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ORIGINAL RESEARCH – QUANTITATIVE

Randomised controlled trial using smartphone website vs leaflet to support antenatal perineal massage practice for pregnant women

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ARTICLE INFO

Article history:

Received 15 August 2015

Received in revised form 14 January 2016

Accepted 27 January 2016

Keywords:

Perineum

Massage

Pregnancy

Instruction

Randomised controlled trial

ABSTRACT

Background: In Japan, the rate of pregnant women who practice antenatal perineal massage was only 15.1%.**Aim:** The aim of this study was to develop and evaluate a smartphone website and a leaflet to support antenatal perineal massage practice for primiparous women.**Methods:** In a randomised control trial, 161 primiparous women were randomly assigned to a smartphone website group ($n = 81$) or a leaflet group ($n = 80$). Data analysis were by per protocol analysis and intention to treat analysis.**Findings:** Of the 161 women participants, 47 in the smartphone website group and 49 in the leaflet group completed all questionnaires. Primary outcome was continuance rate (three times a week over a three week period) of antenatal perineal massage practice. The rates by a per protocol analysis were 51.1% in the smartphone website group and 51.0% in the leaflet group, respectively. There was no significant difference between the groups. Moreover, the rates by an intention to treat analysis were 29.6% in the smartphone website group and 31.3% in the leaflet group, respectively. There was also no significant difference between the groups.

There were no significant differences in the evaluation of perineal massage, childbirth self-efficacy, satisfaction with efforts towards childbirth, and perineal outcomes following childbirth which were measured as secondary outcomes between the groups.

Conclusion: There was no significant difference in continuance rate of antenatal perineal massage practice between those using a smartphone website and those with a leaflet, however, the rate was better than no instructions.© 2016 The Authors. Published by Elsevier Ltd on behalf of Australian College of Midwives. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Summary of relevance:

Issue

The rate of antenatal perineal massage practice is only 15.1% in Japan.

What is already known

The episiotomy rate in Japan is higher than other developed countries and Asian ethnicity was associated with a risk of severe perineal trauma. Antenatal perineal massage for primiparous women was associated with a reduction in the incidence of perineal trauma requiring suturing and episiotomy. However,

half of Japanese medical facilities did not educate about antenatal massage technique.

What this paper adds

We developed two educational materials (a smartphone website and a leaflet) to support antenatal perineal massage practice.

1. Introduction*1.1. Background*

Perineal trauma following childbirth has not only short-term effects such as perineal pain but also long-term effects such as

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coital pain or hesitation for the next delivery.^{1,2} Episiotomies represent one type of trauma. Various guidelines^{3,4} recommend restrictive episiotomies as opposed to routine; however, the episiotomy rate in Japan is 30–100% for primiparous and 10–70% for multiparous pregnant women indicating that at some hospitals episiotomies are routine for primiparous women.⁵ On the other hand, the rates of episiotomies in some comparable countries are 27–28% in the USA, 3–31% in Canada, and 9.9–20.9% in Australia.⁶ The episiotomy rate in Japan is higher than those countries because of less mobility during labour or medical facilities' policy. Moreover Asian ethnicity was associated with a risk of severe perineal trauma such as third-degree or fourth degree lacerations.⁷

Antenatal perineal massage is a preventive method for reducing perineal trauma of childbirth. A systematic review of antenatal perineal massage reported that antenatal perineal massage for primiparous women was associated with a reduction in the incidence of trauma requiring suturing and episiotomy.⁸ In Japan, a previous study also found that pregnant women who practiced perineal massage felt pain or were uncomfortable after starting the massage. However, as they continued the massage, their pain eased and they felt the softening of their perineum.⁹ However, the rate of antenatal perineal massage practice was only 15.1% in Japan.¹⁰ An empirical investigation for identifying factors impeding pregnant women's massage practice reported that these factors included: resistance to touching their perineum, lack of knowledge and some difficulty practicing the massage technique.¹¹ In addition, it was found that women who continued to practice perineal massage felt significantly more positive 'effects on preparation for childbirth' and 'effects on childbirth' when compared to those who stopped practicing the massage. The results suggested that midwives needed to support pregnant women to continue the massage practice.

