

St. Luke's International University, Graduate School

Doctoral Dissertation, 2016

**Effects of Clary Sage and Lavender or Jasmine
Essential Oils Infused in a Foot Bath for Labor Induction on
Oxytocin Level**

**陣痛誘発を意図したクラリセージ・ラベンダー、
ジャスミン精油による足浴前後のオキシトシン変化**

14-DN-011

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Introduction

Background

Studies on oxytocin have increasingly gathered attention in terms of its various effects associated with the strengthening of bonding between mothers and their children, relationships among adults, treatments of people with autism and cancer, progression of labor and delivery, and availability of breast milk (H.-J. Lee, Macbeth, Pagani, & Young, 2009; Matsuzaki, Matsushita, Tomizawa, & Matsui, 2012; Meyer-Lindenberg, Domes, Kirsch, & Heinrichs, 2011; Tom & Assinder, 2010). Oxytocin was previously identified as a hormone that exerted its effects on uterine contraction (Dale, 1906) and was subsequently synthesized (du Vigneaud et al., 1953; du Vigneaud, Ressler, Swan, Roberts, & Katsoyannis, 1954). In maternity areas, synthetic oxytocin is usually used to induce labor (Wing, 2014). In the USA, labor induction was reported in 23% of pregnant women (Osterman & Martin, 2014). In Japan, induction or augmentation of labor was reported in 23% of pregnant women who were more than 36 weeks of gestation (Terada, Matsuda, Ogawa, Matsui, & Satoh, 2013), indicating that synthetic oxytocin was used in one of five pregnant women.

Term delivery between 37 and 41 weeks of gestation is considered normal and entails a low risk for the mother and child. Induction of labor is performed as protection for the mother and child in post-term delivery of more than 41 weeks of gestation. From around 2010, full-term delivery between 39 and 40 weeks of gestation has been considered to be the lowest risk of delivery, particularly in terms of the respiratory outcomes of babies (Fleischman, Oinuma, & Clark, 2010; Oshiro et al., 2009; Reddy et al., 2011; Robinson, Villers, Johnson, & Simpson, 2010; Spong, 2013; Tita et al., 2011; Zhang & Kramer, 2009). However, induction of labor using synthetic oxytocin has also produced negative effects such as an increase in the number of caesarean sections and the use of epidural anesthesia, as well as more intense labor pain (Alfirevic, Kelly, & Dowswell, 2009; Conell-Price, Evans, Hong, Shafer, & Flood, 2008). Moreover, synthetic oxytocin decreases the number of oxytocin receptors (Liedman, Hansson, Igdbashian, & Akerlund, 2009; Phaneuf, Rodríguez Liñares, TambyRaja, MacKenzie,

& López Bernal, 2000) and their sensitivity (Terzidou, 2007; Vrachnis, Malamas, Sifakis, Deligeoroglou, & Iliodromiti, 2011) in the long term, as well as increases the number of children with autism (Gregory, Anthopoulos, Osgood, Grotegut, & Miranda, 2013), bipolar disorder (Freedman, Brown, Shen, & Schaefer, 2015), or attention-deficit/hyperactivity disorder (Kurth & Haussmann, 2011).

Therefore, women who hope to have a healthy and normal delivery adopt various nonmedical methods for induction of labor. In the USA, 28% of pregnant women reportedly adopted alternative and complementary methods for inducing labor (Kozhimannil, Johnson, Attanasio, Gjerdingen, & McGovern, 2013). In particular, aromatherapy which is used by 15% of Australian pregnant women (n = 8200) (Sibbritt, Catling, Adams, Shaw, & Homer, 2014) to induce labor can be applied by midwives (Ibata & Uemura, 2010; Musil, 2013; Omoto, 2005).

In fact, pregnant women use the essential oils of clary sage, lavender, and jasmine by inhaling their scent, using a foot bath with the essential oils, and applying them by massage to induce labor (Ibata & Uemura, 2010; Kino, 1999; Musil, 2013; Omoto, 2005; Samejima, 1999) as well as to augment labor (Buckle, 2014; E. Burns, Blamey, Ersser, Lloyd, & Barnetson, 2000; E. E. Burns, Blamey, Ersser, Barnetson, & Lloyd, 2000; Clark, 2015; Fritz, 2015). Massage applied with lavender essential oil (Zahra, 2013) and a bath diluted with ginger essential oil (Calvert, 2005) as forms of aromatherapy during labor and delivery have been reported to shorten the labor period and delivery time. Although there are some reports about the effects of aromatherapy on labor induction, there is scarce scientific evidence supporting its specific physiologic effects on labor induction. Moreover, pregnant women and midwives usually use aromatherapy on the basis of their empirical knowledge alone.

Development of alternative methods of labor induction remains a high priority, and aromatherapy is considered to be a promising method. Aromatherapy reportedly shortens the delivery period possibly via increased strength of uterine contraction as induced by oxytocin. However, convincing evidence of labor induction by aromatherapy has not yet been fully confirmed. To establish additional evidence regarding the effects of aromatherapy on labor induction, this study clarified the

changes in the oxytocin level as an index of the effect of aromatherapy in relation to labor induction.

Objectives

This study aimed to examine the effects of clary sage and lavender essential oils or jasmine essential oil infused in a foot bath on oxytocin level, subjective uterine contraction, cortisol level, and delivery within 72 hours as limited efficacy, as well as to assess the feasibility of the study protocol for future studies evaluating the effects of aromatherapy on labor induction.

Foot baths examined

Foot bath A: with clary sage and lavender essential oils

Foot bath B: with jasmine essential oil

Foot bath C: with no essential oil

Hypotheses

1. The oxytocin level will increase after using foot baths A and B compared with the oxytocin level before using these foot baths, but the oxytocin level will not change after using foot bath C.
2. The increase in the oxytocin level after using foot baths A and B will be higher than the increase in the oxytocin level after using foot bath C.
3. Subjective uterine contraction will increase after using foot baths A and B, but it will not change after using foot bath C.
4. The cortisol level after using foot baths A and B will be lower than the cortisol level after using foot bath C.
5. More women who use foot baths A and B will deliver within 72 hours than women who use foot bath C.
6. The study protocol will be feasible for participants in terms of limited efficacy, acceptability, and practicality.

Significance of the Study

Aromatherapy is currently used as an adjunct therapy to induce labor. However, scientific evidence supporting its labor-inducing effects remains scarce. In addition, the specific effects of aromatherapy on oxytocin level in relation to labor induction has not apparently been fully clarified. This study provides incremental scientific evidence regarding the effects of aromatherapy on labor induction via changes in the oxytocin level.

Literature Review

Methods of Labor Induction

There are three methods of labor induction: 1) medication with synthetic oxytocin and prostaglandin, 2) mechanical method of amniotomy and membrane stripping, and 3) alternative method of breast stimulation (ACOG Committee on Practice Bulletins -- Obstetrics, 2009; Wing, 2014). