PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Positive deviance for promoting dual-method contraceptive use among women in Uganda: A cluster randomized controlled trial
AUTHORS	Kosugi, Hodaka; Shibanuma, Akira; Kiriya, Junko; Ong, Ken; Mucunguzi, Stephen; Muzoora, Conrad; Jimba, Masamine

VERSION 1 – REVIEW

REVIEWER	Osuafor, Godswill University of Venda
REVIEW RETURNED	01-Feb-2021

GENERAL COMMENTS	General Comment: I want to thank the editor in-chief Of BMJ for the opportunity to review the manuscript on the above title. The topic is very relevant especially in the study setting. The thrust of the study was on promoting dual-method contraceptive use. Data for the study were collected at four intervals. I would have suggested the longitudinal analyses should be applied to the data rather than cross-sectional. In addition, the analyses have so many results which do not add to the objective of the study. The introduction was focusing on sub-Saharan Africa, which gives the impression that the authors have not critically reviewed studies on dual-method use by countries in SSA. The methodology section did describe exhaustively what the study was doing. Some of the things measured or found in the result section did not reflect in the methodology. The reporting of the results should be balanced. Where the control group outperformed the intervention group should be reported as well. The whole manuscript reads like a thesis instead of journal article. The authors should refocus the study on the topic and consider using some of the results to develop another manuscript, there is strong possibility for that. Some of my comments are outlined below in bold. Line 20 Abstract Line 31-33: The statement is not very clear: Primary and secondary outcome measures: The primary outcome was dual-method contraceptive use which was measured in two timeframes: Does it mean in any two of two-, four-, six-, and eight-month follow-up surveys? “dual-method contraceptive use at the last sexual

	intercourse and its consistent use in the two months prior to each follow-up". When was last sexual intercourse measured? Last sexual intercourse? Line 36 : Results: Given that way the outcome is framed, it requires specific expression of percentage or proportion, not just more women in the intervention group. It was not clear how many were in the intervention group compared to the control group. More women in the intervention used dual method at two- and eight-months surveys compared to the control group. What happened at fourth and sixth months? Furthermore, there was a secondary outcome. But the results section was silent about it. Why? Intervention effect lasted throughout the follow up? How were the intervention effects measured and what informed that it lasted? Line 42: Conclusion. What does Positive deviance mean to lay man in simple term? Line 47- 59: Strength and limitation Line 62: Introduction The introduction was based in sub-Saharan Africa (SSA) in terms of unintended pregnancy and HIV thereby creating good impression for the study on dual-method use. It would be better if the new cases of HIV prevalence were about women of reproductive age not just adults. That would make the claim "In SSA, therefore, women of reproductive age bear the dual burden of unintended pregnancies and HIV". Line 74-75: Despite the high incidence rate of HIV, it is not commonly practiced in SSA, especially among women in long-term relationships. What is not commonly practiced in SSA? The thrust of the study in Uganda, since the authors focused on SSA in building their case, there is a need to look for more studies on dual-method use and condom use among married and cohabiting women in SSA countries. One study in Zimbabwe is not enough. Refer to African Journal of Reproductive Health / La Revue Africaine de la Santé Reproductive Vol. 21, No. 1 (March 2017), pp. 64-72 (9 pages); Condom use among married and cohabiting women and its implications for HIV infection…… Journal of Population Research 35(1) DOI: 10.1007/s12546-017-9195-2 etc. Line 88-89: "Effectiveness of behavioral change interventions on the dual-method use among married or in-union women remains lacking." Where is it lacking? Line 101: Method

	I think that study design and setting section should make mention of the population in the study area. Since it is about setting, put in some demographics of the people, the nature of the activities of the people. The mentioning of the health facilities and services they provide were very much acceptable. Juxtaposing characteristics of the study settings and health facilities, one would be wondering if the people actually need intervention. The prevalence of unintended pregnancy and HIV of the study area in my view should form part of the introduction. It should also need to show the prevalence of dual method use in the area if available. In the introduction, it would strengthen the need for the intervention in the study area. Then by the end of the study one should know if the us of dual method has increased, thus giving credit to the intervention in relation to the study objectives. Line 111: Study participants and enrollment. This section presented sample size of 960. It should be good to present the population that participated in the intervention and control groups. Line 139: Intervention. I think the story of how intervention was developed is too long. Line 140-158. It should be better to state clearly the intervention components. Line 159-160 talked about women received counseling focusing on dual-method contraception in addition to regular family planning counseling. What were the key messages in the counselling package? The counselling messages were they the same with the handout given to the women? What were the quotes from the PDs? Line 163-164: Trained research assistants delivered the counseling for about 20 to 30 minutes. Women to intervention group. Line 184-186 counselling on contraceptive use, from female research assistants was 10 to 20 minutes for control. I think this has introduced bias in the two groups. The difference should be on PDs. Everything should be consistent between the two groups. It should be pointed out as a limitation. Line 198: Outcome. The way the responses were measured need to be made more clearer. The primary outcome was dual-method contraceptive use, which was defined as the application of a male or female condom along with an HEC, such as injectables, implants, intrauterine devices, pills, and female sterilization. If the question was about last sexual intercourse, how was it posed? If asked well it should produce “Yes” or “No” answer. The second part of the outcome talked about consistent use dual method use in the last two months before the each follow up. The questions reads “Apart from condoms, have you been using any other forms of protection against pregnancy during the past two months?” This again should produce a “Yes” or “No” answer. Line 209-210: The frequency of condom use was asked with an item: “How often did you and your partner use a male or female condom during the past two months? The authors never stated that

	they would measure frequency of condom use. Which aspect of the objective was this addressing? Line 214-220: Talks about the secondary outcomes. The responses to these were not clearly stated how they were measured. These secondary outcomes may stand alone as another study as they were not reflected in the title. Line 229-231: “Instead, the more measurable outcome of HIV/STI risk communication was added as a possible predictor of dual-method contraceptive use”. This was mentioned as secondary outcome in the abstract, here it is presented as predictor. It may be removed as an outcome and base the study outcome on dual-method use. Line 227-229: An outcome for STI incidence was omitted because we found that the reliability of self-reported STI incidence could be low among the participants during the data collection. Instead, the more measurable outcome of HIV/STI risk communication was added as a possible predictor of dual-method contraceptive use. This is a bit confusing. The authors may have a rethink of what the study was set to measure. Line 232: Data collection. This section is very wordy. Of all that was written, the authors did not mention what was collected as data. It should be made sharper. The authors should look at the outcome section and separate the outcome and data collection process. Under outcome, line 221-230, were about variables deemed as predictors. Therefore, there is a need to sanitize the section in terms of variables included in it. Line 244: Data analysis. Line 261: Ethics. Was this study approved by any recognized research body? Line 273: Results. It is a bit difficult to follow the reporting of the results. I do not see the need for model 1 and model 2 analyses especially in Tables S3 to S17 in the study. The authors should concentrate on model 3 and remove the models 1 and 2 as I do not see their usefulness. Some of the results presented are not relevant to the topic of the study. Line 175: Counselling received three, five, and seven months after enrollment. Line 278 Counseling received at counseling at three, five, and eight months after enrollment. Need to be reconciled.

	Line 279-280: Women in the intervention group were more likely to respond at two months (79.8% vs. 73.1%, p = 0.015) and four months (84.6% vs. 79.4%, p = 0.036). What happened at fourth month and sixth month? Line 281-283 The baseline characteristics were compared between women followed up and those lost to follow-up in each group. Which group? Those that were lost, were they regarded as participants at the end? The comparison of characteristics would be more appropriate for the intervention and the control groups. That should be clearly done in table 2. Table 2 presents the sociodemographic characteristics of 960 women at baseline. All of a sudden Characteristics were similar for the intervention and control groups with a few slight imbalances. It gives impression of a different study altogether. Line 305-307 : However, pregnancy incidence was not significantly different between the groups. Throughout the data collection period, 6 and 15 women became pregnant in the intervention and control groups, respectively. What does this tell us about dual-method use consistence among the intervention group? Line 329: Discussion: The discussion of the study reads like a literature review and mixed with results. Line 338-340 : In the intervention group, 43% and 16% of women reported the dual-method use at the last sexual intercourse and its consistent use, respectively. This should be in result section. Line 343- 344 : The observed effect was consistent with a previous intervention study that combined case management and peer education program for adolescent girls in the USA. This need to be referenced. Line 344-345: The intervention illustrated continued effects on the dual-method use at 12 and 24 months after enrollment. How was this accounted for because the study lasted for 8 months?

REVIEWER	Demie, Takele Saint Paul's Hospital Millennium Medical College, Department of Public Health
REVIEW RETURNED	04-Mar-2021

GENERAL COMMENTS	Dear Editor, Thank you for inviting me and for the opportunity to review this manuscript. I have gone through the manuscript and it is interesting! It is an important topic and understanding more about the Positive deviance for promoting dual-method contraceptive use among women in Uganda: A cluster randomized controlled trial that will contribute much to the literature.

	That said I have several major and minor suggestions to improve this paper: Title The phrase "Positive deviance" is difficult to understand and it may affect the readability of the paper by the general public despite it is interesting for the scientific community. Abstract Despite the abstract was structured, it good to separate the topics using a colon. For instance, placing a colon after Objectives, design, setting, etc. is good. it is a single objective that you wrote but it says "Objectives" Highly effective contraceptives are relative and questionable. Outcome measures How the outcomes were measured? What statistical analysis was performed (including mixed-effects logistic regression analysis)? Results Please include the result of the secondary outcome measure (not included in the results). it is also not considered in the objective above Conclusions The conclusion is only about the primary outcome variable. Recommendations should be there (Not included). In general, the abstract is well structured but not well informative for the general reader (make it comprehensive since it is also a standalone paper by itself). Despite keywords are very important for visibility and indexing and later for literature search, they are not included. please include them below the Abstract Strengths and limitations of this study Better to specify the type of measurement errors (Line 48/49, page 4) Specify the mixed-effects logistic regression analysis performed (line 52, page 4) Introduction On-Page 5, line 72 Highly effective is used which is highly subjective and/or relative. It also needs an Operational definition. Which of contraceptive methods are highly effective and why? They may and may not be highly effective for pregnancy prevention/birth spacing. How do you see this? On line 89 (page 5), at the end of the last sentence, the citation of reference(s) is/are important. Methods Study design and settings (page 6)

	Under the study design and settings, in methods, it is good to add the total population of the district specifying the Women in the age category of 18-49, or at least in their reproductive age. Study participants and enrollment (page 7) Starting from line 112; It is good that the first paragraph under the study participants and enrollment should be placed under the study design and settings in the methods section; indicating that how the HFs and Participants were selected. How the 20 Health facilities (HFs) were selected out of 48 is not clear I think women are the participants, not the HFs, though they were selected from those HFs. Specifically, women who visited the family planning sections of the selected health facilities were the study population (page7, paragraph 2, from line 118 onwards). Again on line 124 of page 7, the works of literature from the USA were considered for the variables considered in the formula for sample size calculation, which is a different setting and not comparable with Uganda. Have you searched for similar pieces of literature in similar (in (socioeconomic status) and/or comparable settings from Low-income countries? Moreover, please specify the sample size calculation formula. Every third woman was approached for selecting the sample. However, the sampling technique should be boldly clear. Which random sampling technique was applied? Are the authors considered every third woman at each HFs? and why? [on the same page, line 128] Randomization and masking Are the HFs or the Women in Union that should be randomized? I believe that the sampled population should be randomized. The flow chart for patient allocation (figure 1) also indicated that. Under the method, on line 136/137, you wrote "Blinding was not feasible in this study". However, there is blinding of the research Assistant. This should be clarified; You may not mask the HFs, but the women (page 8). "The handout included several quotes from the PDs." From line to 165-166 of page 9; Could you please include some of the quotes from the PDs (or a summary form? [page 9] Data collection On page 12, line number 242 to 243; you wrote that "The participants received incentives worth 20,000 UGX (equivalent to 6 USD) for their time after the baseline interview." Since participation is voluntary, don't you think that this may negatively affect the result of the study? [Page 12] Data analysis Should it be all about data analysis? What about data processing? From lines 258 to 260 on page 13 under data analysis; you said "Analyses were conducted an intention-to-treat basis." which is not clear! Also, the authors used STATA version 14 for data analysis but do not express the software used for data processing and how the data itself were processed. Results Participant characteristics

	- This may be confusing. It is all about the selection of the participants but not really the study participants. - Please rename this and change to "Sociodemographic characteristics of the participants" - I recommend you also to move the first paragraph under this section (from line275 through 283 of page 14) along with the first Figure and Supplementary Table 2 to the appropriate sub-section(s) of the methods section. - If you want to rename the sub-topic to "Sociodemographic characteristics", it good to start with the second paragraph on page 14 (from line 285 to 294). Moreover, the result is somewhat very brief and short. It may lack more interpreting the statistical output and may not detailed despite the tables and supplementary tables provided are many. It is only about 2 pages. Discussion Please summarize the limitations of the study on page 19; it seems too long. Conclusion - Change it to Conclusions - Conclusions should reflect the result and discussion. - Please add some recommendations to the conclusions. References Some of the references are old enough or outdated; And they were published at least about 15 years ago while others are about 20 years ago, including; reference number 9, 22, 24, 26, 28, and 29. Please reconsider this (either updating or not using them unless it is a must to use) during your revisions of the manuscript or in your revised version. Figure 1. Flow of participants through the study - This figure and the first paragraph under the result should be merged to the methods section. - However, it is not clear that how many participants (women) were on follow up at 4th, 6th, and 8th months despite the numbers excluded participants at each follow-up time/period due to different reasons. Supplementary files - there are about 17 supplementary tables included to the manuscript; which are too many. - I am not sure that how many supplementary files should be included to a single manuscript. Whether this is considered in the Submission guideline for Author or not, it is too many for me. But it is up to the Editorial Office staffs that decide this number.

VERSION 1 – AUTHOR RESPONSE

Responses to reviewers

We would like to thank you for your careful consideration of our manuscript and valuable suggestions. We have addressed each of the comments. Please see below.

Reviewer #1

No	Reviewer's comment	Authors' response
Title		
1	The phrase "Positive deviance" is difficult to understand and it may affect the readability of the paper by the general public despite it is interesting for the scientific community.	Thank you very much for your valuable comments and suggestions on our manuscript. As we published our preliminary studies using "Positive deviance" in the titles, we would like to keep the original title. Kosugi H, Shibanuma A, Kiriya J, et al. Positive deviance for dual-method promotion among women in Uganda: Study protocol for a cluster randomized controlled trial. Trials 2020; 21: 270. Kosugi H, Shibanuma A, Kiriya J, et al. Positive deviance for dual-method promotion among women in Uganda: A qualitative study. Int. J. Environ. Res. Public Health 2020; 17: 5009. Moreover, the positive deviance approach has been used across the world, and relevant research papers have been published. Therefore, we believe our title will not affect the readability of this manuscript. E.g., Albanna B, Heeks R. Positive deviance, big data, and development: a systematic literature review. Electron J Inf Syst Dev Countr 2019; 85: e12063.
Abstract		
2	Despite the abstract was structured, it good to separate the topics using a colon. For instance, placing a colon after Objectives, design, setting, etc. is good.	The abstract was revised considering your suggestions and the format specified by the journal.
3	It is a single objective that you wrote but it says "Objectives"	It was changed to "Objective." (Line 21)
4	Highly effective contraceptives are relative and questionable.	The term was replaced with non-barrier modern contraceptives throughout the manuscript.
5	Outcome measures- How the outcomes were measured? What statistical analysis was performed (including mixed-effects logistic regression analysis)?	The outcome measures and statistical methods were explained as follows. "The outcome was measured based on participants' self-reports, and the effect of

		intervention was assessed using a mixed-effects logistic regression model. (Lines 32-33)
6	Results-Please include the result of the secondary outcome measure (not included in the results). it is also not considered in the objective above	Considering the other reviewer's comments, we decided to report only the primary outcome in this manuscript. Therefore, the information related to the secondary outcome was excluded from the abstract and main text.
7	Conclusions-The conclusion is only about the primary outcome variable. Recommendations should be there (Not included).	Recommendations were added as follows. "This study demonstrated that the intervention targeting only women can change behaviors of couples to practice dual-method contraception. Because women using non-barrier modern contraceptives may be more reachable than men, interventions targeting such women should be recommended." (Lines 43-46)
8	In general, the abstract is well structured but not well informative for the general reader (make it comprehensive since it is also a standalone paper by itself).	Thank you for the comment. The abstract was revised to provide comprehensive information.
9	Despite keywords are very important for visibility and indexing and later for literature search, they are not included. please include them below the Abstract.	We confirmed that the format specified by the journal does not allow to include keywords.
10	Strengths and limitations of this study-Better to specify the type of measurement errors (Line 48/49, page 4)	The following examples were added. "The outcomes were measured based on participants' self-reports and therefore subject to measurement errors because of recall and social desirability biases" (lines 50-51)
11	Specify the mixed-effects logistic regression analysis performed (line 52, page 4)	A mixed-effects logistic regression model was used to evaluate intervention effects by controlling the cluster effects and the differences in baseline characteristics.
Introduction		
12	On-Page 5, line 72 Highly effective is used which is highly subjective and/or relative. It also needs an Operational definition. Which of contraceptive methods are highly effective and why? They may and may not be highly effective for pregnancy prevention/birth spacing. How do you see this?	Highly effective contraceptives were changed to non-barrier modern contraceptives throughout the manuscript.

13	On line 89 (page 5), at the end of the last sentence, the citation of reference(s) is/are important.	The following reference was added. Lopez LM, Stockton LL, Chen M, et al. Behavioral interventions for improving dual-method contraceptive use. Cochrane Database Syst Rev 2014; 3: Cd010915.
Methods		
14	Study design and settings (page 6) Under the study design and settings, in methods, it is good to add the total population of the district specifying the Women in the age category of 18-49, or at least in their reproductive age.	The total population of the district with the proportion of women of reproductive age was added. "The population of Mbarara District is 472,629 (female = 50.6%; male = 49.4%), and about a half of the female population (45.7%) are estimated within the reproductive ages (15 - 49 years)." (Lines 122-124)
15	Study participants and enrollment (page 7) Starting from line 112; It is good that the first paragraph under the study participants and enrollment should be placed under the study design and settings in the methods section; indicating that how the HFs and Participants were selected.	The first paragraph under the study participants and enrollment was moved to under the study design and settings (Lines 130-135). Moreover, the methods used to select the HFs and recruit participants were explained. (Lines 130-131,147) "To recruit a sufficient number of participants, 20 facilities were purposively selected out of 48 public health facilities in Mbarara District." "Convenience sampling method was used to recruit study participants."
16	How the 20 Health facilities (HFs) were selected out of 48 is not clear I think women are the participants, not the HFs, though they were selected from those HFs. Specifically, women who visited the family planning sections of the selected health facilities were the study population (page7, paragraph 2, from line 118 onwards).	The method was explained (Lines 130-135). We purposively selected 20 out of 48 public health facilities which had a high number of outpatients to recruit a sufficient number of participants. We agree that the participants were women even though HFs were selected as clusters. According to your suggestion, the selection of HFs was moved to the study design and settings from the study participants and enrollment.
17	Again on line 124 of page 7, the works of literature from the USA were considered for the variables considered in the formula for sample size calculation, which is a different setting and not comparable with Uganda. Have you searched for similar pieces of	We conducted a comprehensive literature review of dual-method contraceptive interventions. However, at the time of sample size calculation, there were few behavioral intervention studies targeting general population in low- and middle-income

