RE: Manuscript Number ONG-22-928

Text-Based Breastfeeding Support Compared with Usual Care: A Randomized Controlled Trial

Dear Dr. Bender:

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 Jul 08, 2022, we will assume you wish to withdraw the manuscript from further consideration.

EDITOR COMMENTS:

1. Please clearly articulate that the primary outcome was negative. Further, the secondary analysis by race was likely underpowered. The focus of the manuscript should remain on the primary analysis with a more limited focus on the secondary outcomes.

REVIEWER COMMENTS:

Reviewer #1: This study investigates an important issue: does electronic breastfeeding support through text-messaging improve breastfeeding rates? The intervention, two-way text communication, was administered by one provider following text prompts. The major finding detailed in the study, as stated in the precis, is that text-based breastfeeding communication platform significantly improved breastfeeding exclusivity at 6 weeks postpartum for Black patients.

However, there are major gaps in information that need to be addressed. First, the intervention needs to be better described. Was the support limited to just texts or was there availability for the provider who was answering texts to provide follow up phone calls or additional office-based support? Also, while the manuscript states that to adequately power the study, they would like a sample size of 300, this size does not appear to have been met. Furthermore, the comparisons in Black patients specifically was not an outcome listed for the study and is not powered appropriately, with the total n being 114, and approximately 20 patients lacking data for comparison. There is also no description on how race and ethnicity information was gathered. Finally, the methods and results sections should be edited to provide a better flow to the manuscript.

Below are specific suggestions:

Introduction:
Overall, a thorough review. Line 47 is formatted to a separate paragraph for unclear reasons. Adding background on the racial and ethnic disparities in breastfeeding would make the introduction more robust.

Methods
Line 117 - Although an example text exchange is provided, more details on follow up texts would be helpful. What were the credentials of the person answering texts? How long did it take for texts to be answered? What was the protocol if solutions could not be found via text? Was there standardization of answers based on the content of the questions asked?

Line 123 - This describes how the study was powered to detect change in the population's rate of exclusive breastfeeding. It is unclear if the actual sample size meets this power criteria.

Lines 134 - 141 - Consider modifying where this content is placed in the manuscript.

Information on disparities in breastfeeding based on race/ethnicity should be placed in the introduction. The specific finding that black race was an effect modifier should be presented in results with supporting data.

In the methods, please also include a description of how race and ethnicity were identified. (https://jamanetwork.com/journals/jama/fullarticle/2776936)

Results
Lines 147-148: Consider reformatting the sentence as to not lead with numbers (https://www.aje.com/en/arc/editing-tip-using-numbers-scientific-manuscripts/).

Lines 177-179: Please include the numbers that make up the percentages to better understand the comparison of Black patients in the intervention and non-intervention group.

Lines 180 - 182: While it is clear that the comparison based on race was controlled for public insurance, are there any other modifying factors that could have influenced the comparison that were controlled for? The methodology behind choosing these factors should be detailed in the Methods section.

Line 185: The results state 60% lower, but the data is 66 - 20 = 46, which is closer to 40% lower.

Discussion
Lines 193 - The main outcome of detecting change in the population's rate of exclusive breastfeeding should be further discussed.

Tables 1 & 2 - would expect p-values for the comparisons and identification of the statistical comparisons used to show no difference in populations

Table 4 - This table will need to be edited for ease of processing information. Was total exclusive breastfeeding in black patients 27 out of 114 patients? This is what this table suggests. It is also unclear how the percentages that follow the n are calculated.

Reviewer #2:

193 - 197: Consider explaining more, why you only see significant improvement in breastfeeding uptake/reduction in disparity in Black patients with intervention vs. control. Is there a reduction in bias? Improved access?

149: Given later discussion of diverse cohort, may consider mentioning breakdown of racial/ethnicity data for entire study population.

242: Why more useful in high risk patient population? Black patients as inherently high risk? Given otherwise no difference in demographic or delivery characteristics. May consider re-phrasing?

244: Consider expounding more on this significant finding, which is predominantly focused on a specific racial group?

Reviewer #3: Authors set out to determine in text-based two way communication could improve breastfeeding exclusivity compared to usual text-based care through a RCT.

