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Randomized Controlled Trial using Smartphone Website vs Leaflet to Support  
Antenatal Perineal Massage Practice for Pregnant Women

妊娠中の会陰マッサージの継続を支援するスマートフォンサイト対  
リーフレットによる無作為化比較試験

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## Introduction

### Background

Perineal trauma following childbirth has not only short-term effects such as perineal pain but also long-term effects such as coital pain or hesitation for the next delivery (Okubo, Mitsuhashi & Saito, 2000; Calvert & Fleming, 2003). Episiotomies represent one type of trauma. Various guidelines (Minds, 2013; National Institute for Health & Clinical Excellence, 2014), 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 (Kawai, 2000) indicating that at some hospitals episiotomies are routine for primiparous. On the other hand, the episiotomies rates in some comparable countries are 27-28% in the USA, 3-31% in Canada, and 9.9-20.9% in Australia (Graham, Carroli, Davies & Medves, 2005). The episiotomy rate in Japan is higher than those countries and Dahlen, Ryan, Homer & Cooke (2007) reported that Asian ethnicity was associated with a risk of severe perineal trauma such as third or fourth degree lacerations.

Antenatal perineal massage is a preventive method for reducing perineal trauma of childbirth. Beckmann & Garrett (2013) reported that antenatal perineal massage for primiparous was associated with a reduction in the incidence of trauma requiring suturing and episiotomy. Shimada (2005a) 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. Even so, Takeuchi (2014) reported the rate of antenatal perineal massage practice was only 15.1%. Takeuchi & Horiuchi (2014) conducted an empirical investigation for identifying factors impeding pregnant women's massage practice. As a result, factors impeding the massage practice were, resistance to touching their perineum, lack of knowledge and some difficulty practicing the massage technique. 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' 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. Moreover, in Japan, the internet user rate of those ages 13 to 49 is over 95% (Japanese Ministry of Internal Affairs & Communications, 2013) and the smartphone ownership rate has increased rapidly, rising from 9.7% in 2010 to 49.5% in 2012 (Japanese Ministry of Internal Affairs & Communications, 2013). Dennison, Morrison, Conway & Yardley (2013) reported that young healthy adults had some interest in smartphone application for supporting health-related behavior 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.

### **Objectives**

The purpose of this study was to develop and evaluate two educational materials (a smartphone website vs a leaflet) to support antenatal perineal massage for primiparous women.

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 toward childbirth and (5) decrease perineal trauma following childbirth.

### **Significance of the Study**

Practicing antenatal perineal massage for reducing perineal trauma following childbirth may enhance the flexibility of the perineal tissues and thereby reduce the risk of perineal trauma following childbirth. Moreover, when pregnant women continue to use the massage technique, they may be more satisfied with their efforts toward childbirth and increase their childbirth self-efficacy. In addition, it will be expected that the self-care ability of pregnant women would be improved because they become more conscious about their body through the massage experience, affording them an

opportunity to think of other ways they could employ self-care.

While there are many studies about web-based education using personal computers, the studies about web-based education using smartphones are few. This study will determine the feasibility, versatility and effectiveness of a smartphone website.

### **Definition of Terms**

Antenatal perineal massage: Pregnant women or their partner practice gently stretch the perineal tissue to achieve softening of the perineum for reducing perineal trauma following childbirth.

Childbirth self-efficacy: Pregnant women's confidence that they can cope with various situations and physiological changes during childbirth and before starting labor.

Perineal trauma: Trauma caused by natural means during childbirth and trauma also caused by an episiotomy either indicated or routine.



## Literature Review

### Literature Review

#### **The frequency of perineal trauma following childbirth.**

Kawai (2000) reported that the episiotomy rate was 30-100% for primiparous and 10-70% for multiparous in Japan. On the other hand, Graham et al. (2005) reported that the episiotomies rate were 27-28% in the USA, 3-31% in Canada and 9.9-20.9% in Australia. Thus the episiotomy rate in Japan is higher than those countries. In addition, Alberts, Sedler, Bedrick, Teaf & Peralta (2006) reported that 50% primiparous and 64% multiparous without episiotomies also had no perineal trauma. Likewise, in Japan, the research targeted 4382 women who had vaginal deliveries at midwifery birth centers reported intact rate was 58.3% and first degree perineal laceration rate was 38.4% (Eto & Kataoka, 2008). According to the above results, characteristics of medical facilities seem to have greatly affected the episiotomies rate at medical facilities in Japan.

#### **Influence of perineal trauma.**

##### ***Perineal pain.***

East, Sherburn, Nagle, Said & Forster (2011) interviewed 215 Australian women within 72 hours of a vaginal birth. As the result, they reported that about 90% women felt some perineal pain. In Japan, Sato, Hasegawa & Toyooka, (1994) also reported about 90% women felt some perineal pain after childbirth. Moreover, a literature review on sexual health in the postpartum period reported that perineal pain persisted for a longer period after an assisted delivery compared to natural delivery (Abdool, Thakar & Sultan, 2009). A questionnaire survey targeted 425 postnatal women found that women with episiotomies felt significantly greater pain and less pain relief than those with second-degree lacerations (Takeuchi, 2014). In addition, Tsujioka et al. (1996) conducted a survey to clarify the effect of activity of daily life after an episiotomy. As a result, it was found that the rate of women with episiotomies who felt perineal pain from one to six months postpartum period was higher than the rate of those with perineal lacerations. From the above, the concern

is that perineal pain from an episiotomy is greater and more protracted than from perineal laceration.

***Disruption of daily life.***

Shimonokado, Takahashi, Matsuzaki & Narita (1995) queried 95 postnatal women who received perineal suturing. The results of their survey found that activities that exacerbated strong perineal pain were sitting and having the bed elevated. Shimada (2003) surveyed postnatal women to clarify the disruptions in their daily life and found that those women with episiotomies felt significantly more difficulty sitting and sleeping than those with a first-degree laceration. Takeuchi's study (2014) targeted 425 postnatal women and also found that women with episiotomies felt more difficulty sitting, difficulty moving and suffered from a loss of volition because of perineal pain than those with second-degree lacerations. Accordingly, it was difficult for women who experienced strong perineal pain to adjust their position from supine to sitting so that they could adequately nurse their infants.

***Urinary incontinence.***

Takaoka (2013) conducted a questionnaire survey of 421 postnatal women to identify intrapartum factors that were associated with the prevalence of urinary incontinence in the early postpartum period. As a result, it was found that the rate of early urinary incontinence was more common in women with episiotomies. Moreover, Chang, Chin, Lin, Chao & Lai (2011) reported that the number of women with episiotomies had a higher urinary incontinence score in three months after delivery than those who had not undergone an episiotomy. Accordingly, episiotomy is a risk factor of urinary incontinence.

***Psychologically influence.***

Sato (2004) who surveyed 165 mothers reported that women with episiotomies felt significantly more anxiety about how long their perineal pain would last than those with lacerations. Moreover, Okubo et al. (2000) reported that women with episiotomies were afraid of resuming their sexual relationship and felt their families

lacked an understanding of their perineal pain compared with women with perineal lacerations. Calvert & Fleming (2003) reported in a literature review of episiotomies that perineal pain was generally unrecognized by health professionals.

In addition, Wakita, Irisawa, Horiuchi & Kabeyama (2000) sought to clarify women's acceptance of episiotomies and found some women held negative opinions such as "My perineum was painful after I received an episiotomy", "I can't start my sexual life because of perineal pain from the episiotomy" and "I felt that a laceration was more comfortable than an episiotomy". Oi, Sokabe & Kishi (2000) surveyed postpartum women to identify their anxieties about sexual life. They found many women were anxious and worried about breaking the perineal sutures upon resuming sexual relations. Accordingly, perineal pain following childbirth remains for long time and was a risk factor for sexual dysfunction.

