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A Randomized Controlled Trial on Primigravid Women of Text Messaging Intervention Offering Pregnancy and Childbirth Support

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Abstract : This study aimed to assess the efficacy of a text messaging intervention that offered pregnancy and childbirth support. Participants included 39 primigravid women who were less than 12 weeks pregnant. Text messages were sent twice weekly to the intervention group from week 13 of pregnancy until childbirth. Outcome measures were anxiety levels, lifestyle in the month before birth, pre-birth weight, pregnancy complications, delivery complications, birth weight, thoughts regarding the text messages, and the frequency of viewing of the text messages. For the item “I engage in body stretching,” the average value in the intervention group was significantly higher than that in the control group. For the item “I have regular bowel movements,” the average value in the intervention group was significantly lower. Most participants reported that the intervention was at least somewhat useful. This study indicates that text messaging intervention is practical and can be used to support numerous pregnant women simultaneously at a relatively low cost. Since this is a study pilot trial, large-scale studies are necessary to improve the method and allow for the generalization of the results.

Keywords : mobile health, mobile phone intervention, pregnant women, text messaging.

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Introduction

Women experience a range of physical and psychological changes during pregnancy that may affect their health. Maintaining a healthy lifestyle during this period helps prevent health issues and is important for ensuring safe childbirth. Smoking, hypertension, obesity, and diabetes are risk factors for pregnancy complications [1, 2], and they are associated with increases in the percentage of stillbirths, premature births, and low birth weight infants [1]. To ensure safe childbirth, it is important for healthcare workers to support preg-

nant women.

Mental health interventions for pregnant women are becoming increasingly important in Japan. According to a 2016 study examining maternal deaths in Tokyo's 23 municipal wards over a 10-year period, 63 women died by suicide between pregnancy and one year postpartum, with a suicide rate of 8.7 per 100,000 births [3, 4]. The perinatal suicide rates for the UK and Sweden are 2.3 and 3.7 out of 100,000 births, respectively [3, 4]. The comparatively high rate in Japan indicates the seriousness of the situation.

Appropriate information is necessary to ensure safe

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childbirth, and a prior study reported that pregnant women desire information regarding their pregnancy [5]. Research has reported nutritional deficiencies, excessive nutritional intake, and inappropriate weight gain during pregnancy [6–8], despite pregnant women receiving advice about maintaining a healthy lifestyle. Self-administered health management and self-care during pregnancy are important to ensure a normal pregnancy, normal fetal development, and spontaneous childbirth, and to prevent pregnancy complications. To that end, obtaining accurate information and accessing appropriate social services is necessary.

The use of mobile phone technologies for health promotion has gained impetus in recent years, and research utilizing mobile phone technologies in behavior modification has been increasing. Mobile health (mHealth), as this technology is known, is unaffected by restrictions of place and time, can provide intervention to large numbers of individuals simultaneously, and has an interactive nature. mHealth interventions are thought to be effective in promoting access to social services, healthy behaviors, mental health, and the provision of health-related information. The efficacy of mHealth interventions with respect to health-related behavior has been reported [9, 10], and it is suggested that this kind of healthy lifestyle promotion intervention could also be effective for pregnant women [11].

Our focus was on text messaging interventions, which have been effective in the promotion of physical activity, smoking cessation [12], and behavior modification [13, 14]. Studies utilizing text message interventions have reported improvement in breastfeeding indicators [15] and protective behaviors against air pollution [16]. There are few studies, however, on changes in pregnant women's lifestyle behavior and effects on mental health. To evaluate the effect of intervention more accurately, we limited our study to primiparous women because of differences in knowledge about pregnancy and childbirth between primigravid women and multipara women; knowledge which could affect the impact of text messaging interventions. To the best of our knowledge, there are no randomized controlled trials of text messaging interventions limited to primigravid women. Thus, we autonomously developed a program for automatic delivery of pre-entered text messages to numerous recipients simul-

taneously [17].

This study aimed to assess the efficacy of a text message intervention for ensuring safe childbirth and improving the mental health of primigravid pregnant women. The intervention group received the text message intervention, while a control group did not, and the groups were compared post-intervention to evaluate the efficacy of the intervention.

