RESEARCH ARTICLE

REVISED How to promote 'discipline without tough love' during pregnancy: a randomized controlled trial [version 2; peer review: 1 approved with reservations]

Shunji Suzuki

Japanese Red Cross Katsushika Maternity Hospital, Department of Obstetrics and Gynecology, 5-11-12 Tateishi, Katsushika-ku, Tokyo, 124-0012, Japan

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Abstract

Background: In Japan, the effect of education using the leaflet 'Discipline Without Tough Love' on mothers during caring for their infants have been reported. We examined the effect of this education on pregnant Japanese women.

Methods: The present study was a prospective investigation of all Japanese women with singleton pregnancies who visited our hospital for a perinatal visit at 20-23 weeks' gestation between November 2017 and March 2018 and gave birth at ≥ 37 weeks' gestation at our hospital. We examined the maternal feelings (bonding situation) to babies of women who received the leaflet in comparison with that in women who did not receive it during the health check-up performed routinely at one month after delivery using the Japanese version of the Mother-to-Infant Bonding Scale.

Results: There were no significant differences in maternal feelings for their babies between the two groups of women.

Conclusions: We did not identify any effect of health consultations based on 'Discipline Without Tough Love' during pregnancy on maternal feelings toward babies at one month after delivery. A further study to enlighten pregnant women about parenting without corporal punishment will be needed in Japan.

Registration: Japan Registry of Clinical Trials [1030190112](https://www.clinicaltrials.gov/ct2/show/study?term=1030190112); registered on 5 October 2019.

Keywords

discipline without tough-love, education, pregnant women, Japan

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1. **Hiroko Iwata** , University of Tsukuba, Tsukuba, Japan

Any reports and responses or comments on the article can be found at the end of the article.

This article is included in the **All trials matter** collection.

Corresponding author: Shunji Suzuki (czg83542@mopera.ne.jp)

Author roles: Suzuki S: Conceptualization, Data Curation, Formal Analysis, Funding Acquisition, Investigation, Methodology, Project Administration, Resources, Software, Supervision, Validation, Visualization, Writing – Original Draft Preparation, Writing – Review & Editing

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REVISED Amendments from Version 1

We have revised the manuscript as follows:

Methods: The reviewer's excellent suggestions have complemented my previous inadequate explanations in the Methods. In the Methods, we have added the sentences as follows: (1) the midwives handed the leaflet with explanations what was written, (2) we did not check whether or not the women in the intervention group actually read the leaflet, and (3) we ensured their voluntary participation by allowing them the freedom not to receive leaflets.

In addition, I have provided comments concerning the reliability of MIBS-J.

Results: We ensured their voluntary participation by allowing them the freedom not to receive leaflets. I have added this in the Methods.

Results: Because this was a prospective study, I have separated Table 1 to new Table 1 & 2 tables.

In addition, I have fixed English wording and spelling mistakes in the figure.

Any further responses from the reviewers can be found at the end of the article

Introduction

Children can adapt themselves and their relationship with their caregivers (parents) in a way incomparable to any other stage of life. If children's environment is negatively influenced, development of their brain may be impaired¹⁻⁴. For example, Tomoda *et al.*²⁻⁴ observed that exposure to parental verbal abuse or interparental violence during childhood, leading to 'multiple forms of childhood maltreatment', is associated with the incidence of abnormality of the brain structure and/or mental disorders, such as reactive attachment disorders. Although whether spanking is helpful or harmful to children had continued to be a source of considerable debate, meta-analyses focused specifically on spanking representing about 160,000 children by Gershoff and Grogan-Kaylor⁵ indicated a link between spanking and an increased risk of detrimental child outcomes. In 2016, the rate of Japanese women mistreating their children was reported to be 6–37%⁶.

Based on this background, in 2016 the Japanese Ministry of Health, Labour and Welfare conducted an enlightenment program to help avoid improper childrearing as 'Discipline Without Tough Love: Strategy Of Zero Tough Love' using the leaflet shown in Figure 1⁶. In the leaflet, some of the text for parents is as follows: (1) do not use corporal punishment or ranting for parenting, (2) minimize irritated feelings and send out an 'SOS', and (3) support the growth of children while considering children's emotions and behavior separately because children cannot express an 'SOS' by themselves, even if they fear their parents. In Japan, some regional reports concerning the effect of education using the leaflet on mothers during caring for their infants have already been published⁷. Although it has been considered that the gap between the ideal situation and reality of child rearing in women occurs mainly after childbirth,

Figure 1. Cover of the leaflet 'discipline without tough love: strategy of zero tough love'. The commentaries are as follows:

Parents sometimes may get irritated with their children's attitude during childrearing. Parents sometimes may want to slap or shout at their children. At first glance, the acts of slapping and/or shouting may seem to be effective, but the children usually cannot understand why they were slapped or shouted at. In such situations, the children usually listen to their parents out of fear. Even if your intention regarding hitting and/or shouting is 'tough love' at the beginning, the acts may escalate to become abuse unintentionally. Let's avoid 'tough love' leading to corporal punishment or verbal abuse. Let's keep your emotions hidden from children to raise them healthily.

maternal mental and social conditions during pregnancy are now considered important factors associated with the possibility of subsequent child abuse⁸.

In the current study, therefore, we examined the effect of education using the leaflet 'Discipline Without Tough Love' on Japanese women during pregnancy.

Methods

Ethical issues

This study was conducted after receiving approval from the ethics committee of the Japanese Red Cross Katsushika Maternity Hospital (2017-002). This study was carried out in accordance with the Declaration of Helsinki. Written informed consent from each participant was obtained before enrolment. Blinding was performed in the clinicians responsible for one-month postpartum care.

Trial background

The present study was a prospective investigation of all Japanese women with singleton pregnancies who visited our hospital for a perinatal visit at 20–23 weeks' gestation between November 2017 and March 2018 and delivered a healthy neonate at ≥ 37 weeks' gestation at our hospital as a result. In this study, we excluded women with perinatal complications such as preterm delivery, low-birth-weight infant, and neonatal asphyxia requiring neonatal admission. This was because individual and important mental health care is needed for mothers whose babies have health problems^{9,10}. When this study was planned, the required sample size was 762 participants for 90% power based on a previous observation in Japan¹¹; the trial recruited 882 participants. In our institute, midwives carry out three health consultations during pregnancy to support the healthy lives of pregnant women. These consultations are at about 8–11, 20–23, and 34–36 weeks' gestation. During the study period, at the second health consultation at 20–23 weeks' gestation, the responsible midwife handed the leaflet directly to the pregnant women randomly selected with the comment of 'a leaflet concerning the things to keep in mind for healthy childrearing after delivery'. In detail, pregnant women were randomly assigned to the two groups (with and without the leaflet) early in the morning on the day of health consultations using a web-based randomization system (Research Randomizer) stratified by parity (primipara vs. multipara) according to the computer-generated randomization code. We ensured their voluntary participation by allowing them the freedom not to receive leaflets. The midwives handed the leaflet with explanations what was written. That is, they explained about the child discipline to the pregnant women in the intervention group actively from them; however, we explained to the women in the control group only when asked. Unfortunately, we did not check whether or not the women in the intervention group actually read the leaflet.

Variables assessed

In this study, we examined the maternal feelings (bonding situation) toward babies of women who received the leaflet in comparison with that in women who did not receive it during the routine health check-up performed one month after delivery using the Japanese version of Mother-to-Infant Bonding Scale (MIBS-J), which is a simple self-administrated questionnaire designed to detect problems with a mother's feelings towards her newborn baby^{12–15}. MIBS-J has been demonstrated to be acceptable reliability and reasonable construct validity concerning affection and anger/rejection in Japanese postpartum women¹¹. If a score is higher than 3, there is a possibility that the mother will have problems regarding feelings for her baby. If at least one of the third and fifth questions of MIBS-J (third question: feel resentful toward my baby; fifth question: feel angry toward my baby) is ≥ 1 , the possibility of feeling-related problems also existed^{11,15}.

The items recorded as obstetric and perinatal characteristics that may affect the results were as follows: maternal age, parity, history of abortion, history of infertility treatment, economic problems, results of the modified Violence Against Women Screen (VAWS)^{16–18}, results of the Whooley questions during

the early pregnancy^{18,19}, presence or absence of participation in a parents class, and delivery modes. As a general rule in our institute, whether or not to participate in the parents' class is decided early in the pregnancy.

The modified VAWS is a Japanese screening instrument for intimate partner violence (IPV) to identify pregnant women who have experienced abuse based on scores using a 3-point Likert scale^{13–15}. The total score ranges from 0–9; a score higher than 2 is positive for IPV. Whooley questions comprise a screening instrument for depression in the general adult population including pregnant and postpartum women^{17,20}. If at least one of the two questions is 'yes', we diagnose the woman with depressive symptom.

If a pregnant woman was supported by the hospitalization assistance policy (HAP) system of the Japanese Child Welfare Government, we defined her as having economic problems^{21,22}. The HAP system assists with delivery costs. The main objectives of the HAP system are to help pregnant women who: 1) receive livelihood protection because they are unable to maintain minimum living standards due to poverty, 2) live in households exempt from residence tax, and 3) live in households in which the income tax is less than ¥8,400 (=about \$80 US) per year. In this study, the diagnosis of depression was performed by Japanese psychiatric specialists.

The parents' class in our institute is a participatory group offering guidance in which pregnant women can learn about pregnancy, childbirth, and child rearing together with their partners²³.

In Japan, women without obstetric complications can freely select their birthing facility even at late pregnancy. Our institute is one of the major perinatal centers in Tokyo, Japan (about 2,000 deliveries per year); however, medical care by psychiatrists is not carried out. Therefore, almost all pregnant women complicated by depression receive psychotherapy in nearby psychiatric clinics. Neonatal asphyxia was defined as a neonatal Apgar score at 1 or 5 min of < 7 . Postpartum hemorrhage was defined as an estimated blood loss of $\geq 1,000$ mL. In most cases, the gestational age was defined based on ultrasonography at 9–11 weeks of gestation. In cases with a delayed first visit, the gestational age was confirmed based on Neonatal Neurological Assessment.

Outcomes

The primary end point of was the effect of the leaflet 'Discipline Without Tough -Love' on the score of the MIBS-J in mothers at one month after delivery.

Statistical analysis

Data are expressed as the number (percentage). SPSS Statistics software version 20 (IBM Corp., Armonk, NY, USA) was used for statistical analyses. A chi-square test was used for categorical data, and a p -value < 0.05 was considered significant. Logistic regression analysis was used to estimate odds ratios (ORs) and 95% confidence intervals (CIs).

Results

Study and participant background

Figure 2 shows a flow diagram for the study. During the study period, 882 pregnant women visited our hospital for a perinatal visit and received the midwives' health consultations at 20–23 weeks' gestation. Ultimately, a randomized prospective study was conducted involving 334 women who received the consultations with the leaflet of 'discipline without tough love' and 320 women who received the standard consultations without the leaflet as a control group.

Table 1 shows the characteristics of the two groups of women who examined their maternal feelings at one month after delivery using the MIBS-J as follows: those who received the consultations with the 'discipline without tough love' leaflet ($n = 334$), and those who received the standard consultations without the leaflet ($n = 320$). As shown in Table 1, there were no significant differences in the clinical characteristics such as maternal age, parity, history of infertility treatment, the rate of having economic problems, the rate of positive of the modified VAWS or the Whooleys' question, performed at the first trimester of pregnancy between the two groups. Table 2 shows the delivery modes of the two groups. There were no significant differences in the delivery modes between the two groups. These

indicate that the randomization of this study was performed equally effectively as a result. Individual-level results are available as *Underlying data*²⁴.

Outcomes

Table 3 shows the results of maternal feelings for their babies at one month after delivery using the MIBS-J in the two groups as follows: those who received the consultations with the leaflet of 'discipline without tough love', and those who received the standard consultations without the leaflet. As shown in Table 3, there were no significant differences in the rate of score ≥ 3 , or yes for the third or the fifth question of the MIBS-J indicating problems with maternal feelings between the two groups.

The prevalence of women showing problems with maternal feelings in the control group was 15%. It is estimated that a definitive trial powered to detect the same difference in prevalence would require approximately 556 patients equally divided into the current two groups (two-tailed $\alpha = 0.05$, $\beta = 0.2$). Therefore, the sample size of the current observation would be sufficient. There indicate that the awareness of 'discipline without tough love' through the leaflet during pregnancy was not very effective for the maternal feelings at one month after delivery.