#### **The effectiveness of antenatal perineal massage.**

A systematic review of antenatal perineal massage to evaluate the effect on perineal trauma following childbirth reported that primiparous pregnant women who practiced the massage from 34 weeks gestation, 5-10 minutes per a day and 3-4 times per a week had a significantly reduced incidence of trauma requiring suturing (RR0.91 95%CI [0.86, 0.96]) and episiotomy (RR0.84 95%CI [0.74, 0.95]) compared to those who did not practice the massage (Beckmann & Garrett, 2013).

In addition, Labrecque, Eason & Marcoux, (2001) surveyed 684 pregnant women about their perineal massage practice. They reported that many women commented on pain while massaging or difficulty with the massage technique during the first few weeks, however they said that the pain and the burning sensation had decreased or had disappeared and that massage was easier to perform by the second or third week. In Japan, Shimada (2005a) interviewed eight postnatal women who practiced antenatal perineal massage and women's view on the massage was analyzed qualitatively. As a result, it was found that women 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. Moreover, women perceived that the

massage was one of a number of preparations toward childbirth just like weight control or antenatal exercises. Accordingly, it is suggested that continuing perineal massage enables primiparous women to enhance their self-efficacy about childbirth and reduced the risk of perineal trauma following childbirth.

### **Educational method of antenatal perineal massage.**

Labrecque et al. (1999) conducted a randomized controlled trial with 1522 primiparous pregnant women to evaluate the effectiveness of antenatal perineal massage. As a result, it was found that the practice rate of perineal massage was 96.6% in the intervention group and 5.5% in the control group, respectively. Moreover, other studies (Labrecque, Marcoux, Pinault, Laroche & Martin, 1994; Shipman, Boniface, Teff & McCloghry, 1997; Shimada, 2005b) also reported that the practice rate of perineal massage in the intervention group that received guidance by a leaflet or a description was higher than in the control group that received usual care. The rate was 76.7-91% in the intervention group and 0-5.4% in the control group. In a randomized controlled trial by Mynaugh (1991), women in the intervention group received printed and verbal instruction and a video demonstration of perineal massage and women in the control group received only the printed and verbal instructions. As a result, the practice rate was 35.6% in the intervention group and 18.4% in the control group, respectively.

In these previous studies, educational preparation of perineal massage had been face-to-face using printed material such as pamphlets or leaflets. In addition, researchers suggested that application of educational materials such as a model or a video would make it easier for pregnant women to practice the massage instead of only relying printed material.

### **The effectiveness of web-based education.**

#### ***Overview of literature.***

A literature search found 29 studies classified within the category of web-based education: six were about weight control and drinking; five involved physical activity;

three focused on meals and three were about the prevention of sexually transmitted diseases; two on, smoking and one each for the whole field of health promotion (physical activity, meal and weight control), infection prevention, blood pressure management, and breastfeeding. Web-based education research was used frequently for education on lifestyle disease prevention.

### ***The effectiveness of behavioral change interventions.***

To measure the effectiveness of behavioral change interventions, the following outcome measurements were used: knowledge, awareness and self-efficacy.

Six studies measured change in knowledge as the effect of intervention; four studies reported that after the intervention, knowledge scores in the intervention group were significantly higher than in the control group (Bowen, Horvath & Williams, 2007; Huang et al., 2007; Lovecchio, Wyatt & DeJong, 2010; Irvin et al., 2011). Two studies measured knowledge scores at the follow-up test, however there were no significant changes in knowledge in either group.

Seven studies measured change in awareness as the outcome and six studies reported that awareness in the intervention group improved more than in the control group after the intervention (Oenema, Brug & Lechner, 2001; Huang et al., 2007; Lovecchio et al., 2010; Irvine et al., 2011; Swantz et al., 2011; Yardley, Miller, Schlotz & Little, 2011).

Five studies measured change in self-efficacy. Four studies reported that self-efficacy in the intervention group improved more than in the control group after the intervention (Bowen et al., 2007; Huang, S, J., Huang, W, C., Chang, M. & Chang, J., 2009; Irvine et al., 2011; Swantz et al., 2011). However, in three of the studies that conducted a follow-up test, neither group difference reach significance. Consequently, it may be that web-based education has only a short-term effect on knowledge, awareness and self-efficacy after behavior modification; however further study is needed to ascertain longer-term effects.

### ***Effects on behavioral change.***

Twenty-two studies measured behavioral change. Seventeen of those studies

reported that behavioral change in the intervention group had more significant change than in the control group (Swantz, Noell, Schroeder & Ary, 2006; Bersamin, Paschall, Fearnow-Kenny & Wyrick, 2007; Huang et al., 2007; Hurling et al., 2007; Cunningham, Wild, Cordingley, Mierlo & Humphreys, 2009; Huang et al., 2009; Carpenter, Stoner, Mikko, Dhanak & Parsons, 2010; Hustad, Barnett, Borsari & Jackson, 2010; Lovecchio et al., 2010; Pisinger, Jorgensen, Moller, Dossing & Jorgensen, 2010; Postel, Haan, Huume, Becker & Jong, 2010; Colleran & Lovelady, 2011; Hughes et al., 2011; Irvine et al., 2011; Mouttapa et al., 2011; Paschall, Antin, Ringwalt & Saltz, 2011; Yardly et al., 2011). Moreover, nine of those studies intervened using a tailor-made program and three studies intervened by a program receiving feedback. In addition, five of the seven studies that conducted a follow-up test reported that behavior in the intervention group was retained until the follow-up period (Cunningham et al., 2009; Huang et al., 2009; Hughes et al., 2011; Mouttapa et al., 2011; Yardley et al., 2011). Four of those studies used a tailor-made program for the intervention and the remaining study included a feedback program. Accordingly, web-based education that was included as an individual program or a feedback program had effects on not only behavioral change but also maintenance of behavior.

#### ***Change by behavioral change.***

Fifteen studies reported some changes by behavioral change. Fourteen studies reported physical changes, four studies reported psychological changes, two studies reported quality of life and one study reported change in dose of medicine. Thirteen studies reported the change in the intervention group was significantly greater than in the control group (Rothert et al., 2006; Bersamin et al., 2007; Hurling et al., 2007; Green et al., 2008; Patrick et al., 2009; Bennet et al., 2010; Hustad et al., 2010; Lovecchio et al., 2010; Postel et al., 2010; Colleran & Lovelady, 2011; Hughes et al., 2011; Irvine et al., 2011; Mouttapa et al., 2011). Moreover, follow-up testing was conducted in four studies, and three of those studies reported physical changes such as weight or abdominal circumference decreases in the intervention group were

significantly greater than in the control group (Rothert et al., 2006; Hughes et al., 2011; Mouttapa et al., 2011).

### **Summary of literature review.**

Perineal trauma following childbirth has serious effects for pregnant women including not only perineal pain or disruptions in their daily life but also urinary incontinence or psychologically disturbances. Some studies reported that antenatal perineal massage was associated with improvement of independent toward childbirth or the effectiveness of decreasing perineal trauma for primiparous. Midwives taught pregnant women face-to-face about antenatal perineal massage technique in all previous studies. While many studies around the world reported the effectiveness of web-based education none have included perineal massage.

### **Conceptual Framework of the Study**

Conceptual framework of this study based on social cognitive theory (figure1).

Social cognitive theory developed by Bandura, was one of the learning theories applied to health behavior. Bandura (1963) published a social learning theory, which could occur purely through observation or direct instruction, even in the absence of motor reproduction or direct reinforcement. In addition, Bandura (1977) dealt theoretically with the cognitive concept of self-efficacy for the first time. Moreover, in 1986, social learning theory was renamed to social cognitive theory (Bandura, 1986). In a social cognitive theory, human functioning is the result of the interaction among these three factors: behavioral, personal and environmental. A social cognitive theory has been used in health education or health behavior programs.