Materials and Method

Design and sample

We conducted a randomized controlled trial with 39 women recruited from two obstetric outpatient clinics in Tsu City, Mie Prefecture, Japan from November 1, 2017 to March 31, 2019. The participation criteria were: possessing a mobile phone, over 20 years of age, less than 12 weeks pregnant, single gestation pregnancy, pre-pregnancy body mass index (BMI) range of 18.5–24.9, no physical or psychological conditions, permission obtained from the main treating physician, and being primigravida.

Ethics

The researchers used a booklet to explain to pregnant women the purpose and methods of the study, as well as the aspects of data protection and ethical considerations. They were informed that they could refuse to participate and withdraw at will, and that they would not face any disadvantage for refusing to participate. Written informed consent was then obtained. The study was granted approval by the Mie university Independent Ethics Committee (Approval number 3132). The study was registered with the World Health Organization International Clinical Trials Registry Main ID: JPRN-UMIN000030530 1606064.

Procedure and measures

Participants were allocated to either the intervention or the control group through a roll of the dice (odd number = intervention group; even = control group) and directed to answer a questionnaire. Randomization was performed at each facility. The questionnaire items included age, height, current weight, pre-pregnancy weight, family structure, and employment status. We sent participants the Japanese version of the

State-Trait Anxiety Inventory (STAI) by email in week 12 of pregnancy [18]. They sent the data to researchers after completing the Inventory on their mobile phone. The 40-item STAI contains 20 items evaluating state anxiety, a transitional anxious state occurring in certain circumstances, and 20 items evaluating trait anxiety, which describes anxiety as a relatively stable personality characteristic. Items were rated on a four-point Likert scale ranging from “1 = Not at all” to “4 = Very much so.” Scores range from 40 to 160, with higher scores indicating higher anxiety levels. Shimizu and Imae modified the original STAI for use with the Japanese population [18, 19]. This version was scrutinized by Hidano *et al* [20], who created the latest version of the STAI used in this study [21].

The intervention group received automatic text messages on their mobile phone from our computer program from the 13th week of pregnancy until childbirth. Messages were sent at 12:30 p.m. every Monday and Thursday so that it would be convenient for working women to view them. The 150–250 character Japanese texts conveyed pregnancy-related information: introducing social services, breastfeeding preparation advice, adequate sleep, mental health, weight management, suitable meals, and self-care methods. The content was developed by a maternal nursing researcher, and the length of the sentences and the wording were verified to facilitate readability.

The title of the text intended to reflect the content to aid participants in identifying the message they wished to read. Phone numbers and website links to social services mentioned in the messages were also included to facilitate contact with the services. To avoid giving an impersonal impression, a nickname, registered and chosen by the participants, was included in the computer program and displayed in the delivered text messages, and the content of each text message differed to prevent participants from losing interest. To avoid over-reliance, participants were unable to reply to text messages. We instructed the intervention group not to show texts to others to avoid exposing the control group to the text messages.

We asked all the participants to complete a questionnaire after childbirth at a medical facility. There were 33 questionnaire items regarding pregnancy lifestyle during the month prior to birth. Responses were

evaluated on a five-point Likert scale ranging from “1 = Not at all” to “5 = I did it daily”. Participants also completed the STAI postpartum. We asked the intervention group whether the texts were useful and the extent to which they read the messages. Responses of usefulness were evaluated on a four-point Likert scale ranging from “1 = strongly agree” to “4 = completely disagree”. Responses of extent of reading were evaluated on a five-point Likert scale ranging from “1 = I read all” to “4 = I did not read at all”. We also investigated pre-birth weight, the presence or absence of pregnancy complications, delivery complications, delivery type, and infant birth weight.

Data analyses

The Mann-Whitney U test and Fisher’s exact test were conducted to compare baseline attributes and demographic data for the intervention and control groups. Cohen’s *d* was calculated for the mean and standard deviation to determine size of the effect (≥ 0.2 : small; ≥ 0.5 : medium; and ≥ 0.8 : large effect size), and Cramer’s *V* was calculated using the result of the comparison of percentages (≥ 0.1 : small, ≥ 0.3 : medium, and ≥ 0.5 : large effect size). The same tests were used to compare data collected postpartum to evaluate the efficacy of the text messaging intervention. The Mann-Whitney U test was performed to compare changes in STAI for each group at baseline and at postpartum. For the data from the month prior to childbirth, “Not at all” and “I did it daily” were quantified as values of 1 and 5, respectively, after which averages and standard deviation for both groups were calculated and compared using the Mann-Whitney U test. A *P*-value of less than 0.05 indicated a significant difference, and statistical analysis was conducted using SPSS version 22 for Windows (IBM Corp., Tokyo, Japan).

Results

Of the 39 participants, three transferred to different medical facilities midway through the study. One participant was unable to receive texts owing to a change in email address after providing consent, and replies were not received from seven participants, resulting in missing data. The data from the 28 participants with complete data were analyzed. Fifteen participants

were randomly allocated to the intervention group and 13 to the control group.

Table 1 shows the comparison of attributes of each participant from the intervention and control groups at the 12-week mark, their demographic data, and STAI scores. No significant difference was found between the two groups.

Table 2 shows a comparison of both groups at the time of birth. No significant differences were found in pre-birth weight or BMI, infant birth weight, or STAI scores. There was no significant difference in pregnancy or delivery complications. The STAI-I (state anxiety) at the time of birth was significantly lower than at baseline in the intervention group ($P = 0.03$).

Table 3 displays the group comparison regarding lifestyle during the month prior to childbirth. For the item "I engage in body stretching," the average value for the intervention group was 3.9, whereas the control group's value was significantly lower at 3.1 ($P = 0.046$; effect size = 0.83; 95% confidence interval (CI) = 0.05 to 1.66). For "I have regular bowel movements," the average value for the intervention group

was 3.7, whereas the control group's value was significantly higher at 4.5 ($P = 0.037$; effect size = 0.82; 95% CI = -1.57 to -0.36). No significant difference was found between the intervention and control groups for any other items.

Table 4 shows the intervention group's responses regarding the text messages, as well as their opinions regarding the text messages (reported in percentage based on the number of participants who marked "Strongly agree" or "Agree"). Overall, 100% of the participants answered that "The texts were easy to understand," 93.3% that "The texts were useful in real situations," 93.3% that "I looked forward to reading the texts," and 93.3% that "The text messages were useful, or a little useful." For the item related to information, 86.7% answered that "The texts provided me with necessary information." When asked the reason for that response, 60% responded "The lifestyle advice was useful," 20% answered "Information regarding social resources was useful," and 60% responded "Receiving the text message itself made me happy." An investigation of the frequency of text viewing showed that eighty percent of the participants read all the texts, while 13.3% read 80–99% and 6.7% read 50–79% of the texts. None of the participants answered 49% or less.

Table 1. Baseline Comparison of Demographic Characteristics for Both Groups

	Intervention group n = 15	Control group n = 13	P-value
	Mean (SD)	Mean (SD)	Mann-Whitney U test
Age (years)	30.7 (3.2)	31.5 (3.9)	0.586
Height	157.2 (4.1)	157.9 (6.8)	1.000
Pre-pregnancy weight	49.9 (5.6)	54.0 (10.6)	0.363
Pre-pregnancy BMI	20.1 (1.8)	21.5 (3.5)	0.363
Baseline weight	50.2 (5.7)	54.6 (10.9)	0.440
Baseline BMI	20.3 (1.9)	21.8 (3.6)	0.294
STAI-I (State anxiety)	44.2 (11.4)	44.9 (9.2)	0.650
STAI -II (Trait anxiety)	42.2 (11.0)	41.9 (9.0)	1.000
	n (%)	n (%)	Fisher's exact test
Family structure (living with someone)	15 (100.0)	12 (92.3)	0.464
Currently employed	11 (73.3)	12 (92.3)	0.333

BMI: body mass index, STAI: State-Trait Anxiety Inventory

Table 2. Comparison of Both Groups' Circumstances at Childbirth

	Intervention group n = 15	Control group n = 13	P-value
	Mean (SD)	Mean (SD)	Mann-Whitney U test
Pre-birth weight	60.8 (7.9)	66.2 (11.5)	0.294
Pre-birth BMI	24.6 (2.7)	26.5 (3.9)	0.294
Weight of newborn	3139.1 (378.8)	3154.8 (361.4)	0.928
STAI-I (State anxiety)	38.9 (11.3)	40.2 (9.3)	0.683
STAI-II (Trait anxiety)	42.5 (11.0)	39.5 (10.0)	0.413
	n (%)	n (%)	Fisher's exact test
Pregnancy complications	1 (6.7)	0 (0.0)	1.00
Delivery complications (high-risk births)	0 (0.0)	2 (15.4)	0.206