Introduction: well organized, clearly defines gap
Methods: Great use of pilot studies for feasibility. Power calculation statement needs to be updated. Are you trying to detect a 10% increase (40% to 50%) or a 50% increase (from 40% overall)? (Lines 123-127)

Result: nicely outlined

Conclusion: Well formatted. Contextualizes findings with what is known

STATISTICAL EDITOR COMMENTS:

lines 23-24: Need to show the rates for the intervention and control group and the resulting stats result, since this was the primary outcome.

lines 28-29: Regarding the difference in the intervention arm (39.5% vs 56.0%), then there is not only NS difference, but the comparison is underpowered, so it cannot be generalized from these data.

lines 118-119, 123-127: The primary outcome was defined for all intervention vs all usual care, it was not a priori based on subsets by race. Therefore, the comparisons by race are secondary outcomes and any that were NS were also underpowered, as seen by applying the calculation supplied by the Authors.

Table 1: Need units for gestational age.

Table 2: Need units for gestational age and for Max wgt loss.

Tables 1 and 2 included all patients and the assignment of treatment group was randomized. For the subset analyses by race, need to include Tables similar to #1 and #2 but for Blacks and for non-Blacks, to show the reader that the randomization of baseline characteristics was achieved. The treatment groups were randomized by blocks of 4, but not by race, so the treatment vs usual care groups may be randomly allocated, while subsets may not necessarily be randomized.

Table 3: Need to clearly separate the primary from all secondary outcomes. The column headings have incorrect totals, should be N = 93 and 92, not 106 and 110.

Table 4: See previous comments, these are all secondary outcomes and only one comparison was statistically significant at p < 0.05. The column totals are incorrect, should be N = 93 and 92. Need to include totals for each sub column, which are 43,50,50,42. This illustrates the issue of random allocation overall by treatment vs usual care, but within the Blacks, there were 43 intervention vs 50 usual care while for Non-Blacks, the proportion was reversed with 50 intervention and 42 usual care. Therefore to compare effect of intervention in one racial group vs another is biased by non random allocation of the intervention.

Fig 2: Should include extension of Flow diagram to show randomization among Black and non-Black subsets.

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. Clinical trials must include a data sharing statement. Please add the following questions and your answers to the end of the manuscript after the References section:

Authors' Data Sharing Statement
Will individual participant data be available (including data dictionaries)? No.
What data in particular will be shared? Not available.
What other documents will be available? Not available.
When will data be available (start and end dates)? Not applicable.
By what access criteria will data be shared (including with whom, for what types of analyses, and by what mechanism)? Not applicable.

8. Please add whether you received IRB or Ethics Committee approval or exemption to your Methods. Include the name of the IRB or Ethics Committee. If you received an exemption, explain why in this section.

9. 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.

10. 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

11. 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.

12. 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

13. 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.

14. 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.

15. 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.

16. 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.

17. 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.

18. 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.

19. 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.
20. Figures

Figure 1: Is permission needed to reprint these texts? Please upload as a figure file on Editorial Manager.

Figures 2-3: Please upload as figure files on Editorial Manager.

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If your article is accepted, you will receive an email from the Editorial Office asking you to choose a publication route (traditional or open access). Please keep an eye out for that future email and be sure to respond to it promptly.

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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 Jul 08, 2022, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Jason D. Wright, MD
Editor-in-Chief

2020 IMPACT FACTOR: 7.661
2020 IMPACT FACTOR RANKING: 3rd out of 83 ob/gyn journals

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To: Jason D. Wright, MD, Editor in Chief, Obstetrics and Gynecology

From: Whitney Bender, MD

Re: Manuscript ONG-22-928 entitled: “Text-Based Breastfeeding Support Compared with Usual Care: A Randomized Controlled Trial”

July 4, 2022

Dear Dr. Wright,

The following reviews were noted and we appreciate the opportunity to respond to the inquiries. We have addressed the comments to the best of our ability and revised the manuscript accordingly. We believe that this research is of significant interest to the readership of Obstetrics and Gynecology. Thank you for your consideration of our work.

We have enclosed the revised manuscript and included both a clean version as well as a version that highlights the changes made to the original manuscript (“track changes” version). The page numbers and lines listed below refer to the “track changes” version.

EDITOR COMMENTS:

1. Please clearly articulate that the primary outcome was negative. Further, the secondary analysis by race was likely underpowered. The focus of the manuscript should remain on the primary analysis with a more limited focus on the secondary outcomes.

Response: We have amended portions of the abstract and discussion to make these findings more obvious.