	literature in similar (in (socioeconomic status) and/or comparable settings from Low-income countries?	countries, including SSA countries. Therefore, we used a study conducted in USA, which examined an educational intervention similar to this study, to calculate the sample size.
18	Moreover, please specify the sample size calculation formula.	The sample size was calculated by using Open Epi version 3, considering the effect size reported in a previous study, an intraclass correlation coefficient and a dropout rate. The power of the study was set at 80%, and the significance level was set at 5%. We added a reference to Open Epi to allow readers to check the sample size calculation formula for dichotomous outcome variables in an equivalence RCT. (Lines 269-270)
19	Every third woman was approached for selecting the sample. However, the sampling technique should be boldly clear. Which random sampling technique was applied? Are the authors considered every third woman at each HFs? and why? [on the same page, line 128]	As described above, we selected 20 HFs purposively as clusters. Then, we used the convenience sampling method to recruit women at these HFs. To minimize selection bias, research assistants recruited every third woman visiting the family planning section at each HF. The sentence was revised according to your suggestion. "Convenience sampling method was used to recruit study participants. Female research assistants recruited women at the selected health facilities. They approached every third woman visiting the family planning section at each facility to minimize selection bias and informed them the opportunity to participate in the study." (Lines 147-150)
20	Randomization and masking Are the HFs or the Women in Union that should be randomized? I believe that the sampled population should be randomized. The flow chart for patient allocation (figure 1) also indicated that.	We conducted a cluster randomized controlled trial to minimize contamination among participants, so HFs were randomized with a 1:1 allocation ratio as the flow chart (figure 1) indicates. The following sentence was added about the allocation of the sampled population. "Then, 960 women were allocated to the intervention (n = 480) or control group (n = 480) based on the facilities at which they were recruited." (Lines 157-158)
21	Under the method, on line 136/137, you wrote "Blinding was not feasible in this study". However, there is blinding of the research Assistant. This should be clarified;	Blinding was not feasible in this study. We could not mask the allocation from the participants, the staff of all the health facilities, and the research assistants engaged in baseline data collection and workshops due to the nature of the intervention. However, the

	You may not mask the HFs, but the women (page8)	intervention allocation was not disclosed to the research assistants who performed the outcome assessment. The sentence was revised for clarification. "Blinding was not feasible in this study due to the nature of the intervention. However, the research assistants who performed the outcome assessment were not informed the intervention allocation" (Lines 160-162)
22	"The handout included several quotes from the PDs." From line to 165-166 of page 9; Could you please include some of the quotes from the PDs (or a summary form? [page 9]	One quote of the PDs was added, and the reference to the preliminary study was also included. (Lines 181-183)
23	Data collection On page 12, line number 242 to 243; you wrote that "The participants received incentives worth 20,000 UGX (equivalent to 6 USD) for their time after the baseline interview." Since participation is voluntary, don't you think that this may negatively affect the result of the study? [Page 12]	We agree that incentives could negatively affect the result of the study by increasing expectation of participants and pressure to provide desirable answers. However, at the same time, it was necessary to compensate participants' time used for the baseline survey and develop positive relationships with the research team for future communication (e.g., follow-ups and counselling). We explained to participants that their responses will be kept confidential to minimize social desirability bias, as explained in limitations (p.19)
24	Data analysis Should it be all about data analysis? What about data processing? From lines 258 to 260 on page 13 under data analysis; you said "Analyses were conducted on an intention-to-treat basis." which is not clear! Also, the authors used STATA version 14 for data analysis but do not express the software used for data processing and how the data itself were processed.	Data analysis methods were elaborated more. Analyses were conducted based on the intention-to-treat principle in which design participants were analyzed in their original allocation to examine the effectiveness of the intervention. We used EpiData for data entry and STATA for data processing and statistical analyses. The sentence below was added. "Data were entered using EpiData version 3, and the data processing and statistical analyses were performed using Stata version 14." (Lines 269-270)
Results		
25	Moreover, the result is somewhat very brief and short. It may lack more interpreting the statistical output and may not detailed	Additional statistical outputs and the results of the sensitivity analysis were added to the result.

	despite the tables and supplementary tables provided are many. It is only about 2 pages.	
Discussion		
26	Please summarize the limitations of the study on page 19; it seems too long	We summarized the limitations of the study on page 19 according to your suggestion.
Conclusions		
27	- Change it to Conclusions - Conclusions should reflect the result and discussion. - Please add some recommendations to the conclusions.	It was changed to conclusions. Some recommendations were also added based on the results and the discussion. "Because women using non-barrier modern contraceptives may be more reachable than men, interventions targeting such women should be recommended." (Lines 416-417)
References		
28	Some of the references are old enough or outdated; And they were published at least about 15 years ago while others are about 20 years ago, including; reference number 9, 22, 24, 26, 28, and 29. Please reconsider this (either updating or not using them unless it is a must to use) during your revisions of the manuscript or in your revised version.	All the references were reviewed, and some were updated. However, we have to use some references, mainly those related to data collection tools such as reference numbers 24 and 26.
Figures and supplementary files		
29	Figure 1. Flow of participants through the study - This figure and the first paragraph under the result should be merged to the methods section. - However, it is not clear that how many participants (women) were on follow up at 4th, 6th, and 8th months despite the numbers excluded participants at each follow-up time/period due to different reasons	We added the subsection of participant flow with Figure 1 (Flow of participants). It was separated from the subsection of participant characteristics to avoid confusions, according to your suggestion. The numbers of participants included at each follow-up point in the intervention and control groups were bolded in Figure 1.
30	Supplementary files - there are about 17 supplementary tables included to the manuscript; which are too many. - I am not sure that how many supplementary files should be included to a	The number of supplementary tables was reduced, and their contents were revised.