BMI: body mass index, STAI: State-Trait Anxiety Inventory

Table 3. Comparison of Both Groups' Lifestyles One Month Prior to Childbirth

	Intervention group n = 15	Control group n = 13	<i>P</i> -value		Intervention group n = 15	Control group n = 13	<i>P</i> -value
	Mean (SD)	Mean (SD)	Mann-Whitney U test		Mean (SD)	Mean (SD)	Mann-Whitney U test
I eat a variety of vegetables	3.8(0.8)	3.9(1.1)	0.751	I have regular bowel movements	3.7(1.1)	4.5(0.9)	0.037*
I eat a variety of fruits	3.7(1.2)	3.0(1.2)	0.142	To prevent leukorrhea, I keep my external reproductive organs clean	3.6(1.0)	3.7(1.0)	0.892
I eat fried and fast food	2.9(0.8)	2.8(0.4)	1.000	When I frequently need to urinate, I reduce my intake of water	1.6(0.8)	1.3(0.8)	0.254
I eat desserts	3.3(1.0)	3.6(0.9)	0.413	I go to the restroom when I strongly need to pee	4.0(1.5)	4.1(1.4)	0.928
I eat pork, chicken, or fish in every meal	4.3(0.8)	3.8(1.1)	0.185	I have noticed swelling of the upper ankle, face, and hands	3.1(1.6)	4.4(0.9)	0.065
I drink milk (2 glasses per day)	2.3(1.4)	2.8(1.5)	0.440	Since the 7th month of my pregnancy, I have been counting fetal movements, as suggested	4.7(0.7)	4.5(0.7)	0.525
I drink fruit juice	1.9(1.1)	2.4(1.3)	0.294	If the fetal movement count is less than 10, I wait to see if it happens again on another day	3.0(1.9)	3.5(1.9)	0.555
When I am hungry, I eat anything I want	2.3(1.2)	2.7(1.2)	0.316	If I have fluid leaking from the vagina, but no pain, I wait to see if it happens again on another day	1.3(1.0)	1.0(0.0)	0.786
I eat grilled meat that is rare to medium rare	1.4(0.6)	1.2(0.4)	0.618	I try to avoid stress, make a clear mind	3.7(1.1)	3.6(1.0)	0.964
I take vitamins received from the hospital	1.5(0.8)	1.2(0.6)	0.413	I know the hospital's emergency phone number	4.6(0.8)	4.2(1.5)	0.650
I take herbs	1.7(1.1)	1.2(0.4)	0.235	I will go to the hospital immediately after the onset of labor pain	2.5(1.5)	2.9(1.8)	0.683
I exercise by walking	3.8(1.0)	3.5(1.2)	0.555	I have been trained on how to manage labor pain	3.0(1.6)	2.2(1.2)	0.201
I engage in body stretching	3.9(0.8)	3.1(1.2)	0.046*	I have been trained on how to push	3.0(1.6)	1.9(1.0)	0.052
I take a short daytime nap	3.9(1.0)	3.7(1.4)	0.892				
I brush my teeth after a meal	4.1(1.0)	3.3(1.5)	0.185				
I squeeze the muscle when my leg cramps	2.6(1.2)	2.5(1.8)	0.786				
I often notice whether my urine is a dark color or cloudy	2.1(1.2)	2.4(1.0)	0.413				
I try to sit and stand upright	2.9(1.1)	3.0(1.3)	0.821				
I talk to the baby when he/she kicks	3.5(0.9)	3.9(1.3)	0.387				
I have abstained from sexual intercourse for more than a month	4.2(1.4)	4.0(1.7)	1.000				

SD: standard deviation

Discussion

This is the first randomized controlled trial of supporting primiparous women's pregnancy and childbirth with text messaging. The study was a pilot trial and the sample size was small, so the evaluation of

these results must be used with caution.

The survey showed that many participants in the intervention group reported engagement in body stretching during the last month of pregnancy. Stretching is physical exercise in which a specific muscle or tendon is deliberately flexed or stretched. It is effective in