__________________________________________________________

REVIEWER COMMENTS:

Reviewer #1:
This study investigates an important issue: does electronic breastfeeding support through text-messaging improve breastfeeding rates? The intervention, two-way text communication, was administered by one provider following text prompts. The major finding detailed in the study, as stated in the precis, is that text-based breastfeeding communication platform significantly improved breastfeeding exclusivity at 6 weeks postpartum for Black patients

Reviewer 1/Comment 1: However, there are major gaps in information that need to be addressed. First, the intervention needs to be better described. Was the support limited to just texts or was there availability for the provider who was answering texts to provide follow up phone calls or additional office-based support?
Response: Thank you for identifying the need for additional information regarding the intervention. We have added a paragraph to page 7, lines 130-135 that reads: “These questions were responded to by the primary author on a daily basis. The primary author is a board-certified obstetrician gynecologist with a special interest in breastfeeding medicine. Questions and concerns were addressed on the same calendar day they were received via two-way text communication. There were no set standardized responses. In the rare instance that issues could not be remedied by text message, referrals for telehealth or in-person visits with lactation or healthcare providers were made.”

Reviewer 1/Comment 2: Also, while the manuscript states that to adequately power the study, they would like a sample size of 300, this size does not appear to have been met.

Response: Thank you for this inquiry. The sample size of 300 was the total that was required, assuming the loss to follow-up in the run in period. We did end up enrolling 300 subjects (line 165) and we were able to achieve our desired sample size of 190 (95 in each arm). This has also been clarified in line 142-143 of the methods.

Reviewer 1/Comment 3: Furthermore, the comparisons in Black patients specifically was not an outcome listed for the study and is not powered appropriately, with the total n being 114, and approximately 20 patients lacking data for comparison. There is also no description on how race and ethnicity information was gathered.

Response: Thank you for this comment. We had a planned stratified analysis by Black and non-Black race (line 158-159 in methods). These data were obtained from the EMR and based on self-report (lines 157-158 in methods).

Reviewer 1/Comment 4: Finally, the methods and results sections should be edited to provide a better flow to the manuscript.

Response: The methods and results sections have been edited at the reviewer’s suggestion.

Reviewer 1/Comment 5:
Below are specific suggestions:
Introduction: Overall, a thorough review. Line 47 is formatted to a separate paragraph for unclear reasons. Adding background on the racial and ethnic disparities in breastfeeding would make the introduction more robust.

Response: We have fixed the formatting error. Thank you for the suggestion on expanding our background. We have amended lines 51-63 to review the current literature on racial disparities in breastfeeding outcomes as follows:

“Currently, 84% of parents attempt breastfeeding with 25.6% of parents exclusively breastfeeding at 6 months and 35.3% of parents reporting some breastfeeding at 12 months.1 Black parents have a lower rate of breastfeeding initiation, continuation, and exclusivity compared to their non-Black counterparts.4,5

The vast difference in the rates of breastfeeding initiation, continuation, and exclusivity is suggestive of an imbalance between a parent’s desire to breastfeed and potential barriers or difficulties that may impact the parent’s ability to attain the goals set forth by those organizations. It has been reported that
black parents, in particular, may face a disproportionate number of barriers to successful breastfeeding.”

Reviewer 1/Comment 6: Methods: Line 117 - Although an example text exchange is provided, more details on follow up texts would be helpful. What were the credentials of the person answering texts? How long did it take for texts to be answered? What was the protocol if solutions could not be found via text? Was there standardization of answers based on the content of the questions asked?

Response: We have added a paragraph to page 7, lines 130-135 for additional clarification that reads: “These questions were responded to by the primary author on a daily basis. The primary author is a board-certified obstetrician gynecologist with a special interest in breastfeeding medicine. Questions and concerns were addressed on the same calendar day received via two-way text communication. There were no set standardized responses. In the rare instance that issues could not be remedied by text message, referrals for telehealth or in-person visits with lactation or healthcare providers were made.”

Reviewer 1/Comment 7: Line 123 - This describes how the study was powered to detect change in the population’s rate of exclusive breastfeeding. It is unclear if the actual sample size meets this power criteria.

Response: A sample size of 190 was required to detect a difference in our primary outcome. Although 216 subjects were randomized, we had data on the primary outcome for 185 subjects.

We have made amendments to the discussion to make it clear that we were underpowered to detect differences in secondary analysis and secondary outcomes.

Reviewer 1/Comment 8: Lines 134 - 141 - Consider modifying where this content is placed in the manuscript.

Information on disparities in breastfeeding based on race/ethnicity should be placed in the introduction. The specific finding that black race was an effect modifier should be presented in results with supporting data.

