided in titles.
* Abbreviations, jargon, trade names, formulas, and obsolete terminology should not be used.
* Titles should include "A Randomized Controlled Trial," "A Meta-Analysis," "A Systematic Review," or "A Cost-Effectiveness Analysis" as appropriate, in the subtitle. If your manuscript is not one of these four types, do not specify the type of manuscript in the title.

Response: Thank you for this information. We have ensured to not make the title a declarative statement or a question. There are no introductory phrases in the title. Terminology that should be avoided is not present in the title. We have included the term a “randomized trial” in our title to specify the type of manuscript.

Title: Fasting versus fed: A randomized trial on oral intake prior to the 1 hour oral glucose tolerance test

10. Specific rules govern the use of acknowledgments in the journal. Please review the following guidelines and edit your title page as needed:

* All financial support of the study must be acknowledged.
* Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.
* All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission was obtained from all individuals named in the acknowledgments.
* If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting or indicate whether the meeting was held virtually).
* If your manuscript was uploaded to a preprint server prior to submitting your manuscript to Obstetrics & Gynecology, add the following statement to your title page: "Before submission to Obstetrics & Gynecology, this article was posted to a preprint server at: [URL]."
* Do not use only authors' initials in the acknowledgement or Financial Disclosure; spell out their names the way they appear in the byline.

Response: We thank the editorial board for this information:
* The financial support of the study is acknowledged - This work was supported by pilot funding from the Stanford Diabetes Research Center (P30DK116074 – 1/1/2021 – 12/31/2021) as well as by funding from the Stanford University School of Medicine - Division of Maternal-Fetal Medicine.

* We did not use any manuscript preparation assistance.
* All persons who contributed to the work but not sufficiently to be authors are acknowledged and written permission was obtained.
* The study was presented as SMFM in 2022 and was reported in the acknowledgements: "Poster presentation at the 42nd Annual Pregnancy Meeting - Society of Maternal-Fetal Medicine meeting. Virtual. 2022."
* This manuscript was not uploaded to a preprint server prior to submitting this manuscript.
* We did not use only authors' initials in the acknowledgement or Financial Disclosure and spelled out their names the way they appear in the byline.

11. Be sure that each statement and any data in the abstract are also stated in the body of your manuscript, tables, or figures. Statements and data that appear in the abstract must also appear in the body text for consistency. Make sure there are no inconsistencies between the abstract and the manuscript, and that the abstract has a clear conclusion statement based on the results found in the manuscript.

In addition, the abstract length should follow journal guidelines. Please provide a word count.

Original Research: 300 words

Response: Thank you for this comment. We added the word count to the abstract as 300 words and have ensured that the statements and data in the abstract are also reflected in the body of our manuscript, tables, and figures. There are no inconsistencies between the abstract and the manuscript.

12. Abstracts for clinical trials should be structured according to the journal's standard format. The Methods section should include the primary outcome and sample size justification. The Results section should begin with the dates of enrollment to the study, a description of demographics, and the primary outcome analysis. Please review the sample abstract that is located online at http://edmgr.ovid.com/ong/accounts/sampleabstract_RCT.pdfand edit your abstract as needed.

Response: Thank you for the information above. The abstract has been edited in accordance to the guidelines posted.

13. Only standard abbreviations and acronyms are allowed. A selected list is available online at http://edmgr.ovid.com/ong/accounts/abbreviations.pdf. Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.

Response: Thank you for this online list. We have only used standard abbreviations and acronyms in the manuscript.

14. The journal does not use the virgule symbol (/) in sentences with words, except with ratios. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

Response: Thank you for this comment. We have removed the virgule symbol in sentences with words within the manuscript.

15. ACOG avoids using "provider." Please replace "provider" throughout your paper with either a specific term that defines the group to which are referring (for example, "physicians," "nurses," etc.), or use "health care professional" if a specific term is not applicable.

Response: Thank you for this comment. We have replaced the word provider with health care professional.

16. In your abstract, manuscript Results sections, and tables, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001").

Express all percentages to one decimal place (for example, 11.1%"). Do not use whole numbers for percentages.

Response: Thank you for these guidelines. We added the mean difference of a variable between the two groups for our primary and secondary outcomes in table 2 to show the effect size. We are not exceeding 3 decimal places for the P-Value. In addition, have ensured that all percentages are to one decimal place.

17. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available at http://edmgr.ovid.com/ong/accounts/table_checklist.pdf.

Response: Thank you for this comment. We have reviewed the checklist to ensure that the tables conform to the guidelines of the journal.

18. Please review examples of our current reference style at https://edmgr.ovid.com/ong/accounts/ifa_suppl_refstyle.pdf. Include the digital object identifier (DOI) with any journal article references and an accessed date with website references.

Unpublished data, in-press items, personal communications, letters to the editor, theses, package inserts, submissions, meeting presentations, and abstracts may be included in the text but not in the formal reference list. Please cite them on the line in parentheses.

If you cite ACOG documents in your manuscript, be sure the references you are citing are still current and available. Check the Clinical Guidance page at https://www.acog.org/clinical (click on "Clinical Guidance" at the top). If the reference is still available on the site and isn't listed as "Withdrawn," it's still a current document. In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript.

Please make sure your references are numbered in order of appearance in the text.

Response: Thank you for the information regarding the current reference style. We have updated the citing of the ACOG practice bulletin in the suggested format and also changed some of the lettering from all caps to lower case for 2 of the article titles.

"ACOG Clinical Document: Gestational Diabetes Mellitus. ACOG Practice Bulletin No. 190. American College of Obstetricians and Gynecologists. *Obstet Gynecol*. 2018;131(2):e49-e64. doi:10.1097/AOG.0000000000002501"

The references are numbered in order of appearance in the text.

19. Figures 1-3: Please upload as figure files on Editorial Manager.

Response: Thank you for this comment. The figures have now been uploaded as figure files.

20. Authors whose manuscripts have been accepted for publication have the option to pay an article processing charge and publish open access. With this choice, articles are made freely available online immediately upon publication. An information sheet is available at http://links.lww.com/LWW-ES/A48. The cost for publishing an article as open access can be found at https://wkauthorservices.editage.com/open-access/hybrid.html.

Response: Thank you for this information. We have opted not to publish as open access.

This research was presented as a poster presentation at the Society for Maternal-Fetal Medicine's 42nd Annual Pregnancy Meeting in February of 2022. During this time, we were contacted by Dr. Malavika Prabhu and Dr. Karen Gibbins, on the editorial board, who graciously encouraged us to submit this research to *Obstetrics & Gynecology*.

Each named author has substantially contributed to this research project and is in agreement with the content of the manuscript. Permission has been obtained from all persons named in the acknowledgements. The material presented is original research, has not been previously published and has not been submitted for publication elsewhere while under consideration.

Author declaration of transparency: The lead author affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

I, Meryl Sperling, have reviewed and edited the submission to omit any identifying information. I hereby submit this self-blinded manuscript for consideration in *Obstetrics & Gynecology*.

Thank you very much for your consideration.

Warm regards,

Meryl Sperling, MD MA
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[redacted]