In this study, the assumption is that antenatal perineal massage can be continued through not only personal factors but also the environmental factor of communication with other pregnant women in the same situation or through a professional. The researcher developed the following hypothesis: if primiparous pregnant women used a smartphone website supporting antenatal perineal massage practice, then they would, (1) continue perineal massage practice until childbirth, (2) feel the effects of the massage,

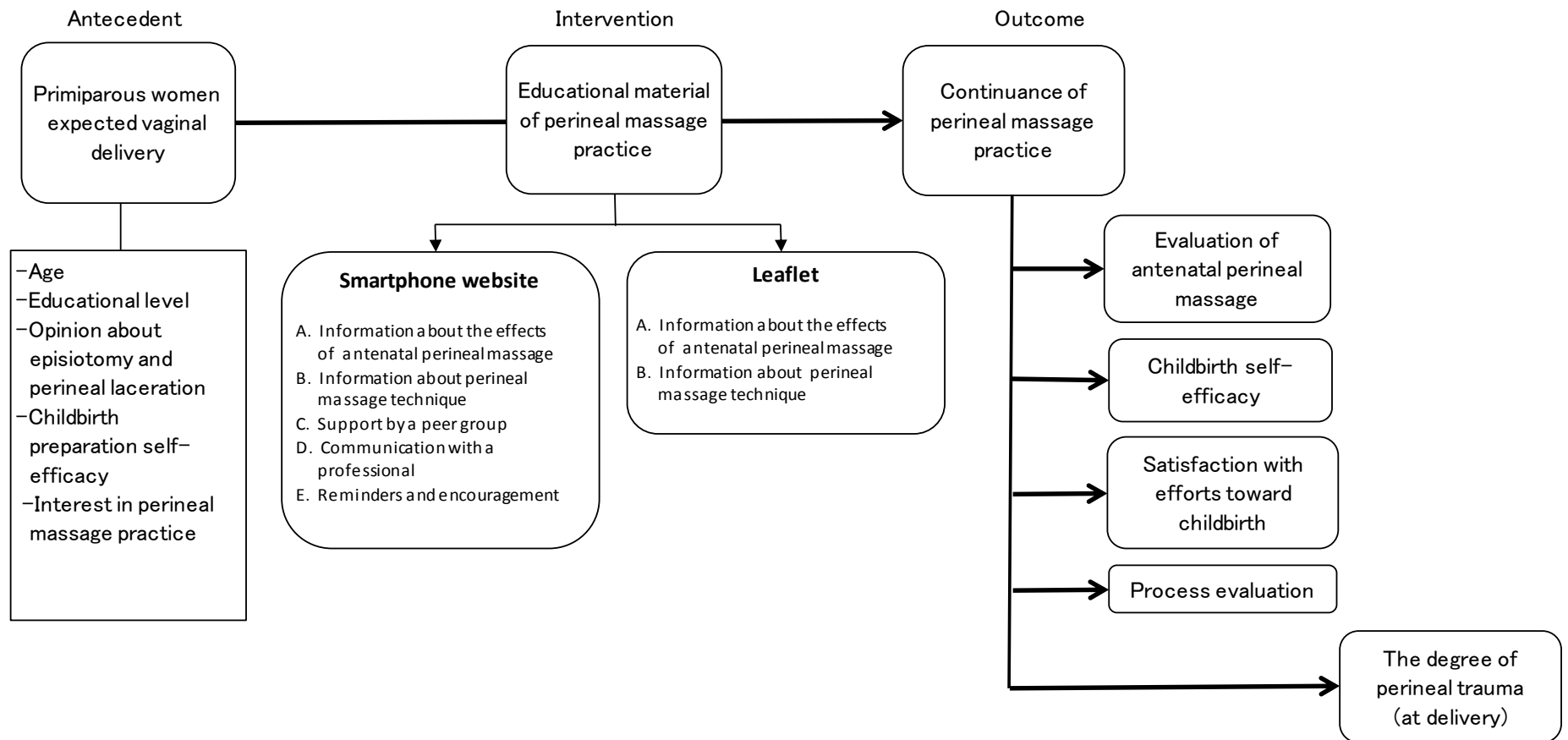


Figure 1. Conceptual framework of the study



(3) improve childbirth self-efficacy, (4) indicate satisfaction with efforts toward childbirth and (5) decrease perineal trauma following childbirth.

## Methods

### Study Design

A randomized controlled trial was conducted in order to determine more effective material for continuing perineal massage practice. Participants were randomly assigned to one of two groups: a smartphone website group (S-web group) and a leaflet group (LF group).

S-web group	$O_1-X_1-O_2$
LF group	$O_3-X_2-O_4$

$O_{1,3}$ : pre-test    $X_1$  : a smartphone website intervention    $X_2$  : a leaflet intervention    $O_{2,4}$ : post-test

### 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 labor, and was conducted three times a week.

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

### Setting and Participants

This study 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.

### Sample Size

Sample size in this study was calculated based on a previous study that verified the effect of web-based education (Huang et al., 2007). 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.

### **Research Period**

Questionnaires were distributed and collected over an eight-month period from April 2014 to November 2014.

### **Randomization**

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

### **Procedure for Conducting the Study**

#### **Recruitment.**

The researcher sent a letter to prospective institutions explaining the study's purpose to ask for their cooperation with the study <Appendix 1>. Their intention to cooperate with the study was confirmed by their returning a postcard <Appendix 2>. After receiving consent from the institutions, the researcher went to the settings and explained the study to the entire staff. The researcher had put up posters at the outpatient wards the week prior to beginning recruitment <Appendix 3>. When eligible women at 30-33 weeks' gestation visited the hospital for their prenatal checkup, the researcher or research assistants handed them a leaflet and introduced them to the study <Appendix 4>. Upon receiving consent to receive an explanation about the study, the researcher or research assistants explained the study verbally

and provided a description of the study <Appendix 5>. If the woman consented to participate, she was provided with a written informed consent form to sign <Appendix 6>.

### **Data collection.**

After participants signed the informed consent form, the researcher or the research assistant gave participants a description of the study, pre-test, diary, post-test, a written stop notification and an instruction of the smartphone website for the S-web group or a leaflet about perineal massage for the LF group <Appendices 7-14>. Women in both groups completed the pre-test around the 34th week of gestation and put the questionnaire in the envelope and then into the collection box or a 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 and put it in the envelope and into the collection box or a post. Numbers were written on the questionnaires to match the pre-test and the post-test. In addition, the researcher sent reminder mails to participants who did not answer the questionnaires.

### **Interventions**

#### **S-web group.**

##### ***Development of a smartphone website.***

The basic configuration of this study was the development of a smartphone website supporting antenatal perineal massage practice. The purpose of this smartphone website was so that pregnant women could recognize the effectiveness of antenatal perineal massage and continue the massage until childbirth. Some contents of a smartphone website supporting antenatal perineal massage practice were developed based on results of a literature review and a preliminary study by the researcher (Table1, Appendix 15). 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. The contents contained five elements as follows: A) information about the effects of antenatal

Table 1

*Contents of Educational Materials*

	Smartphone Website	Leaflet
<b>A. Information about the effects of antenatal perineal massage</b>	<ul style="list-style-type: none"> <li>-Prevention of perineal laceration and episiotomy</li> <li>-Preparation toward childbirth</li> <li>-Women's perception of antenatal perineal massage</li> </ul>	-Prevention of perineal laceration and episiotomy
<b>B. Information about perineal massage technique</b>	<ul style="list-style-type: none"> <li>- Caution points before practicing the massage</li> <li>- Kinds of the oil which is used for the massage</li> <li>- Amount of the oil which is used for the massage</li> <li>- Timing to practice the massage</li> <li>- Part of the body which performed the massage</li> <li>- Fingers which use for the massage</li> <li>- Posture of practicing the massage</li> <li>- How to move fingers</li> <li>- Pressure to apply the massage</li> <li>- Time practicing the massage</li> <li>- FAQ</li> </ul>	<ul style="list-style-type: none"> <li>- Caution points before practicing the massage</li> <li>- Kinds of the oil which is used for the massage</li> <li>- Timing to practice the massage</li> <li>- Part of the body which performed the massage</li> <li>- How to move fingers</li> <li>- Time practicing the massage</li> </ul>
<b>C. Support by a peer group</b>	<b>A message board</b>	-
<b>D. Communication with a professional</b>	<b>An inquiry form</b>	-
<b>E. Reminders and encouragement</b>	<ul style="list-style-type: none"> <li>- A reminding notification (once a week)</li> <li>- An e-mail of encouragement according to the frequency of the massage practice</li> </ul>	-

perineal massage; B) information about the massage technique; C) support by a peer group; D) communication with a professional and E) reminders and encouragement.

*Information about the effects of antenatal perineal massage.*

This information consisted of basic knowledge. It included 1) the reduction of the risk of perineal trauma following childbirth, 2) the importance of antenatal perineal massage as a preparation toward childbirth and 3) women's perception of antenatal perineal massage.

*Information about perineal massage technique.*

Pregnant women need to acquire skills so they can perform the massage by themselves or with their partners. By the results of a preliminary study, pregnant women noted several difficulties: 'how to move fingers' and 'how deeply should a finger be inserted into the vagina' (Takeuchi & Horiuchi, 2014). Therefore the information consisted of written instructions, pictures and illustrations to make it easier to understand. To be effective, they should begin perineal massage at 34 weeks gestation and massage for 5-10 minutes per day and 3-4 times per week. In addition, prior to the massage all participants were asked to perform a sensitivity patch test by applying the massage oil, on a thin part of the skin such as the upper arm or thigh and check for an allergic reaction after 24 hours.

*Support by a peer group.*

When people can predict their situation and results of their behavior before they encounter the situation, this outcome prediction can reduce their anxiety and improve capabilities to cope with the situation. Moreover, methods for learning the prediction include observation of other people in a similar situation and listening about the similar situation from other people (Baranowski, Perry & Parcel, 2002). In this website, a message board was set to communicate with other pregnant women sharing the same situation.

### *Communication with a professional.*

According to the literature review about web-based education, programs that included counseling with a professional had an effect on behavioral change. In this website, an inquiry form was available so that participants could ask a professional questions at any time.

### *Reminder and encouragement.*

A reminding notification was sent out once a week. The women received an e-mail of encouragement according to the frequency of their massage practice.

### ***The process of the smartphone website.***

At first, 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, they received e-mails, which included the form that reported the frequency of practicing the massage each week. After women answered the form, they receive comments by e-mail according to number of times they had practiced perineal massage. When a woman inputted an inquiry form, the researcher received the inquiry and replied. After giving birth, the women inputted the answers on a questionnaire about the process evaluation at the website <Appendix 16>.

After the post-test was returned, the researcher matched ID numbers of pre-test and post-test, and verified that the ID number and the smartphone address for the website matched. The researcher then deleted their address from the administrative screen.

### **LF group.**

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

women in the LF group a leaflet and post-test, and recommended they practice the massage after 34 weeks gestation, 5-10 minutes per day and 3-4 times per week. Moreover, the researcher asked the women to perform the patch test before starting the massage. After delivery the women completed the post-test and put it in an opaque envelope and then into the collection box or by post.

### **Outcome Measurements**

A substruction of the relationships between the measured concepts and the measurements in this study is depicted in Figure 2.

#### **Status of implementation of perineal massage practice.**

There were three items to measure the logistics of women's perineal massage practice. They were the number of times for perineal massage practice, the duration of perineal massage practice, and the person (self or other) who practiced the massage.

#### **Evaluation of antenatal perineal massage.**

##### ***Women's opinions on the practice of prenatal perineal massage.***

The measurement, 'women's opinions on the practice of prenatal perineal massage' developed by Labrecque et al. (2001), was used to measure women's view on the practice of antenatal perineal massage. It is 17-item six-point Likert scale ranging from 1 (*not at all*) to 6 (*very much*). It has established face and concurrent validity. The Cronbach's alphas for the three factors were, .83 (preparation for birth) .81 (acceptability) and .79 (partner relationship). Would the women do perineal massage again for the next birth and would she recommend the method to another, were also asked.

##### ***The Japanese version of 'women's opinions on the practice of prenatal perineal massage'.***

The researcher developed a 'Japanese version of women's opinions on the practice of prenatal perineal massage'. After permission to produce a Japanese



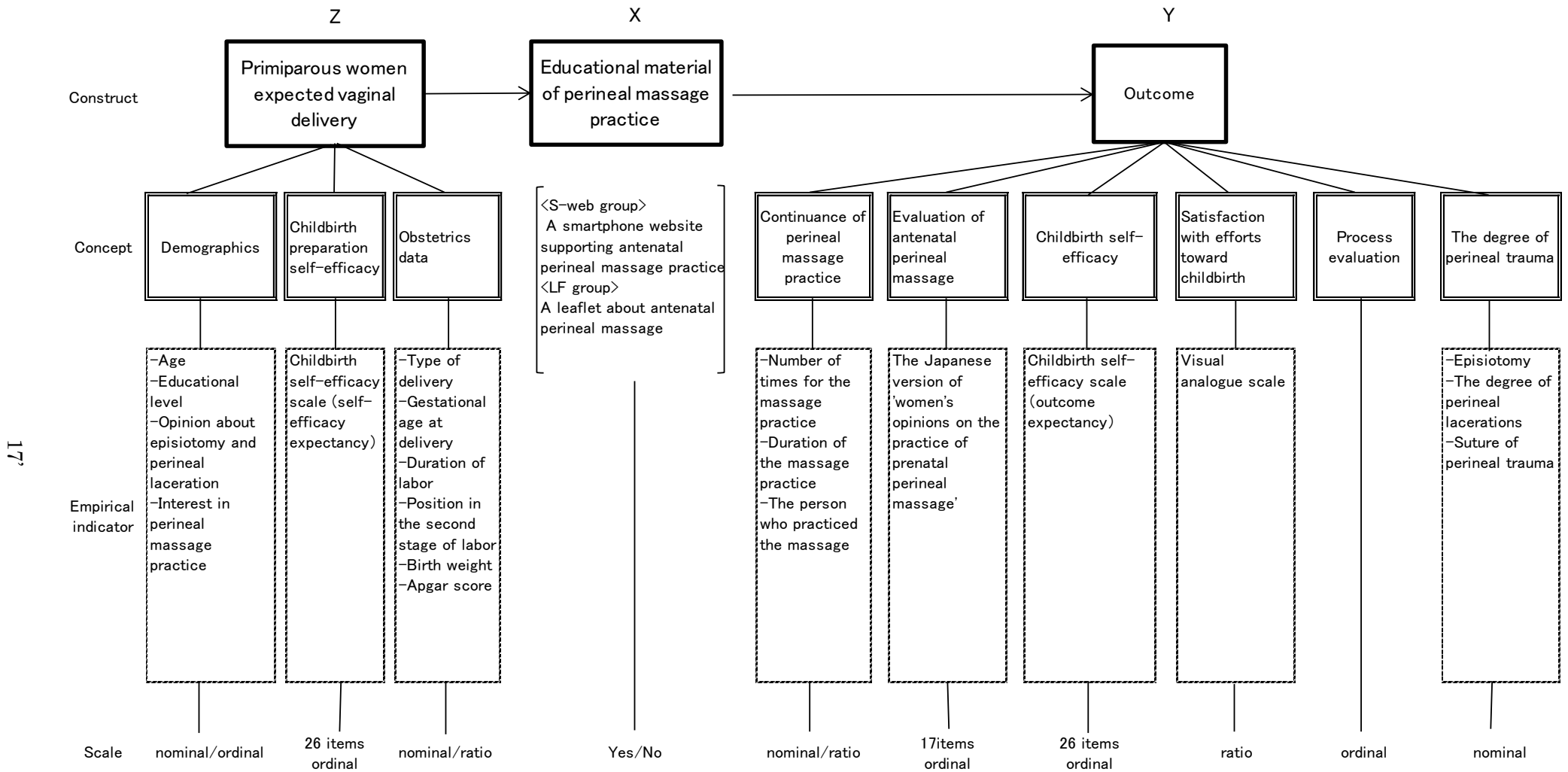


Figure 2. Substruction of the study

version was obtained from the original author, Michel Labrecque, '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). The Cronbach's alpha was .926 indicating high internal consistency. Questions that asked whether women would perform the massage for their next pregnancy and whether they would recommend perineal massage to another pregnant women were the same as the original.