In the methods, please also include a description of how race and ethnicity were identified. (https://urldefense.com/v3/__https://jamanetwork.com/journals/jama/fullarticle/2776936__;!!JqxBPMkl7mU0UjWTV-kbNbjBnIxLgel4mTaI5Qgx-6V-BYQCuVZTvqN2FkmX8QH0Gxl6xttMY1M_ZzuwKE53jpt25 )

Response: As suggested with the amendments to the introduction, we have removed the line on racial disparities from the methods section.

We apologize for the lack of supporting data on the identification of effect modification. We have included an additional sentence in the Results. Lines 209-210 now read: “Black race was found to be an effect modifier after comparing stratum specific estimates for non-Black race and Black race using a test of homogeneity”
We apologize for the lack of clarification on racial identification; this omission has been corrected. Lines 157-158 in the Methods section now reads, “Race and ethnicity were abstracted from the electronic medical record (EMR). This data is self-reported at time of patient registration in the health system. We performed a planned stratified analysis by Black and non-Black race.”

Results
Reviewer 1/Comment 9: Lines 147-148: Consider reformatting the sentence as to not lead with numbers (https://urldefense.com/v3/__https://www.aje.com/en/arc/editing-tip-using-numbers-scientific-manuscripts/__JqxBPMk!imU0UjWTv-kbNbjBnJxLgel4mTal5Qgx-6V-BYQQCuvZTVvqN2FkmX8QH0Gxul6xttMY1M_ZzuwlKLI4BP9$).

Response: This sentence has been reformatted to read “At the time of study enrollment, ninety-four percent of subjects intended to exclusively breastfeed.”

Reviewer 1/Comment 10: Lines 177-179: Please include the numbers that make up the percentages to better understand the comparison of Black patients in the intervention and non-intervention group.

Response: The amended sentence now reads “However, when limiting the analysis to subjects who identify as Black, a statistically higher proportion of patients in the intervention group were exclusively breastfeeding at 6 weeks postpartum when compared to patients in the usual care group (17/43, 39.5% v. 10/50, 20.0%, \( p =0.039 \)).”

Reviewer 1/Comment 11: Lines 180 - 182: While it is clear that the comparison based on race was controlled for public insurance, are there any other modifying factors that could have influenced the comparison that were controlled for? The methodology behind choosing these factors should be detailed in the Methods section.

Response: Thank you for this inquiry. The reviewer makes an important point. As this was a randomized trial, there were not surprisingly no differences in demographic or clinical differences between the intervention and control group either overall or when stratified by race. We had originally thought that readers would want to ensure that results were not different when controlling for insurance, even though it was not a true confounder. After additional consideration, we have decided to remove that sentence, since insurance was not a true confounder statistically, nor did it impact the overall effect size when forced into the model.

Reviewer 1/Comment 12: Line 185: The results state 60% lower, but the data is 66 - 20 = 46, which is closer to 40% lower.

Response: We appreciate the opportunity for clarification on this statement. The sentence incorrectly quoted an absolute % reduction. We have now included odds ratio to better represent this difference. The amended paragraph on Page 10, lines 223-227 now read “As noted in Table 4, the odds of breastfeeding exclusivity were 87% lower for Black subjects in the usual care arm compared to non-Black subjects (20.0% v. 66.7%, OR 0.13, 95% CI 0.05-0.32, \( p <0.0001 \)). In the intervention arm, the magnitude of difference in breastfeeding exclusivity was much less with no statistical difference between Black and non-Black breastfeeding rates (39.5 vs. 56.0%, OR 0.51, 95% CI .22-1.18, \( p=0.11 \)).”
Discussion
Reviewer 1/Comment 13: Lines 193 - The main outcome of detecting change in the population's rate of exclusive breastfeeding should be further discussed.

Response: The first sentence of the discussion section has been amended to explicitly state the following: “This randomized trial found that a postpartum text-based communication platform did not alter rates of breastfeeding exclusivity in the overall population”

Reviewer 1/Comment 14: Tables 1 & 2 - would expect p-values for the comparisons and identification of the statistical comparisons used to show no difference in populations

Response: Thank you for this comment. Based on the CONSORT guidelines regarding standardized and transparent reporting of trials, p-values are not generally included for tables presenting baseline data within a randomized trial. The authors were following these guidelines; however, we would be happy to add in the p-values at the editor’s discretion.