Figure 2. Flow diagram of the study.

Table 1. Characteristics of the two groups of women who examined their maternal feelings at one month after delivery using the Japanese version of Mother-to-Infant Bonding Scale (MIBS-J). The groups consist of those who received consultations with the leaflet of 'discipline without tough love' (n = 334), and those received standard consultations without the leaflet (n = 320).

	Consultations with the leaflet	Standard consultations (control group)	P-value	Odds ratio	95% CI
Total	334	320			
Maternal age					
<20 years	4 (1%)	3 (1%)	1.00	1.23	0.31-5.0
20–34 years	229 (69%)	212 (66%)	Reference	1	
≥35 years	101 (30%)	105 (33%)	0.50	0.890	0.64-1.2
Nulliparity					
Yes	169 (51%)	167 (52%)	0.70	0.938	0.69-1.3
No	165 (49%)	153 (48%)	Reference	1	
History of abortion					
No	309 (91%)	292 (91%)	Reference	1	
Yes	25 (8%)	28 (9%)	0.57	0.844	0.48-1.5
History of infertility treatment					
No	330 (93%)	291 (91%)	Reference	1	
Yes	23 (7%)	29 (9%)	0.25	0.700	0.40-1.2
Economic problems					
No	314 (94%)	305 (95%)	Reference	1	
Yes	20 (6%)	15 (5%)	0.49	1.30	0.66-2.5
Positive for modified VAWS					
No	319 (96%)	299 (93%)	Reference	1	
Yes	15 (4%)	21 (7%)	0.30	0.670	0.34-1.3
Positive for Whooley questions					
No	275 (82%)	269 (84%)	Reference	1	
Yes	59 (18%)	51 (16%)	0.60	1.13	0.75-1.7
Participation in parents' class					
No	312 (93%)	305 (95%)	Reference	1	
Yes	22 (7%)	15 (5%)	0.31	1.43	0.74-2.8

CI, confidence interval; VAWS, Violence Against Women Screen.

Table 2. Delivery modes of the two groups of women who examined their maternal feelings at one month after delivery using the Japanese version of Mother-to-Infant Bonding Scale (MIBS-J). The groups consist of those who received consultations with the leaflet of 'discipline without tough love' (n = 334), and those received standard consultations without the leaflet (n = 320).

	Consultations with the leaflet	Standard consultations (control group)	P-value	Odds ratio	95% CI
Total	334	320			
Delivery modes					
Spontaneous delivery	248 (74%)	220 (69%)	Reference	1	
Instrumental delivery	16 (5%)	23 (7%)	0.18	0.617	0.32-1.2
Cesarean section	70 (21%)	77 (24%)	0.26	0.806	0.56-1.2

CI, confidence interval.

Table 3. Results of maternal feelings for their babies at one month after delivery using the Japanese version of Mother-to-Infant Bonding Scale (MIBS-J) in the two groups. The groups consist of those who received consultations with the leaflet of 'discipline without tough love' (n = 334), and those received standard consultations without the leaflet (n = 320).

	Consultations with the leaflet	Standard consultations (control group)	P-value	Odds ratio	95% CI
Total	334	320			
No problems	275 (82%)	271 (85%)	Reference	1	
Possibility of problems					
Total	59 (18%)	49 (15%)	0.46	1.19	0.79-1.8
Score ≥ 3 *	53 (16%)	45 (14%)	0.51	1.16	0.76-1.8
Yes for the third question*	22 (7%)	17 (5%)	0.51	1.26	0.67-2.4
Yes for the fifth question*	16 (5%)	12 (4%)	0.56	1.31	0.62-2.8

CI, confidence interval.

*Total score and the answer for the third and fifth question of the Japanese version of Mother-to-Infant Bonding Scale (MIBS-J).