Table 4. Intervention Group's Responses Regarding the Text Messages

Opinion regarding the text messages (Percentage reporting "Strongly agree" or "Agree")	n (%)
The texts provided me with necessary information	13 (86.7)
The texts were useful in real situations	14 (93.3)
The texts were easy to understand	15 (100.0)
I looked forward to reading the texts	14 (93.3)
The text messages were useful, or a little useful	14 (93.3)
Reasons why the texts were useful	
The lifestyle advice was useful	9 (60.0)
Information regarding social resources was useful	3 (20.0)
Receiving the text message itself made me happy	9 (60.0)
Text viewing frequency	
All	12 (80.0)
80–99%	2 (13.3)
50–79%	1 (6.7)
10–49%	0 (0.0)
0	0 (0.0)

increasing body flexibility and has been reported to reduce back pain in pregnant women [22, 23]. Approximately 70–78.9% of pregnant women report having back pain [24]. They also have difficulty maintaining a standing position and lifting heavy objects, which contribute to an impaired quality of life [24]. One study has reported that stretching improves symptoms of depression [25]. We did not measure back pain and depressive symptoms in the present study, but we speculate that had we measured these, the intervention group might have reported improved outcomes. Only simple stretching methods were introduced to the intervention group via text message in this study, and thus the effect on pregnant women may have been limited. There is a need to provide professional and detailed information on stretching to achieve a higher effect of increased body flexibility, reduced back pain and so on.

The average value for the intervention group was lower than the control group for the questionnaire item concerning bowel movement regularity. Although these results are difficult to interpret, one possible reason could be the control group's high average val-

ues for "eating vegetables" and "milk intake," as well as the low average value for "meat intake"; this may relate to bowel movement regularity. Another possibility is that since this question did not cover actual defecation frequency and was merely a subjective response, it may be that the intervention group's threshold regarding irregular bowel movements was lowered owing to sensitization from receiving the text messages about bowel movements. It is possible that the intervention group may have become more likely than the control group to view their bowel movements as being irregular.

We expected that the text messaging intervention would reduce the risk of pregnancy complications and delivery complications, but due to the low number of pregnancy complications and delivery complications overall, we were not able to prove that our interventions would reduce those risks. This may have been due to the fact that there was not much difference between the two groups in lifestyle prior to childbirth.

Participant satisfaction with the delivered text messages was high, suggesting that we were able to deliver the necessary information to the pregnant women. The convenience of being able to access useful information on a mobile phone at any time is also thought to have led to a high level of satisfaction. The participants' viewing frequency of the messages was also high, possibly a reflection of the ubiquity and functionality of mobile phones; being comprehensible and providing useful information are considered factors that increased the efficacy of the intervention.

Mental health during the perinatal period is vulnerable to instability, such as through maternity blues and postpartum depression. Although we thought our text message intervention might reduce anxiety by delivering appropriate information, the anticipated effects were not confirmed. The text message content largely pertained to lifestyle factors, as well as introducing social services and systems. By comparison, there were only a few messages for improving mental health and their content was abstract. On the other hand, as STAI-I (state anxiety) at the time of childbirth was significantly lower than at baseline in the intervention group, the text messaging approach may also suggest the potential to improve mental health. If the emphasis had been on improving mental health, it would have been necessary

to increase the number of text messages pertaining to improving mental health and to deliver messages with practical content, such as relaxation methods and strategies for coping with stress.

Strengths, limitations, and suggestions for future research

A strength of this study is that the participants were exclusively primiparous women. As a result, the effects of differences in knowledge owing to childbirth experience were eliminated. There were, however, some limitations. First, the sample size was small, because participation was limited to primiparas. Conducting large-scale studies is necessary to produce more evidence. It will also be important to develop more effective content in collaboration with obstetric specialists in the future. The pregnant women in the current study read most of the messages we sent, and their satisfaction was high, so we assume that sending more effective content will promote greater healthy lifestyle behaviors in pregnant women and improve mother and infant health. The second limitation was the use of self-reported data, which can entail bias. Third, text messaging may have influenced health instruction, but the current study did not examine differences in health instruction between the intervention and control groups. Fourth, the 33 questionnaire items regarding the participants' pregnancy lifestyle have not been proven reliable and valid. Finally, although significant differences were indicated for stretching and regularity of bowel movements, these were based on subjective evaluations; as such, one must exercise caution in the interpretation of results, considering the fact that actual duration of exercise and number of excretions were not investigated. More objective outcome measures should be utilized in future studies to more accurately assess intervention efficacy.

Conclusions

Our results should be evaluated cautiously, due to study limitations, but the high level of satisfaction with the message content and the fact that most of the participants read all the texts attest to the practicality and feasibility of this approach, which can be used to provide support to numerous people at a relatively low cost. It would also be possible to send messages

that cater to a group's specific attributes and regional factors, since it is easy to customize message content. It is hoped that the text message program will play a positive role in ensuring safe and healthy childbirths in other regions as well.

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