#### **Childbirth self-efficacy.**

Childbirth self-efficacy was measured using the childbirth self-efficacy scale developed by Kameda, Shimada, Tabuchi, Sekizuka & Sakai (2005). 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. The wording of the questions was different for items in outcome and self-efficacy expectancies. Validity and reliability of this scale was confirmed (Kameda et al., 2005). In this study, the 26 items for self-efficacy expectancies were included in the pre-test and the 26 items for outcome expectancies were included in the post-test. Items were rated using a five-point Likert scale. Score ranged from 26 to 130 and 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.

#### **Satisfaction with efforts toward childbirth.**

A visual analogue scale to rate their satisfaction with efforts toward childbirth was used. It was scored from 0 (*not satisfied*) to 100 (*satisfied*).

### **Demographics and obstetric data.**

The questionnaire contained questions about demographic characteristics: age, educational level, opinion about episiotomy and perineal laceration, and interest in perineal massage practice.

Obstetric data consisted of eight items: type of delivery, gestational age at delivery, duration of labor, position in the second stage of labor, episiotomy, the degree of perineal lacerations, suture of perineal trauma, birth weight and Apgar scores (1 minute and 5 minutes). The researcher gathered these data from the medical record.

### **Process evaluation.**

There were four items asking women about 1) comprehensibility, 2) the agreement with expectation, 3) usefulness and 4) satisfaction with the material (the smartphone website or the leaflet). Items were rated using a four-point Likert scale: 1) *I didn't think so at all*, to 4) *I think so very much*. Moreover, the frequency of use the materials were collected.

For participants' opportunity to elaborate, an open-ended section was available in the post-test. Participants in both groups wrote freely about their opinions about the material (the smartphone website or the leaflet) or perineal massage practice.

### **Analysis**

All analyses were carried out through SPSS version 21.0 J. as follows: 1) descriptive statistics were used to summarize the participant's characteristics; 2) chi-square test was used to compare categorical data and t-test was used to compare continuous data if participant's 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 analyzed by both an intent 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. The open-ended comments yielding qualitative data were analyzed using content analysis.

### **Ethical Consideration**

The Institutional Review Board at St. Luke's International University, Tokyo, Japan approved this study (No.14-001). Women were informed verbally and given a written description of the following: 1) participating in this study is voluntary, therefore, even if they refused or stopped halfway, there will be no disadvantage; 2) collected data will only be used for the study purpose; 3) collected data will be conserved for three years after finishing the study and the data will be masked; 4) data will be kept in a safe place and put through a shredder after a reasonable period of time; 5) if women feel perineal pain while they participate in the study, they will be able to receive a medical examination by a doctor and 6) this study is conducted as a doctoral dissertation, therefore, the findings may be presented at conferences and published in academic journals.

## Results

### Sample and Demographic Characteristics and Retention Rates

The flow of participants for data collection is shown in Figure 3. 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). In the S-web group, 47 (58.0%) of participants completed all questionnaires. Moreover, thirty four women were withdrawn for the following reasons: refused to continue (n = 7), failed to return the pre-test (n = 10) and failed to return the post-test (n = 17). On the other hand, in the LF group 49 (61.3%) of participants completed all questionnaires. Thirty one women were withdrawn for the following reasons: refused to continue (n = 9), failed to return the pre-test (n = 10), and failed to return the post-test (n = 12).

Table 2 describes baseline characteristics according to the study groups. Among women who completed the pre-test, the mean ages were 32.4 years ( $SD = 4.37$ ) in the S-web group and 32.6 years ( $SD = 4.43$ ) in the LF group, respectively. Almost all women in both groups had an undergraduate college level of education. Moreover, approximately 80% of women in both groups wanted to avoid perineal lacerations if possible. On the other hand, about half women in both groups wanted to avoid an episiotomy, if possible. The rate of women who were very interested in perineal massage practice in the LF group was higher than in the S-web group, however, there was no significant difference between the groups ( $\chi^2(1) = .578, p = .447$ ). Moreover, there were no significant differences in total scores and subscale scores of childbirth self-efficacy (self-efficacy expectancies) between the groups.

Table 3 describes the delivery characteristics other than perineal outcome of both groups. Among women in both groups completing the post-test, approximately 75% had spontaneous deliveries. There were no significant differences in delivery characteristics other than perineal outcome between the groups.

### Continuance Rate

Characteristics of perineal massage practice is displayed in Table 4. Among women

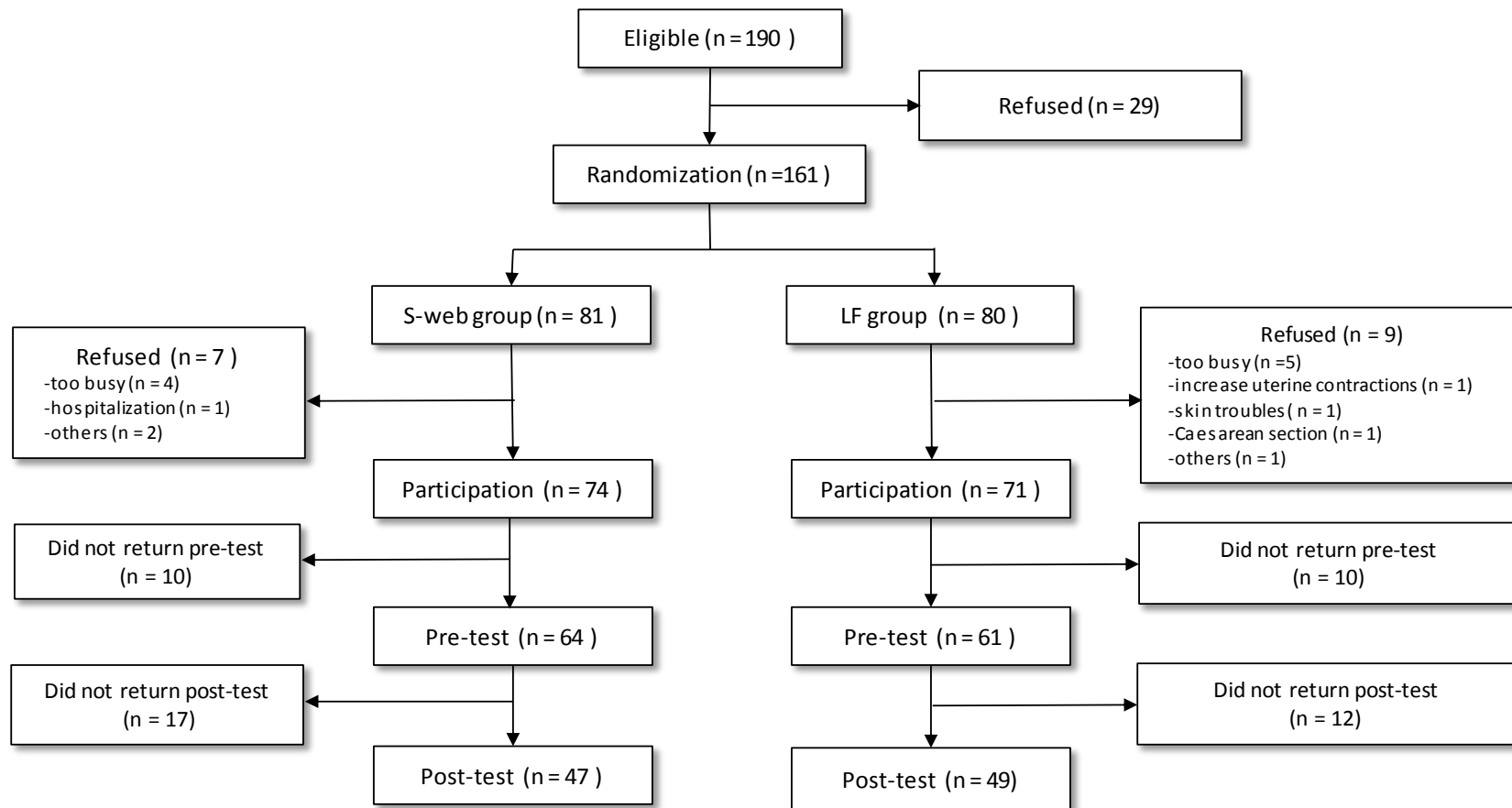


Figure 3. Flow of participants for data collection

Table 2  
*Baseline Characteristics of Women according to Study Groups*

	S-web (n = 64)	LF (n = 61)
Age(yr): mean [SD]	32.4 [4.37]	32.6 [4.43]
Educational level: n (%)		
Junior high school or high school	5 (7.8)	2 (3.3)
Diploma	11 (17.2)	16 (26.2)
Undergraduate	45 (70.3)	38 (62.3)
Graduate	3 (4.7)	5 (8.2)
Opinion about perineal laceration: n (%)		
Not acceptable	9 (14.1)	6 (9.8)
If possible	51 (79.7)	49 (80.3)
Acceptable	4 (6.3)	6 (9.8)
Opinion about episiotomy: n (%)		
Not acceptable	2 (3.1)	2 (3.3)
If possible	34 (53.1)	36 (60.6)
Acceptable	28 (43.8)	22 (36.7)
Interest in perineal massage practice: n (%)		
Strong	18 (28.1)	21 (34.4)
Moderate	41 (64.1)	37 (60.7)
Little	5 (7.8)	3 (4.9)
Childbirth self-efficacy (self-efficacy expectancy): mean [SD]		
total scale score	86.4 [14.48]	87.8 [13.53]
preparation for coping with childbirth and emotional control	33.0 [7.41]	32.8 [6.53]
preparation for labor pain and acceptance of support	23.1 [3.23]	24.1 [3.15]
preparation for childbirth in my own way	17.2 [3.35]	17.8 [3.48]
preparation for judgement a symptom of onset and coping behavior	13.1 [3.36]	13.2 [2.60]

Table 3

*Delivery Characteristics other than Perineal Outcome according 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)
Cesarean section	6 (12.8)	6 (12.2)
Gestational age at delivery (wk): mean [SD]	39.4 [1.28]	39.2 [1.31]
Duration of labor(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 labor: 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 minute: n (%)		
$\geq$ 8 points	45 (95.7)	67 (93.9)
$\leq$ 7 points	2 (4.3)	4 (6.1)
Apgar score at 5 minutes: n (%)		
$\geq$ 8 points	45 (95.7)	48 (98.0)
$\leq$ 7 points	2 (4.3)	1 (2.0)



Table 4

*Characteristics of Perineal Massage Practice according to Study Groups*

	S-web (n = 47)	LF (n = 49)	p value
Massaged $\geq 1$ time: n (%)	45 (95.7)	47 (95.9)	.966
Days with massage: mean [SD]	14.2 [9.76]	13.7 [8.52]	.808
Days with massage for $\geq 5$ minutes: mean [SD]	5.2 [6.05]	7.8 [7.52]	.060
Weeks with $\geq 1$ massages: mean [SD]	4.9 [1.96]	4.8 [2.28]	.712
Weeks with $\geq 3$ massages: mean [SD]	2.6 [2.16]	2.8 [2.12]	.753
Time with massage (min): mean [SD]	4.0 [2.39]	4.9 [3.06]	.121
Massaged person: n (%)			
Only themselves	41 (91.1)	42 (89.4)	.992
Collaborated with partner	4 (8.9)	5 (10.6)	

completing the post-test, the vast majority in both groups practiced the massage more than one time (95.7% in the S-web group and 95.9% in the LF group, respectively). Mean number of days with massage were 14.2 days ( $SD = 9.76$ ) in the S-web group and 13.7 days ( $SD = 8.52$ ) in the LF group. The number of days of massage for over 5 minutes in the LF group ( $7.8 \text{ days} \pm 7.52$ ) was larger than those in the S-web group ( $5.2 \text{ days} \pm 6.05$ ), however, this difference did not reach statistical significance ( $t(91) = 1.90, p = .060$ ). Moreover, the mean duration massaged 'more than once a week' were 4.9 weeks ( $SD = 1.96$ ) in the S-web group and 4.8 weeks ( $SD = 2.28$ ) in the LF group, and the mean duration massaged 'more than three times a week' were 2.6 weeks ( $SD = 2.16$ ) in the S-web group and 2.8 weeks ( $SD = 2.12$ ) in the LF group. In addition, the mean times of massage was 4.0 minutes ( $SD = 2.39$ ) in the S-web group and 4.9 minutes ( $SD = 3.06$ ) in the LF group. Almost all women performed the massage by themselves, only about 10% collaborated with their partner.

Primary outcome 'continuance rate of perineal massage practice' is shown in Table 5. 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 intent 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 ( $\chi^2(1) = .050, p = .823$ ).

Among women completing all questionnaires, most of the women in both groups performed the massage once a week over three week period. (87.2% (41/47) in the S-web group and 83.7% (41/49) in the LF group, respectively). There was no significant difference between the groups ( $\chi^2(1) = .244, p = .621$ ). The rates by an intent to treat analysis were 50.6% (41/81) in the S-web group and 51.3% (41/80) in the LF group, respectively. There was also no significant difference between the groups ( $\chi^2(1) = .006, p = .936$ ).

### **Evaluation of Antenatal Perineal Massage**

The 'Japanese version of women's opinions on the practice of prenatal perineal massage' score was compared between the two groups. This scale consists of four-factor;

Table 5

*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 $\geq$ 3times and 3weeks	24 (51.1)	25 (51.0)	.997
Massaged $\geq$ 1time 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 $\geq$ 3times and 3weeks	24 (29.6)	25 (31.3)	.823
Massaged $\geq$ 1 time and 3 weeks	41 (50.6)	41 (51.3)	.936

‘enjoyment and easiness of the massage’, ‘effect of preparation for childbirth’, ‘effect of massage on delivery’ and ‘relationship with partner’. 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 another pregnant women. There was no significant difference between the groups ( $\chi^2(3) = 2.91, p = .406$ ).

### **Childbirth Self-efficacy**

The mean score of childbirth self-efficacy scale (outcome expectancies) were compared between the groups. The mean score 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 ( $t(123) = .544, p = .587$ ).

### **Satisfaction with Efforts toward Childbirth**

Satisfaction with efforts toward 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 ( $t(90) = 1.28, p = .212$ ).

### **Perineal Outcomes**

Perineal outcomes in both group are shown in Table 6. 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 ( $\chi^2(1) = 1.15, p = .283$ ).

Table 6

*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)	
First-degree	3 (7.3)	9 (20.9)	
Second-degree	10 (24.4)	9 (20.9)	.449
Episiotomy	24 (58.5)	23 (53.5)	
Third-degree	0 (0.0)	0 (0.0)	

*Note,* excluded cesarean section (6 women in S-web group and 6 women in LF group)

## **Process Evaluation**

### **Acceptability.**

Four items were asked about 1) comprehensibility, 2) agreement with expectation, 3) usefulness and 4) satisfaction with the materials (the smartphone website or the leaflet). They responded using a four-point Likert scale.

Process evaluation according to study groups shown in Figure 4 . There were no significant differences in each 4 items between the groups. The results about the smartphone website were as follows: content easy to understand (85.7%); agreed with their expectation (78.6%); useful for practicing perineal massage (82.2%) and satisfied with the contents (75.0%). And the results about the leaflet were as follows: content easy to understand (83.3%); agreed with their expectation (73.0%); useful for practicing perineal massage (83.3%) and satisfied with the contents (70.9%). A few women in the LF group and no women in the S-web group answered “I don’t think so at all” for each of the 4 items. Moreover, the rates of women who answered “I think so very much” about agreement with expectation, usefulness and satisfaction with the contents in the S-web group were larger than those in the LF group, however, there were no significant differences between the groups.

Some women in the S-web group reported that the massage was more fun because of the bright design of the website. In addition, some mentioned that the smartphone website became the motivation to perform the massage. Some women said that they could keep up their motivation because they had to report the frequency of practicing the massage once a week. On the other hand, some women in the LF group commented that they did not resist reading because the leaflet was simple and cute.

### **Demand.**

Some women in both groups commented about actual use. Some women in both groups thought the smartphone website or the leaflet provided the opportunity to start perineal massage. Some women in the S-web group reported they could perform perineal massage because the smartphone website provided specific content.

Moreover, some demands were reported. Some women aged over 40 in the S-

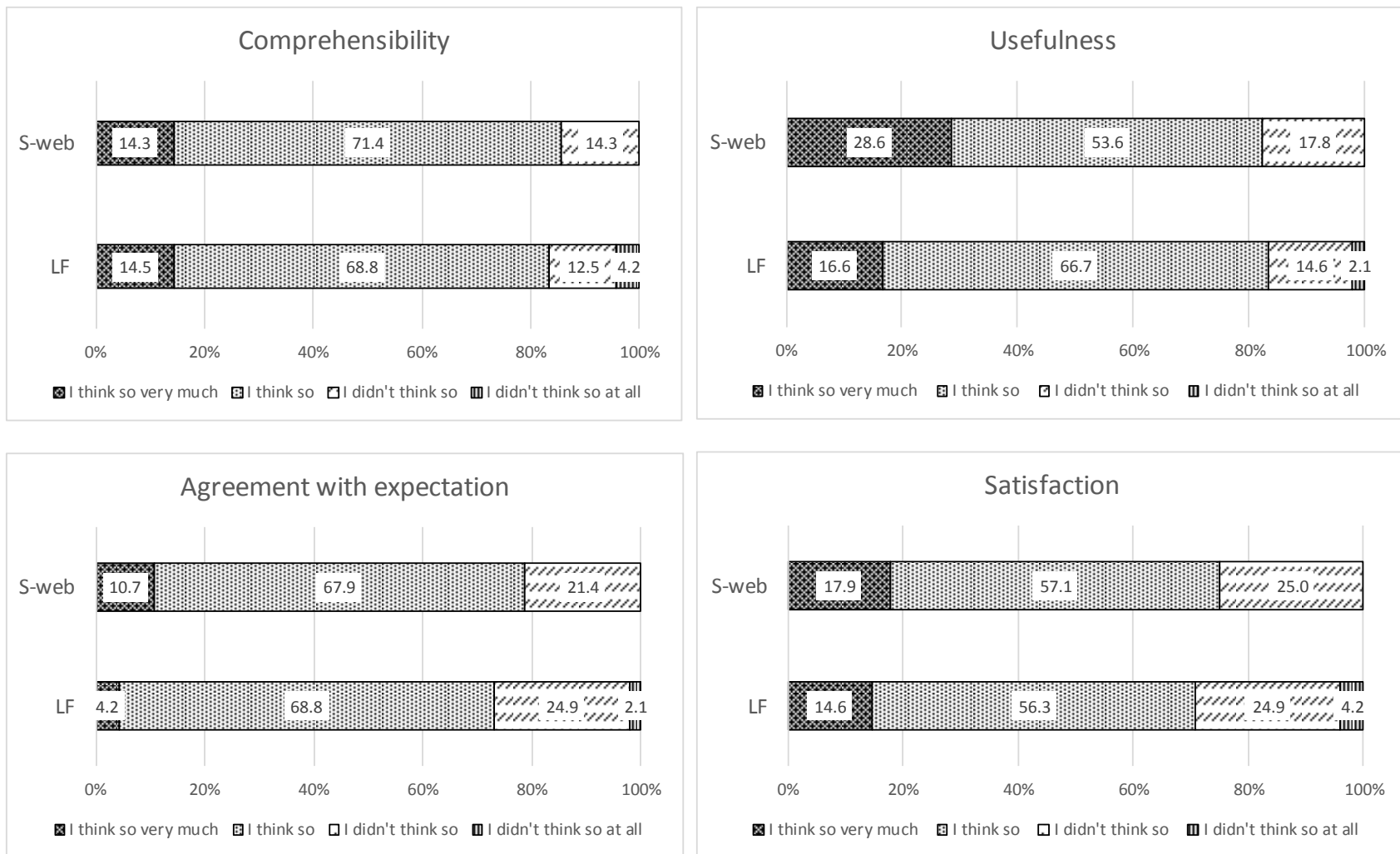


Figure 4. Process evaluation according to study groups

web group mentioned that a leaflet was better than the website because their eyes became more tired during pregnancy. Moreover, some women in the S-web group said that they never were sure whether their massage technique was correct. Some commented about improvements of the smartphone website such as use of animation and regular updating contents.

Two women in the LF group asked questions about perineal massage by e-mail. The questions were about the effectiveness of applying oil to a perineum and perineal massage technique such as 'which fingers were used for the massage', 'how deeply a finger should be inserted into the vagina', 'which part of the body received the massage' and 'amount of pressure to apply the massage'. Some in the LF group mentioned that it was better to describe specific content of the perineal massage technique and to use pictures.

### **Implementation.**

Of the 81 women in the S-web group, 16 women (19.8%) did not register the smartphone website. Two women asked how to register the smartphone website by e-mail. Among the 65 women who registered, the reply rate of reporting the frequency of practicing the massage once a week averaged 43.6% during the data collection period. Moreover, two women inquired using the inquiry form. The question was whether baby oil could use for perineal massage. No women posted a comment on a message board in the website. By contrast, among women in the LF group completing the post-test, 89.8% women used the leaflet.

### **Women's perception of antenatal perineal massage practice**

Some women shared their perception of antenatal perineal massage practice. There offered many positive comments. Many women in both groups commented that perineal massage helped them psychologically to prepare for childbirth. Moreover, most women in both groups said that perineal massage was painful at first, however, the pain had decreased and they felt the softening their perineum as they continued the massage. Some in both groups also reported that they wanted to continue the



massage for the next delivery and hoped that the practice of perineal massage could become more widespread because their pregnant friends did not know about the massage technique. Some women in the S-web group reported that they could become more conscious about their body by using a mirror or touching their perineum for the first time. Moreover, some women in the S-web group commented that they did not feel pain at the internal examinations because of continuing perineal massage. On the other hand, some women in the LF group said that the perineal massage was easy, pleasant and became their daily habit after taking their bath.

On the other hand, there were some negative comments. Some women in both groups reported that it was very sad to have an episiotomy even though they had continued the massage. Moreover, some women in both groups regretted not starting the massage early.

Massage technical problems were reported such as resistance to inserting a finger into the vagina, difficulty reaching the vagina because their belly was too large and difficulty continuing the massage for 5-10 minutes.

## Discussion

### **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 intent to treat analysis. In a previous study, among women who got information about perineal massage through textbooks at hospitals or prenatal magazines, the rates of women who could perform the massage over three times a week until childbirth were 12.9 - 15.9% (Takeuchi & Horiuchi, 2014). Moreover, it was reported that continuance rates of perineal massage were 2.9 - 5.4% among women who receive no massage instruction (Labrecque et al., 1999; Shipman et al., 2007). Therefore, continuance rates in this study were higher than the results of those studies. Furthermore, in these studies, pregnant women got 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.'s (1999) study was 65.1% and the rate in Shimada's (2005b) study was 76.7%. Therefore, the rate in this study was lower compared with these studies. Shimada (2005b) checked on whether participants performed the massage by self-report diary, telephone and asking at the prenatal checkup. Labrecque et al. (1999) also telephoned women in the massage group to encouragement compliance. As described above, in these studies, there was the ongoing communication between participants and professionals, however there was not that type of communication in this study. Therefore, besides just giving instructional material, what is needed is follow-up such as confirming whether pregnant women could perform the massage or whether they had some questions about the massage at the prenatal checkup. Moreover, understanding the need for changing one's behavior is an important factor for motivating behavioral change. It is difficult for primiparous women to imagine perineal trauma, as they have never experienced it. Therefore even though they may

know about perineal trauma it is a weaker motivator because of their lack of experience. In this study, even though the materials provided information indicating that antenatal perineal massage might prevent perineal lacerations and episiotomy for participants it still might not be enough to convince women of the importance of practicing the massage.

There were no significant difference in continuance rate of the massage between the S-web group and the LF group. The contents of the smartphone website included a message board in order to communicate with other pregnant women and an inquiry form which participants could ask a questions at any time. However, those contents could not be used effectively because of few comments. Moreover, the reply rate of reporting the frequency of practicing the massage once a week was 43.6%. From the above, the smartphone website might be only a tool for reading because a peculiarity of the smartphone website could not be sufficiently utilized. This may have reduced the difference between the effect of the smartphone website and those of the leaflet. Furthermore, in previous studies, web-based education included an individual program such as an action plan(Cunningham et al., 2009; Huang et al., 2009; Hughes et al., 2011; Mouttapa et al., 2011; Yardley et al., 2011). It referred participants to appropriate programs, and provided revised plans as needed or provided a feedback program such as tailored feedback based on participants' plan or perceived difficulty of carrying out the behavior. That had an effect on not only achieving behavioral change but also on maintenance of desired behavior. However, such strategies were not included in the smarphone website of this study. Therefore, future research efforts will need to reconsider the structure of the smartphone website program in order to provide a more effective material for primiparous women.

### **Secondary Outcomes**

Evaluation of antenatal perineal massage, childbirth self-efficacy, satisfaction with efforts toward childbirth, the degree of perineal trauma following childbirth 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 toward childbirth. Takeuchi & Horiuchi (2014) 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 (Mochizuki, Matsuoka, Misumi, Shimizu & Kimura, 2008; Ip, Tang & Goggins, 2009), 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 in perineal outcomes following childbirth between the groups. The episiotomy rates in both groups were over 50% in this study. Shimada (2005b) 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 continued 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.

## **Process Evaluation**

### **Acceptability.**

From the point of view of comprehensibility, agreement with expectation, usefulness and satisfaction with the smartphone website or the leaflet, almost all women in both groups answered that the contents of the materials were easy to understand and useful for practicing perineal massage. These materials might help participants to acquire knowledge of perineal massage because the contents included information about the effectiveness of the massage and the massage technique.

### **Demand.**

Some women in both groups commented that they did not know about antenatal perineal massage until they participated this study, however, they could perform the

massage because of the materials. Therefore, both materials were useful for pregnant women who had no prior knowledge of perineal massage. Shimizu (2011) reported that 51.6% of Japanese urban medical facilities did not educate about antenatal perineal massage. Therefore, it is inferred that many women do not receive education about the massage by midwives during pregnancy. These materials are considered to be effective in providing knowledge of the massage for such women.

Some women in the S-web group commented in the open-ended section that the smartphone website was useful, others felt a leaflet was better than the smartphone website. Because learning styles differ, educational material according to pregnant women's lifestyle or environment should be provided.

Some requests for information about antenatal perineal massage technique were reported. In the smartphone website, the contents included pictures using a foam model for explaining the massage technique. While some reported that the smartphone was helpful because the contents were concrete, others said that animation might make easier to understand. Gaqliano (1988) reviewed 25 well designed studies about video efficacy in patient education and found that video education for patient education succeeded as well as traditional education and was sometimes better for increasing short-term knowledge. In addition, Mynaugh (1991) reported that the rate of practicing perineal massage in women who received a video demonstration was higher than those in women who received only the printed and verbal instructions. From the above, not only still pictures but also animation may be more effective to promote understanding the technique relating to the movement of the massage. Also, the combination of instruction practical skill, for example, a professional actually performing the massage at the time of a prenatal examination may be more effective to promote understanding the technique because some women commented that they never were sure whether their massage technique was correct.

### **Implementation.**

In this study, the researcher or research assistants explained how to register the smartphone website verbally and provided instruction for women in the S-web

group. However, about 20% women did not register and there were inquiries about it from two women. It might have been too difficult to find the icon for the new member registration because the icon size was small. It will require making the instructions easier to understand or change the design. Moreover, in the smartphone website, a user name, a password and an e-mail address were required to create the account in order to allow only participants of the study to use the smartphone website. Dennison et al. (2013) conducted focus group discussions with thirteen university students and three junior staff members at a university to explore young adults' perspectives on smartphone applications related to health behavior change. As a result, it was reported that some preferred password access, but other complained about the effort involved in creating accounts and entering passwords. Accordingly, the operation of registration might be a factor of lowering the registration rate. An easier registration process must be devised.

The message board allows users to share information and emotional encouragement by posting messages. In this study, it was expected that participants would use the message board and the inquiry form which were particular to the smartphone website for interaction and communication among the participants or between participants and a professional, however, these tools were rarely used. In the randomized control trial by Liebreich, Plotnikoff, Courneya & Boule (2009), participants in the intervention group received the program which included personalized weekly e-mail or message board and new topics were posted once a week by the study coordinator. Moreover, in a randomized control trial by Turner-McGrievy & Tate (2011), participants in the intervention group, which received a podcast (an audio file that can be listened to on a computer or mobile media player), mobile support communication (Twitter) and mobile diet monitoring application were encouraged to post at least daily to Twitter. However, such strategies were not made in this study. In this study participants were encouraged to use the smartphone website and its tools but perhaps it needed clearer expectations to engage with the desired research process. Moreover, the researcher gave women in the S-web group simple instructions about the smartphone website, however, it did not lead to using

the tools. Therefore, beside just giving instructions, researchers might need to recommend active participation on the message board or directly tell participants to make an inquiry at any time if they had some questions. In addition, it may be better if more interesting and attractive topics are frequently updated on the message board or an opportunity for participants to gathering in order to make friends before using the smartphone website to encourage its use more effectively.

On the other hand, in the LF group, about 90% women used the leaflet among women completing the post-test. If women have a leaflet, they can read it at any time without the operation skill. Therefore, the leaflet might be easier to access the information than the smartphone website.

### **Limitations of the Study and Suggestions for Future Studies**

This study was limited in several ways. The number of required subjects was compromised because the withdrawal rate was high (42.0% in S-web group and 38.7% 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 the response rate. In this study, the researcher gave participants the post-test 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 the researchers hands the post-test directly to the participant or has it sent by post after childbirth. 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.

Massage compliance was measured by self-report in the diary, which could be biased and inaccurate. Moreover, among women who completed all questionnaires, almost all women performed perineal massage. Only women who performed the massage might send the diary and the post-test to the researcher because women volunteered to participate in this study. Participants need to be told to complete the post-test and tools to keep their interest in the study even if they did not perform perineal massage.

Future studies are recommended to clarify the reason why pregnant women stop practicing antenatal perineal massage and revise the materials based on the results of this study. Moreover, the purpose of antenatal perineal massage is to decrease perineal trauma following childbirth. Therefore, an increased sample size is needed in order to evaluate the effects of antenatal perineal massage on perineal outcomes following childbirth.



## Conclusion

One hundred sixty one primiparous women were randomly assigned to a smartphone website group (S-web group) and a leaflet group (LF group); the effectiveness of those educational materials were evaluated.

1. Of the 161 women participated this study, 47 in the S-web group and 49 in the LF group completed all questionnaires.
2. 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 S-web group and 51.0% in the LF group, respectively. There was no significant difference between the groups. Moreover, the rates by an intent to treat analysis were 29.6% in the S-web group and 31.3 % in the LF group, respectively. There was also no significant difference between the groups.
3. There were no significant differences in the evaluation of antenatal perineal massage, childbirth self-efficacy, satisfaction with efforts toward childbirth, and perineal outcomes following childbirth which were measured as secondary outcomes between the groups.
4. In the process evaluation, about 80% women in both groups answered that these materials were useful. Moreover, 16 women (19.8%) did not registered at the smartphone website and the reply rate of reporting the frequency of practicing the massage a week was 43.6%. By contrast, 89.8% in the LF group used the leaflet.

From the above, there was no significant difference in continuance of antenatal perineal massage practice between users of the smartphone website and the leaflet. Additionally, the process evaluation revealed that all of the materials were useful for participants.

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