Discussion

Unfortunately, in the current study we could not identify any effect of our health consultations with the 'discipline without tough love' leaflet at 20–23 weeks' gestation on maternal feelings for babies at one month after delivery in pregnant Japanese women, although the effect of education using the leaflet on mothers during childcare of their infants was observed based on some regional reports in Japan⁷. Because the current study is the first trial of the guidance concerning 'discipline without tough love' with the leaflet during pregnancy in Japan, a consideration

of the guidance methods and/or the leaflet itself may be necessary in the future. However, the period of pregnancy may be too early to teach mothers about ideal childrearing. Alternatively, the timing of one month after delivery may have been too early to assess the problems with maternal feelings toward children. In Japan, the percentage of mothers guilty of child mistreatment has been reported to be about 37% with children aged 3 years old, but only 6% with children of 3–4 months⁶. Therefore, the pregnant Japanese women may not be possible to imagine that they may abuse their children.

As mentioned in the *Introduction*, even ‘tough love’ such as rough words and/or striking will traumatize children, even when used as discipline^{1–4}. Therefore, we hope to spread enlightenment to avoid ‘discipline with tough love’. Based on these goals, the current study was performed; however, we did not obtain the expected results. We will perform further studies to enlighten pregnant women about using ‘discipline without tough love’ in Japan.

We understand that there are some limitations in this study. A first limitation relates to the duration of the trial; the long-term impact of the leaflet cannot be addressed. Because, child abuse had been observed to increase with the age of children⁶. Therefore, further additional studies with long-term follow-up periods may be needed such as a study at two years after delivery using the MIBS-J. In this study, the intervention was carried out as planned; however, the subjects could not be blinded by receiving the leaflet. In addition, some regional differences of the number of child neglect and emotional abuse have been observed between urban areas and other areas in Japan²⁴. For example, child neglect has been discovered higher in urban areas²⁴. Therefore, the same results may not be able to be expected in other Japanese institutes.

In this study, unfortunately we did not check whether or not the women in the intervention group actually read the leaflet.

However, in conclusion we could not identify an effect of health consultations concerning ‘discipline without tough love’ during pregnancy on maternal feelings for babies at one month after delivery.

Data availability

Underlying data

Figshare: Data for ‘How to promote ‘discipline without tough love’ during pregnancy’. <https://doi.org/10.6084/m9.figshare.10259672.v1>²⁴.

This project contains data on maternal characteristics and effect of the leaflet on maternal feeling at one month after delivery.

Reporting guidelines

CONSORT checklist for ‘How to promote ‘discipline without tough love’ during pregnancy’. <https://doi.org/10.6084/m9.figshare.10308275.v1>²⁵.

Underlying data are available under the terms of the [Creative Commons Zero “No rights reserved” data waiver](#) (CC0 1.0 Public domain dedication).

The completed CONSORT checklist is available under the terms of the [Creative Commons Attribution 4.0 International license](#) (CC-BY 4.0).

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Open Peer Review

Current Peer Review Status: ?

Version 2

Reviewer Report 22 April 2021

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Hiroko Iwata

Faculty of Medicine, University of Tsukuba, Tsukuba, Ibaraki, Japan

You have done a great job in revising the paper. It has been improved significantly. Yet, some parts of your revision gave me unclear impressions.

Results:

1. Re: voluntary participation, the author responded "We ensured their voluntary participation by allowing them the freedom not to receive leaflets". My concern is how and when the researcher obtained informed consent. Did the author conduct a random assignment after obtaining the participant's consent?
2. Table 1 & 2 are still confusing. Are these tables just about characteristics of two groups? And that the author compared if there were any differences between the groups? If so, why didn't the author analyze using chi-square test? What do p-value, odds ratio, and 95%CI mean for each variable?

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Reproductive health, Maternity, Parenthood, Nursing

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 17 Oct 2022

Shunji Suzuki, Department of Obstetrics and Gynecology, 5-11-12 Tateishi, Katsushika-ku, Japan

Dear Professor Hiroko Iwata,

We are very, very sorry for the very, very late reply because we couldn't access the submission site of the HP. We would like to thank you for the comments and critique of our manuscript. We have been able to respond to your comments and we believe the paper has been strengthened.

We conducted the random assignment after obtaining the women's consent. We have added them in the Methods.

We have deleted the odds ratios and 95% CI. The results of Tables 1 & 2 were re-analyzed using the chi-square test. There were no differences between the two groups.

Thank you for considering our paper.
We are very, very sorry, again.