Midwives' educational efforts have traditionally been face-to-face. However, with advances in technology as was noted earlier the internet is being used as an educational tool and the positive effects of web-based education are reported around the world.^{12–37} Moreover, in Japan, the internet user rate of those ages 13–49 is over 95% and the smartphone ownership rate has increased rapidly, rising from 9.7% in 2010 to 64.2% in 2014.³⁸ Dennison et al.³⁹ reported that young healthy adults had some interest in smartphone application for supporting health-related behaviour change. Midwives' educational efforts might also be able to adapt to this type of educational technology. Accordingly, this study focused on the smartphone, which is predicted to increase in ownership rate among the population, and consequently develop a smartphone website supporting perineal massage practice.

1.2. Purpose

To develop and evaluate two educational materials (a smartphone website vs a leaflet) to support antenatal perineal massage for primiparous women.

1.3. Hypothesis

The hypothesis of this study was if primiparous women used a smartphone website, they would; (1) continue antenatal perineal massage practice until childbirth, (2) feel the effects of the massage, (3) improve childbirth self-efficacy, (4) indicate satisfaction with efforts towards childbirth and (5) decrease perineal trauma following childbirth compared with those who used a leaflet.

2. Methods

2.1. Study design and participants

A randomised controlled trial was conducted at three hospitals and two clinics in Tokyo, Japan. Participants were recruited who corresponded to all the following at 30–33 weeks of gestation: (1) progress of pregnancy was normal; (2) primiparous; (3) could read and write Japanese and (4) had a smartphone. Questionnaires were distributed and collected over an eight-month period from April 2014 to November 2014. Participants completed questionnaires before starting perineal massage and after giving birth. The Institutional Review Board at St. Luke's International University, Tokyo, Japan approved this study (No. 14-001).

2.2. Study outcomes

Primary outcome was continuance rate of antenatal perineal massage practice. This study regarded 'continuance' as the practice of antenatal perineal massage that began about three weeks before labour, and was conducted three times a week.

Secondary outcomes were; (1) evaluation of perineal massage, (2) satisfaction with efforts towards childbirth, (3) childbirth self-efficacy and (4) the degree of perineal trauma following childbirth.

2.3. Sample size

Sample size in this study was calculated based on a previous study that verified the effect of web-based education.¹⁹ In that study, pregnant women in the intervention group received web-based education about breastfeeding and those in the control group received education as usual. As a result, the continuance rate of breastfeeding at six weeks postpartum was 80% in the intervention group and 58.3% in the control group. Therefore, based on this difference, the sample size was calculated as 53 women in each group to detect a difference between groups at a 5% level of significance with 80% power. Considering the dropout rate to be 20% from previous studies, the sample size needed was 67 women in each group.

2.4. Randomisation

After participants gave their written consent, the researcher or research assistants randomly assigned them to the smartphone website or leaflet by a permuted block method to ensure that approximately equal numbers of women was allocated to each group. The group allocation was concealed in the numbered sealed opaque envelope which was developed by a statistician. Participants were asked not to reveal their group assignment to any medical staff and other pregnant women.

2.5. Data collection

When eligible women at 30–33 weeks' gestation visited the hospital for their prenatal checkup, they were recruited by the researcher or research assistants. If the woman consented to participate, she was provided with a written informed consent form to sign. After participants signed the informed consent form, the researcher or the research assistant gave participants a pre-test questionnaire, a diary and a post-test questionnaire, as well as either instructions for the smartphone website for the smartphone website group (S-web group) or a leaflet about perineal massage for the leaflet group (LF group). Women in both groups completed the pre-test questionnaire around the 34th week of gestation and put the questionnaire in the envelope and then into the collection

box or in the post. All participants were asked to record in a diary indicating whether they or their partner had done the massage. After giving birth, all participants completed the post-test questionnaire and put it in the envelope and into the collection box or in the post. Numbers were written on the questionnaires to match the pre-test and the post-test questionnaire.

2.6. Interventions

2.6.1. Smartphone website

The smartphone website was developed based on results of a literature review by the researcher so that pregnant women could recognise the effectiveness of antenatal perineal massage and continue the massage until childbirth. The contents contained five elements as follows: (1) information about the effects of antenatal perineal massage; (2) information about the massage technique; (3) support by a peer group; (4) communication with a professional and (5) reminders and encouragement. Information about the effects of antenatal perineal massage and the massage technique consisted of basic knowledge. A message board was set to communicate with other pregnant women sharing the same situation as support by a peer group. In addition, an inquiry form was available so that participants could ask a professional questions at any time as communication with a professional. Moreover, participants received e-mails, which included the form that reported frequency of practicing the massage each week as a reminding notification. The woman received an e-mail of encouragement according to the number of times of their massage practice. Five women who had experienced birth and midwives who had the experience of guiding antenatal perineal massage tested the face validity and the content validity of the smartphone website. Women in the S-web group were asked to register themselves as a member at the website. The women could login into the website after receiving an email of registration completion. When the women used the website, reminding notifications were sent out once a week. When a woman inputted an inquiry form, the researcher received the inquiry and replied.

2.6.2. Leaflet

The researcher developed a leaflet of information about perineal massage based on textbooks at hospitals and prenatal magazines. These contents contained two elements as follows: (1) information about the effects of antenatal perineal massage and (2) information about the massage technique.

Women in both groups were advised to practice the massage after 34 weeks gestation, 5–10 min per day and 3–4 times per week.

2.7. Measures

2.7.1. Primary outcome

The primary outcome was continuance rate of antenatal perineal massage practice, collected by a diary.

2.7.2. Secondary outcome

The Japanese version of ‘women’s opinions on the practice of prenatal perineal massage’ was used to assess evaluation of antenatal perineal massage. The researcher developed this scale after permission to produce a Japanese version was obtained from the original author, Labrecque et al.,⁴⁰ ‘women’s opinions on the practice of prenatal perineal massage’ was translated into Japanese and a bilingual speaker who was a native speaker of English produced a reverse translation. The questionnaire was re-evaluated by a discussion with a nursing researcher based on its results, and the ‘Japanese version of women’s opinions on the

practice of prenatal perineal massage’ was completed. This four-factor scale consists of 17 items; enjoyment and easiness of the massage (6 items), effect of preparation for childbirth (6 items), effect of massage on delivery (3 items) and relationship with partner (2 items) ranging from 1 (*not at all*) to 6 (*very much*). The Cronbach’s alpha was .926 indicating high internal consistency. Questions that asked whether women would perform the massage during their next pregnancy and whether they would recommend perineal massage to other pregnant women were the same as the original. Childbirth self-efficacy was measured using the childbirth self-efficacy scale developed by Kameda et al.⁴¹ This scale measures outcome expectancies and self-efficacy expectancies to cope with childbirth. This scale consists of 26 items for outcome expectancies and 26 items for self-efficacy expectancies. Validity and reliability of this scale was confirmed.⁴¹ Items were rated using a five-point Likert scale, the higher the points, the higher outcome expectancies or self-efficacy expectancies. For this study, the coefficient alpha of outcome expectancies was .947 and self-efficacy expectancies was .939 indicating high internal consistency. A visual analogue scale was used to rate their satisfaction with efforts towards childbirth was used. Demographics and obstetric data were also collected by the medical record.

2.8. Analysis

All analyses were carried out through SPSS version 21.0J, as follows: (1) descriptive statistics were used to summarise the participants’ characteristics; (2) Chi-square test was used to compare categorical data and *t*-test was used to compare continuous data if participants’ characteristics differed among the S-web group and the LF group and (3) Chi-square test and *t*-test were used to compare the outcomes of the S-web group and the LF group. The primary outcome was analysed by both an intention to treat analysis and a per protocol analysis. Moreover, secondary outcomes were examined by a per protocol analysis. All statistical tests were done using a two-sided 5% level of significance.

3. Results

The flow of participants for data collection is shown in Fig. 1. There were 190 meeting the eligibility criteria during the study period and of those 29 refused to participate. Therefore 161 eligible women were randomly assigned to either the S-web group ($n = 81$) or the LF group ($n = 80$). Finally, 47 (58.0%) in the S-web group and 49 (61.3%) in the LF group completed all questionnaires.

Baseline characteristics and birth outcomes were similar in the both groups (Tables 1 and 2).

3.1. Continuance rate

Primary outcome of ‘continuance rate of perineal massage’ is shown in Table 3. The rates by a per protocol analysis were 51.1% (24/47) in the S-web group and 51.0% (25/49) in the LF group, respectively. There was no significant difference between the groups ($\chi^2(1) = .000, p = .997$). Moreover, the rates by an intention to treat analysis were 29.6% (24/81) in the S-web group and 31.3% (25/80) in the LF group. There was no significant difference between the groups ($\chi^2(1) = .050, p = .823$).