	single manuscript. Whether this is considered in the Submission guideline for Author or not, it is too many for me. But it is up to the Editorial Office staffs that decide this number. [Editor's note: we do not specify the number of supplementary tables so please include what you feel is necessary	

Reviewer #2

No	Reviewer's comment	Authors' response
Abstract		
1	Line 31-33: The statement is not very clear: Primary and secondary outcome measures: The primary outcome was dual-method contraceptive use which was measured in two timeframes: Does it mean in any two of two-, four-, six-, and eight-month follow-up surveys? "dual-method contraceptive use at the last sexual intercourse and its consistent use in the two months prior to each follow-up". When was last sexual intercourse measured? Last sexual intercourse?	Thank you very much for your valuable comments. The two timeframes mean here dual-method contraceptive use at the last sexual intercourse and its consistent use in the two months prior to each follow-up. To make this point clear, the sentence was revised as follows. "Dual-method contraceptive use which was measured in two timeframes: its use at the last sexual intercourse and its consistent use in the two months prior to each follow-up." (Lines 30-32)
2	Line 36 : Results: Given that way the outcome is framed, it requires specific expression of percentage or proportion, not just more women in the intervention group. It was not clear how many were in the intervention group compared to the control group.	Due to the word limits, the intervention effects were presented using adjusted odds ratios which compare the proportion of women using dual-method contraceptives between intervention and control groups in the abstract. However, the following explanation were added in the results according to your suggestion. "At eight months, more women reported dual-method contraception use in the intervention group compared to the control group (dual-method contraceptive use at last sexual intercourse: 20.9% vs. 8.7%; $p < 0.001$; consistent dual-method contraceptive use: 11.2% vs. 1.3%; $p < 0.001$)." (Lines 317-320)

3	More women in the intervention used dual method at two- and eight-months surveys compared to the control group. What happened at fourth and sixth months?	Because of the word limit, we had reported only months which showed statistically significant intervention effects. At four and six months, the differences in proportion of women using dual-method contraception at the last sexual intercourse were not statistically significant. However, following your suggestion, the sentence below was added. "At four and six months, however, the proportion of dual-method contraceptive users was not significantly different between the two groups." (Lines 36-38)
4	Furthermore, there was a secondary outcome. But the results section was silent about it. Why?	Because of the word limit, we had included only results related to the primary outcome in the abstract. We excluded results related to the secondary outcomes according to your suggestion from the abstract and main text.
5	Line 42: Conclusion. What does Positive deviance mean to lay man in simple term?	Implication of positive deviance for male partners was added in conclusion as follows: "This study demonstrated that the intervention targeting only women can change behaviors of couples to practice dual-method contraception. Because women using non-barrier modern contraceptives may be more reachable than men, interventions targeting such women should be recommended." (Lines 43-46)
Introduction		
5	Line 62: Introduction The introduction was based in sub-Saharan Africa (SSA) in terms of unintended pregnancy and HIV thereby creating good impression for the study on dual-method use. It would be better if the new cases of HIV prevalence were about women of reproductive age not just adults. That would make the claim "In SSA, therefore, women of reproductive age bear the dual burden of unintended pregnancies and HIV".	We agreed that it is important to mention about the new cases of HIV infections among women of reproductive age, not only adult women. The following sentence was added. "Women contract HIV five to seven years of age earlier than men, and women aged 15–24 years are 2.4 times more likely to become infected with HIV than their male counterparts." (Lines 70-72)
6	Line 74-75: Despite the high incidence rate of HIV, it is not commonly practiced in SSA, especially among women in long-term relationships. What is not commonly practiced in SSA?	Dual-method contraception is not commonly practiced. The sentence was revised to make the subject clear. (Lines 78-80)