Sincerely yours,

Shunji Suzuki, MD
Department of Obstetrics and Gynecology,
Japanese Red Cross Katsushika Maternity Hospital

Competing Interests: No competing interests were disclosed.

Version 1

Reviewer Report 06 April 2021

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Hiroko Iwata

Faculty of Medicine, University of Tsukuba, Tsukuba, Ibaraki, Japan

Thank you for the opportunity to review your manuscript. I hope my comments below help you improve the paper.

Methods:

1. P3: Readers may want to know more about the intervention. Is it that a midwife handed the leaflet with/without explanations? Did you check if the women in the intervention group actually read the leaflet at some point of care?

2. P4: Please provide reliability and validity information on MIBS-J.

Results:

1. P4: I wonder if randomization is conducted after obtaining informed consent from potential participants. Under "Study and participant background", there is a description of "During the study period, 882 pregnant women visited our hospital for a perinatal visit", and that figure 2 indicates all 882 women were assessed for eligibility. Did the author ensure voluntary participations?
2. P4: Because both groups receive some kind of consultations, the author should provide brief contents of consultations in a control group. This is related with the impact of the intervention.
3. P5: Table 1 needs to be revised appropriately. Table 1 looks like results of logistic regression, not just participants' characteristics, however, the outcome is the score of the MIBS-J, which may be a continuous variable. It is really confusing. If the author used categorical data, not a continuous data (i.e., the score of the MIBS-J) when conducting logistic regression, you should say so in Methods section. Likewise, table 2 also needs to be revised.

Discussion:

1. P7: What do you mean by "Therefore, pregnant Japanese women may be less likely to abuse their children during pregnancy"?

Structure, grammar and style:

1. Figure 2: Please correct "Analuzed" to "Analyzed".

Is the work clearly and accurately presented and does it cite the current literature?

Partly

Is the study design appropriate and is the work technically sound?

Yes

Are sufficient details of methods and analysis provided to allow replication by others?

Partly

If applicable, is the statistical analysis and its interpretation appropriate?

I cannot comment. A qualified statistician is required.

Are all the source data underlying the results available to ensure full reproducibility?

Yes

Are the conclusions drawn adequately supported by the results?

Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Reproductive health, Maternity, Parenthood, Nursing

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 14 Apr 2021

Shunji Suzuki, Department of Obstetrics and Gynecology, 5-11-12 Tateishi, Katsushika-ku, Japan

April 11, 2021

Editorial office

Dear Editors,

I would like to thank you and Dr. Hiroko Iwata for the comments and critique of our manuscript entitled 'How to promote 'discipline without tough love' during pregnancy: a randomized controlled trial. I have been able to respond positively to each suggestion and we believe the paper has been strengthened. The changes are highlighted with red color.

To Dr. Hiroko Iwata,

Thank you very much for your suggestions. I have been able to respond positively to your each suggestion.

Methods 1: The midwives handed the leaflet with explanations what was written; however, we did not check whether or not the women in the intervention group actually read the leaflet. I have added these in the Methods & Discussion.

Methods 2: I have provided the suggested information in Ref 11.

Results 1: We ensured their voluntary participation by allowing them the freedom not to receive leaflets. I have added this in the Methods.

Results 2: The midwives handed the leaflet with explanations what was written. That is, they explained about the child discipline to the pregnant women in the intervention group actively from them; however, we explained to the women in the control group only when asked. I have added these in the Methods.

Results 3: Thank you very much for your suggestion. Because this is a prospective study, I have separated Table 1 to 2 tables (Table 1 & 2).

Results 4: I have re-written to 'Therefore, the pregnant Japanese women may not be possible to imagine that they may abuse their children'.

Results 5: Thank you very much for your pointing out.

Thank you very much for your excellent suggestions, again.

I do hope and trust that with these changes the manuscript is now acceptable for indexing.

Thank you for considering my paper.

Sincerely yours,

Shunji Suzuki, MD
Department of Obstetrics and Gynecology,
Japanese Red Cross Katsushika Maternity Hospital
5-11-12-2 Tateishi, Katsushika-ku, Tokyo 124-0012 Japan
Tel: +81-3-3693-5211
Fax: +81-3-3694-8725
e-mail: czg83542@mopera.ne.jp

Competing Interests: None

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