Reviewer 1/Comment 15: Table 4 - This table will need to be edited for ease of processing information. Was total exclusive breastfeeding in black patients 27 out of 114 patients? This is what this table suggests. It is also unclear how the percentages that follow the n are calculated.

Response: Additional headings have been created to separate primary outcomes from secondary outcomes. We have also included the n for intervention and usual care with the Black and non-Black groups.

Reviewer #2:
Reviewer 2/Comment 1: 193 - 197: Consider explaining more, why you only see significant improvement in breastfeeding uptake/reduction in disparity in Black patients with intervention vs. control. Is there a reduction in bias? Improved access?

Response: Thank you for this question. We have added an additional paragraph in the discussion with our speculations on this on page 13, lines 297-304. “The reason for differential effect in our Black v. non-Black study population remains unclear. Prior studies have suggested that Black mothers report needing more specific information on breastfeeding; it is possible that the informational content provided in the intervention arm was able to fill this knowledge gap. The supportive and motivational content presented in the intervention arm may also have altered breastfeeding perceptions among our Black subjects. Similarly, this content may have provided a surrogate support system for Black subjects who may be lacking in personal or professional breastfeeding assistance. This is an area for future exploration.”

Reviewer 2/Comment 2: 149: Given later discussion of diverse cohort, may consider mentioning breakdown of racial/ethnicity data for entire study population.

Response: This information has been added to Table 1 and Figure 2.
Reviewer 2/Comment 3: 242: Why more useful in high risk patient population? Black patients as inherently high risk? Given otherwise no difference in demographic or delivery characteristics. May consider re-phrasing?

Response: This has been rephrased to say “In summary, although this study found no benefit to the overall population, this data supports the use of breastfeeding text messaging and mobile support by postpartum care providers for Black patients, a group known to have lower rates of breastfeeding initiation, exclusivity, and duration.”

Reviewer 2/Comment 4: 244: Consider expounding more on this significant finding, which is predominantly focused on a specific racial group?

Response: See our response to comment 1.

Reviewer #3: Authors set out to determine in text-based two way communication could improve breastfeeding exclusivity compared to usual text-based care through a RCT.

Introduction: well organized, clearly defines gap

Methods: Great use of pilot studies for feasibility.
Reviewer 3/Comment 1: Power calculation statement needs to be updated. Are you trying to detect a 10% increase (40% to 50%) or a 50% increase (from 40% overall)? (Lines 123-127)

Response: We have amended this sentence to read: “Enrollment of 95 subjects in each group was required to detect a 50% increase in exclusivity to 60% a two-sided alpha level of 5% and a power of 80%.”

Result: nicely outlined

Conclusion: Well formatted. Contextualizes findings with what is known

STATISTICAL EDITOR COMMENTS:

Statistical Editor Comment 1: lines 23-24: Need to show the rates for the intervention and control group and the resulting stats result, since this was the primary outcome.

Response: We have added this information. The line now reads “Among the185 subjects (85.6%) with data available for the primary outcome, there was no difference in breastfeeding exclusivity by treatment group (Intervention 48.4% v. Usual Care 41.3%, p =0.33).”

Statistical Editor Comment 2: lines 28-29: Regarding the difference in the intervention arm (39.5% vs 56.0%), then there is not only NS difference, but the comparison is underpowered, so it cannot be generalized from these data.
Response: Thank you for this comment. This comparison specifically looks at a racial disparity, e.g. closing the gap between the two racial groups when comparing intervention and usual care groups. In the usual care group, there was a 4-fold difference in the primary outcome (20% versus 66.7%) which was no longer present in the intervention arm. Understanding that we are underpowered, there is still a reduction in the magnitude of the difference and this was confirmed by evaluating an interaction term (noted in the methods, lines 158-161 and in the results, lines 209-210). We have changed the wording in the abstract from “enrollment in the intervention arm eliminated the Black/non-Black disparity” to “enrollment in the intervention arm decreased the Black/non-Black disparity.”

Statistical Editor Comment 3: lines 118-119, 123-127: The primary outcome was defined for all intervention vs all usual care, it was not a priori based on subsets by race. Therefore, the comparisons by race are secondary outcomes and any that were NS were also underpowered, as seen by applying the calculation supplied by the Authors.

Response: This is correct. We have made amendments to the discussion to make it clear that we were underpowered to detect differences in secondary analysis and secondary outcomes.

Statistical Editor Comment 4: Table 1: Need units for gestational age.

Response: This omission has been corrected

Statistical Editor Comment 5: Table 2: Need units for gestational age and for Max wgt loss.