7	The thrust of the study in Uganda, since the authors focused on SSA in building their case, there is a need to look for more studies on dual-method use and condom use among married and cohabiting women in SSA countries. One study in Zimbabwe is not enough. Refer to African Journal of Reproductive Health / La Revue Africaine de la Santé Reproductive Vol. 21, No. 1 (March 2017), pp. 64-72 (9 pages); Condom use among married and cohabiting women and its implications for HIV infection..... Journal of Population Research 35(1) DOI: 10.1007/s12546-017-9195-2 etc.	Although research on dual-method contraception is limited, findings from studies in Kenya and Zimbabwe added important evidence. We agreed that we need to look more studies on condom use among married couples in the introduction. Many thanks for sharing the useful and relevant article to our study. The findings of the previous study were included. "In South Africa, only 16.2% of married and cohabiting women reported consistent condom use, and they faced several barriers can lessen the acceptability of condom use, such as infidelity and distrust within relationships." (Lines 81-83)
8	Line 88-89: "Effectiveness of behavioral change interventions on the dual-method use among married or in-union women remains lacking." Where is it lacking?	The evidence on effectiveness of behavioral change interventions on dual-method and condom use among married and cohabitating women is lacking globally. In the sentence, the lack of evidence specifically in SSA countries was discussed. It was clarified in the sentence. (Lines 95-97)
Methods		
9	I think that study design and setting section should make mention of the population in the study area. Since it is about setting, put in some demographics of the people, the nature of the activities of the people. The mentioning of the health facilities and services they provide were very much acceptable. Juxtaposing characteristics of the study settings and health facilities, one would be wondering if the people actually need intervention.	Based on your suggestion, the total population and the proportion of women of reproductive age in the study area were added. (Lines 122-124)
10	The prevalence of unintended pregnancy and HIV of the study area in my view should form part of the introduction. It should also need to show the prevalence of dual method use in the area if available. In the introduction, it would strengthen the need for the intervention in the study area. Then by the end of the study one should know if the us of dual method has increased, thus giving credit to the intervention in relation to the study objectives.	Based on your suggestion, Uganda's situations in terms of HIV infection, contraceptive and condom use were included in the introduction. Please see lines 98-106. The prevalence of dual-method contraceptive use in the study area is not available. We remained the details of the study area (Mbarara District) in the method section. Please see lines 122-129.
11	Line 111: Study participants and enrollment. This section presented sample size of 960. It should be good to present the population that participated in the intervention and control groups.	960 women were assigned to intervention or control group with a 1:1 allocation ratio. The participants received the intervention based on the facilities at which they were recruited.

		Based on your suggestion, we added the following sentence to present the population that participated in the intervention and control groups. "Then, 960 women were allocated to the intervention (n = 480) or control group (n = 480) based on the facilities at which they were recruited." (Lines 157-158)
12	Line 139: Intervention. I think the story of how intervention was developed is too long. Line 140- 158. It should be better to state clearly the intervention components.	Based on your suggestion, the sub-section was revised to include only the intervention components. The process of developing the intervention was excluded.
13	Line 159-160 talked about women received counseling focusing on dual-method contraception in addition to regular family planning counseling. What were the key messages in the counselling package? The counselling messages were they the same with the handout given to the women? What were the quotes from the PDs?	The key messages in the counselling package were summarized in Table 1. The handout summarized key counselling messages given to the women. Table 1 was revised to make the differences in interventions given to the intervention and control groups clear. One quote of the PDs was added as an example. (Lines 181-183)
14	Line 163-164: Trained research assistants delivered the counseling for about 20 to 30 minutes. Women to intervention group. Line 184-186 counselling on contraceptive use, from female research assistants was 10 to 20 minutes for control. I think this has introduced bias in the two groups. The difference should be on PDs. Everything should be consistent between the two groups. It should be pointed out as a limitation.	The differences in counseling time between the two groups were due to additional contents based on the PD approach for the intervention group. Other interventions were consistent between the two groups. Based on your suggestion, Table 1 was revised to highlight differences in the interventions provided to each group.
15	Line 198: Outcome. The way the responses were measured need to be made more clearer. The primary outcome was dual-method contraceptive use, which was defined as the application of a male or female condom along with an HEC, such as injectables, implants, intrauterine devices, pills, and female sterilization. If the question was about last sexual intercourse, how was it posed? If asked well it should produce "Yes" or "No" answer. The second part of the outcome talked about consistent use dual method use in the last two months before the each follow up. The questions reads "Apart from condoms, have you been using any other forms of protection against pregnancy during the past two months?" This again should produce a "Yes" or "No" answer.	We combined three questions regarding non-barrier contraceptive use, condom use at the last sexual intercourse, and its frequency in the past two months to measure the primary outcome. Based on your comment, the outcome measurement was explained in clearer way. Please see lines 221-233.