3.2. Evaluation of perineal massage

The ‘Japanese version of women’s opinions on the practice of prenatal perineal massage’ score was compared between the

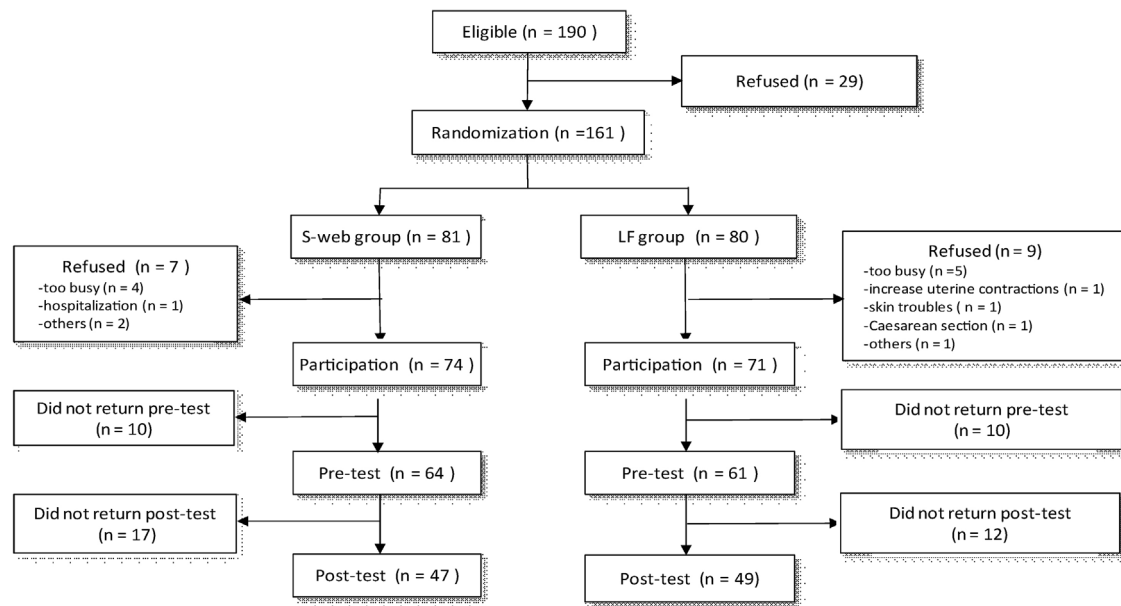


Fig. 1. Flow of participants for data collection.

two groups. The mean score of the scale was 52.3 ($SD = 15.41$) in the S-web group and 51.7 ($SD = 14.41$) in the LF group, respectively. There was no significant difference between the groups ($t(92) = .187, p = .852$).

The majority of women (68.1% in the S-web group and 72.3% in the LF group, respectively) reported that they would massage again for the next delivery, and 6.4% in the LF group and 0% of the S-web group had no intention of doing the massage again.

Approximately half of women (56.8% in the S-web group and 53.2% in the LF group, respectively) would recommend the

massage to other pregnant women. There was no significant difference between the groups ($\chi^2(3) = 2.91, p = .406$).

3.3. Childbirth self-efficacy

The mean score of outcome expectancies was 93.4 ($SD = 13.81$) in the S-web group and 94.1 ($SD = 16.79$) in the LF group, respectively. There were no significant differences in those score between the groups ($t(123) = .544, p = .587$).

3.4. Satisfaction with efforts towards childbirth

Satisfaction with efforts towards childbirth in the S-web group was 76.0 ($SD = 17.99$), and those in the LF group was 71.1 ($SD = 19.80$), respectively. There was no statistical significance ($t(90) = 1.28, p = .212$).

Table 1
Baseline characteristics of women according to study groups.

	S-web (n=47)	LF (n=49)
Age(yr): mean [SD]	32.7 [4.59]	32.5 [4.18]
Educational level: n (%)		
Junior high school or high school	4 (8.5)	1 (2.0)
Diploma	7 (14.9)	13 (26.5)
Undergraduate	33 (70.2)	30 (61.2)
Graduate	3 (6.4)	5 (10.2)
Opinion about perineal laceration: n (%)		
Not acceptable	7 (14.9)	5 (10.2)
If possible	38 (80.9)	40 (81.6)
Acceptable	2 (4.3)	4 (8.2)
Opinion about episiotomy: n (%)		
Not acceptable	2 (4.3)	2 (4.2)
If necessary	22 (46.8)	31 (64.6)
Acceptable	23 (48.9)	15 (31.3)
Interest in perineal massage practice: n (%)		
Strong	13 (27.7)	18 (36.7)
Moderate	30 (63.8)	29 (59.2)
Little	4 (8.5)	2 (4.1)
Childbirth self-efficacy (self-efficacy expectancy): mean [SD]		
Total scale score	86.5 [15.29]	88.4 [13.86]
Preparation for coping with childbirth and emotional control	33.3 [7.90]	33.0 [6.86]
Preparation for labour pain and acceptance of support	22.8 [3.21]	24.4 [2.75]
Preparation for childbirth in my own way	17.1 [3.42]	17.9 [3.50]
Preparation for judgement a symptom of onset and coping behaviour	13.4 [3.66]	13.2 [2.71]

