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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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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.

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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

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