Response: This omission has been corrected.

Statistical Editor Comment 6: Tables 1 and 2 included all patients and the assignment of treatment group was randomized. For the subset analyses by race, need to include Tables similar to #1 and #2 but for Blacks and for non-Blacks, to show the reader that the randomization of baseline characteristics was achieved. The treatment groups were randomized by blocks of 4, but not by race, so the treatment vs usual care groups may be randomly allocated, while subsets may not necessarily be randomized.

Response: Additional tables (supplemental Table 1 and Supplemental Table 2) have been added to the manuscript and include this baseline information.

Statistical Editor Comment 7: Table 3: Need to clearly separate the primary from all secondary outcomes. The column headings have incorrect totals, should be N = 93 and 92, not 106 and 110.

Response: Additional headings have been created to separate primary outcomes from secondary outcomes. These subsections are also more clearly labeled with n for that particular outcome.

Statistical Editor Comment 8: Table 4: See previous comments, these are all secondary outcomes and only one comparison was statistically significant at p < 0.05 The column totals are incorrect, should be N = 93 and 92. Need to include totals for each sub column, which are 43,50,50,42. This illustrates the issue of random allocation overall by treatment vs usual care, but within the Blacks, there were 43 intervention vs 50 usual care while for Non-Blacks, the proportion was reversed with 50 intervention and 42 usual care. Therefore to compare effect of intervention in one racial group vs another is biased by non random allocation of the intervention.
Response: We appreciate the need for clarification. Additional headings have been created to separate primary outcomes from secondary outcomes. These subsections are also more clearly labeled with n for that particular outcome.

Statistical Editor Comment 9: Fig 2: Should include extension of Flow diagram to show randomization among Black and non-Black subsets.

Response: The suggested change has been made.

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: Noted.

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: We have no funding information to disclose. Clinical trial number was added to line 36 of the abstract. IRB is now specifically named in Methods in Lines 79-80.

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: Noted.

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: Race was felt to be an important demographic variable given reported disparities in Black v. non-Black breastfeeding rates as noted in lines 52-53. Race and ethnicity are self-reported by the patient on registration to the health system; this information was abstracted from the EMR. This is noted in Methods lines 148-149. Table 1. Demographic Characteristics has been amended to demonstrate more detailed breakdown of racial categories in alphabetical order at request of reviewer #2. We chose to group non-Black subjects for analysis of breastfeeding outcomes by race given small number of non-Black, non-White subjects and prior breastfeeding literature on Black v. non-Black subjects.

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: Noted.

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: Noted

7. Clinical trials must include a data sharing statement. Please add the following questions and your answers to the end of the manuscript after the References section:

Authors' Data Sharing Statement
Will individual participant data be available (including data dictionaries)? No.
What data in particular will be shared? Not available.
What other documents will be available? Not available.
When will data be available (start and end dates)? Not applicable.
By what access criteria will data be shared (including with whom, for what types of analyses, and by what mechanism)? Not applicable.

Response: This information has been added to Page 16 Lines 332-337.

8. Please add whether you received IRB or Ethics Committee approval or exemption to your Methods. Include the name of the IRB or Ethics Committee. If you received an exemption, explain why in this section.

Response: This information has been added to Methods lines 79-80.

9. 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: Noted

10. 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: Our word count is 2913.

11. 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.

Response: Noted.

12. 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: Noted. Abstract word count is 300.

13. 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](http://edmgr.ovid.com/ong/accounts/sampleabstract_RCT.pdf) and edit your abstract as needed.

Response: Noted.

14. Only standard abbreviations and acronyms are allowed. A selected list is available online at [http://edmgr.ovid.com/ong/accounts/abbreviations.pdf](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: Noted.

15. 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: Noted. These symbols have been removed from manuscript text.
16. ACOG avoids using "provider." Please replace "provider" throughout your paper with either a specific term that defines the group to which you are referring (for example, "physicians,
"nurses," etc.), or use "health care professional" if a specific term is not applicable.

Response: Noted. This wording has been removed.

17. 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: Noted. Odds ratios have been added to key results in the result section.

18. 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: Noted.

19. 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.

Response: Noted and formatted as directed.

20. Figures
Figure 1: Is permission needed to reprint these texts? Please upload as a figure file on Editorial Manager.

Response: These are internet generated replications of actual text conversations. No permission is needed.

Figures 2-3: Please upload as figure files on Editorial Manager.

Response: Noted and corrected.

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