Table 2
Birth outcomes of women according to study groups.

	S-web (n=47)	LF (n=49)
Type of delivery: n (%)		
Spontaneous	35 (74.5)	38 (77.6)
Assisted delivery	6 (12.8)	5 (10.2)
Caesarean section	6 (12.8)	6 (12.2)
Gestational age at delivery (wk): mean [SD]	39.4 [1.28]	39.2 [1.31]
Duration of labour (min): mean [SD]	704.7 [522.28]	631.0 [430.98]
Mean birth weight (g): mean [SD]	3049.7 [303.31]	3071.1 [404.06]
Position in the second stage of labour: n (%)		
Lithotomy position	37 (90.2)	35 (81.4)
Lateral position	4 (9.8)	4 (9.3)
Hands and knees posture	0 (0.0)	4 (9.3)
Apgar score at 1 min: n (%)		
≥ 8 points	45 (95.7)	67 (93.9)
≤ 7 points	2 (4.3)	4 (6.1)
Apgar score at 5 min: n (%)		
≥ 8 points	45 (95.7)	48 (98.0)
≤ 7 points	2 (4.3)	1 (2.0)

Table 3
Continuance rates of perineal massage practice according to study groups.

Per protocol analysis	S-web (n = 47) n (%)	LF (n = 49) n (%)	p value
Massaged ≥ 3 times and 3 weeks	24 (51.1)	25 (51.0)	.997
Massaged ≥ 1 time and 3 weeks	41 (87.2)	41 (83.7)	.621
Intent to treat analysis	S-web (n = 81) n (%)	LF (n = 80) n (%)	p value
Massaged ≥ 3 times and 3 weeks	24 (29.6)	25 (31.3)	.823
Massaged ≥ 1 time and 3 weeks	41 (50.6)	41 (51.3)	.936

Table 4
Perineal outcomes according to study groups.

	S-web (n = 41)	LF (n = 43)	p value
Perineal outcome: n (%)			
Intact	4 (9.8)	2 (4.6)	.449
First-degree	3 (7.3)	9 (20.9)	
Second-degree	10 (24.4)	9 (20.9)	
Episiotomy	24 (58.5)	23 (53.5)	
Third-degree	0 (0.0)	0 (0.0)	

3.5. Perineal outcomes

Perineal outcomes in both group are shown in Table 4. Among women who delivered vaginally, episiotomies rates in both groups were high, 58.5% in the S-web group and 53.5% in the LF group, respectively. There was no significant difference in perineal outcome between the groups ($\chi^2(4) = 3.70$, $p = .449$). Severe perineal lacerations (third and fourth degree lacerations) did not occur in either group. Most women who delivered vaginally and had perineal trauma received suturing (92.7% in the S-web group and 97.7% in the LF group, respectively). There was no significant difference between the groups ($\chi^2(1) = 1.15$, $p = .283$).

4. Discussion

4.1. Primary outcome: continuance of antenatal perineal massage

In this study, continuance rates (three times a week over a three week period) were 51.1% in the S-web group and 51.0% in the LF group by a per protocol analysis and 29.6% in the S-web group and 31.3% in the LF group by an intention to treat analysis. In previous studies, among women who received information about perineal massage through textbooks at hospitals or prenatal magazines, the rates of women who perform the massage over three times a week until childbirth were 12.9–15.9%.¹¹ Moreover, it was reported that continuance rates of perineal massage were 2.9–5.4% among women who receive no massage instruction.^{42,43} Therefore, continuance rates in this study were higher than the results of those studies. Furthermore, in the previous studies, pregnant women received information about the massage by themselves; on the other hand, in this study, communication with a professional happened when the researcher provided information for participants. This communication between participants and a professional might have had an effect on continuance of the massage.