	Line 209-210: The frequency of condom use was asked with an item: “How often did you and your partner use a male or female condom during the past two months? The authors never stated that they would measure frequency of condom use. Which aspect of the objective was this addressing?	
16	Line 214-220: Talks about the secondary outcomes. The responses to these were not clearly stated how they were measured. These secondary outcomes may stand alone as another study as they were not reflected in the title.	Given your comment, we decided to report only the primary outcome in this manuscript. Therefore, information related to the secondary outcome was excluded from the abstract and main text.
17	Line 229-231: “Instead, the more measurable outcome of HIV/STI risk communication was added as a possible predictor of dual-method contraceptive use”. This was mentioned as secondary outcome in the abstract, here it is presented as predictor. It may be removed as an outcome and base the study outcome on dual-method use.	It had been included as the secondary outcome of the intervention. Considering your comment, we decided to report only the primary outcome in this manuscript.
18	Line 227-229: An outcome for STI incidence was omitted because we found that the reliability of self- reported STI incidence could be low among the participants during the data collection. Instead, the more measurable outcome of HIV/STI risk communication was added as a possible predictor of dual- method contraceptive use. This is a bit confusing. The authors may have a rethink of what the study was set to measure.	Please see the response above.
19	Line 232: Data collection. This section is very wordy. Of all that was written, the authors did not mention what was collected as data. It should be made sharper. The authors should look at the outcome section and separate the outcome and data collection process. Under outcome, line 221-230, were about variables deemed as predictors. Therefore, there is a need to sanitize the section in terms of variables included in it.	Description of the secondary outcome was deleted from the outcomes sub-section. We also separated other variables, related to socio-demographic characteristics at baseline, as other information from the outcomes sub-section.
20	Line 261: Ethics. Was this study approved by any recognized research body?	The study was approved by the Research Ethics Committee of the Graduate School of Medicine, University of Tokyo (2019085NI), Institutional Research and Ethics Committee of Mbarara University of Science and Technology (IRB15/06-19), and Uganda National Council of Science and Technology (HS439ES). These were listed in footnotes as ethics approval (Lines 439-442)
Results		

21	Line 273:. It is a bit difficult to follow the reporting of the results. I do not see the need for model 1 and model 2 analyses especially in Tables S3 to S17 in the study. The authors should concentrate on model 3 and remove the models 1 and 2 as I do not see their usefulness. Some of the results presented are not relevant to the topic of the study.	According to your suggestion, Model 3 was used as the main model not model 2. Only crude odds ratio (OR) based on Model 1 and adjusted OR based on Model 3 (it was renamed as Model 2) were reported. Accordingly, the supplementally tables were also revised.
22	Line 175: Counselling received three, five, and seven months after enrollment. Line 278 Counseling received at counseling at three, five, and eight months after enrollment. Need to be reconciled.	Line 278 was revised as follows: "…. counseling at three, five, and seven months after enrollment, respectively"
23	Line 279-280: Women in the intervention group were more likely to respond at two months (79.8% vs. 73.1%, p = 0.015) and four months (84.6% vs. 79.4%, p = 0.036). What happened at fourth month and sixth month?	This paragraph explains difference in response rates at each follow up point between intervention and control groups. We did not observe statistically significant differences in the response rates between the two groups at six and eight months. The following explanation was added. "No statistically significant differences were observed in the response rates between the two groups at six and eight months." (Lines 294-295)
24	Line 281-283 The baseline characteristics were compared between women followed up and those lost to follow-up in each group. Which group? Those that were lost, were they regarded as participants at the end? The comparison of characteristics would be more appropriate for the intervention and the control groups. That should be clearly done in table 2. Table 2 presents the sociodemographic characteristics of 960 women at baseline. All of a sudden Characteristics were similar for the intervention and control groups with a few slight imbalances. It gives impression of a different study altogether.	Line 281-283 was results of the sensitivity analysis presented in Supplementary Table 2. It compared baseline characteristics between women followed up and those lost to follow-up in the intervention and control groups at follow-up points. It was clarified considering your comment. Please see lines 291-293. "The most of baseline characteristics, however, were balanced between women lost to follow-up and those reached in both intervention and control groups. Therefore, the risk of bias was estimated to be low." Table 2 compares the baseline characteristics of women between the intervention and control groups. Moreover, participant characteristics were separated from the description of participant flow to improve readability.
25	Line 305-307 : However, pregnancy incidence was not significantly different between the groups. Throughout the data collection period, 6 and 15 women became pregnant in the intervention and control groups, respectively. What does this tell us	It had been included to illustrate the possible effect of the intervention on the biological outcome (pregnancy incidence). However, we decided to focus on the primary outcome (dual-method contraceptive use) in this

	about dual-method use consistence among the intervention group?	manuscript. These sentences were deleted accordingly.
Discussion		
26	Line 329: The discussion of the study reads like a literature review and mixed with results.	The discussion was revised by excluding data which were already presented in results and adding more implication from the results considering your suggestion.
27	Line 338-340 : In the intervention group, 43% and 16% of women reported the dual-method use at the last sexual intercourse and its consistent use, respectively. This should be in result section.	The sentence was deleted to avoid repeating the figures already reported in the result section.
28	Line 343- 344 : The observed effect was consistent with a previous intervention study that combined case management and peer education program for adolescent girls in the USA. This need to be referenced.	The following reference was added. Sieving RE, McRee AL, McMorris BJ, et al. Prime time: Sexual health outcomes at 24 months for a clinic-linked
29	Line 344-345: The intervention illustrated continued effects on the dual-method use at 12 and 24 months after enrollment. How was this accounted for because the study lasted for 8 monts?	The intervention referred to the previous study conducted in the USA mentioned in the previous sentence.

VERSION 2 – REVIEW

REVIEWER	Demie, Takele Saint Paul's Hospital Millennium Medical College, Department of Public Health
REVIEW RETURNED	26-Jun-2021

GENERAL COMMENTS	I thank the authors for their nice revisions.