In previous studies, among women who received instruction about perineal massage, the continuance rate in Labrecque et al.'s⁴² study was 65.1% and the rate in Shimada's⁴⁴ study was 76.7%. Therefore, the rate in this study was lower compared with these studies. Shimada⁴⁴ checked on whether participants performed the massage by self-report diary, telephone and asking at the prenatal checkup. Labrecque et al.⁴² also telephoned women

in the massage group to encouragement to continue the massage. While these studies provided ongoing communication between participants and professionals, this was lacking in the study described here. Therefore, besides just giving instructional material, what is needed is follow-up such as confirming whether pregnant women performed the massage or whether they had some questions about the massage at the prenatal checkup.

4.2. Secondary outcomes

Evaluation of perineal massage, childbirth self-efficacy, satisfaction with efforts towards childbirth, perineal trauma were measured as secondary outcomes. Firstly, there was no significant difference in evaluation of perineal massage between the groups presumably because women in both groups performed perineal massage and continuance rates in both groups were similar. Secondly, there were no significant differences in childbirth self-efficacy and satisfaction with efforts towards childbirth. Takeuchi and Horiuchi¹¹ reported that self-efficacy, 'childbirth in my own way', of primiparous women who practiced perineal massage was significantly larger than who did not practice. However, previous studies reported that physical exercise or acquisition of the knowledge of childbirth during pregnancy were also associated with childbirth self-efficacy,^{45,46} accordingly perineal massage practice is only one of the factors influencing these self-efficacy variables. Materials in this study did not have enough of a significant effect to influence these variables. Lastly, there were no differences between the groups in perineal outcomes following childbirth. The episiotomy rates in both groups were over 50% in this study. Shimada⁴⁴ found that the episiotomy rate in the massage group was reduced by 21%. If the episiotomy rate were to be reduced from 50% to 30% when women continue perineal massage, the sample size needed would be 93 women in each group to detect a difference between the groups at a 5% level of significance with 80% power. Therefore, an increased sample size is needed in order to verify the effects of perineal massage on perineal outcomes following childbirth.

4.3. Limitations and suggestions for future studies

This study was limited in several ways. Firstly, among women who completed all questionnaires, almost all women performed perineal massage. There might be participants' motivation or interest in perineal massage as confounding factors of this study.

Secondly, The number of required subjects was compromised because the withdrawal rate was high (44.4% in S-web group and 38.8% in LF group, respectively). The researcher sent reminder mails to participants who did not answer the questionnaires. However, the mail did not lead to the desired response rate. In this study, the researcher gave participants the post-test questionnaire when participants signed the informed consent form. However, it might be a better strategy for the researcher to have participants report their delivery and then researchers hands the post-test questionnaire directly to the participant or has it sent by post after childbirth. Moreover, it might be need to devise such as providing an incentive every time when participants report frequency of practicing the massage each week or asking directly when they visit the hospital for their prenatal checkup in order to keep response rate. In the future, it will be important to continue to keep in touch with the participants because the researcher did not regularly communicate with each participant in this study. Moreover, sample size was calculated based on the study of breastfeeding website, which compared the website to usual care. However, in this study, the website was compared to a leaflet. Therefore, not only the withdrawal rate was high, but also sample size might be small because a leaflet was more effective than usual care.

Finally, participants in the LF group provided a leaflet as usual care group in this study. However, participants got information about perineal massage technique because the contents of the leaflet contained information about the effects of the massage and the massage technique. Therefore, the website and leaflet would need to compare with no treatment as usual group in order to evaluate these materials.

The purpose of antenatal perineal massage is to enhance the flexibility of perineum for reducing perineal trauma of childbirth. In the future, it needs to indicate the true efficacy of the massage using the physiological indexes such as the flexibility of skin. In addition, it needs to develop the educational programme in order to reduce episiotomies for medical staff because episiotomies are routine for primiparous women at some hospitals in Japan.

Conflict of interest

The authors declare that they have no conflicts of interest.

Acknowledgments

We thank all the women who participated in this research and the staff who accepted our research. We are grateful to Dr. Sarah E. Porter, Oregon Health and Science University (retired), for editing. This work was supported by Grant-in-Aid for Scientific Research (KAKENHI) (2014–2016) and YAMAJI FUMIKO NURSING RESEARCH FUND.

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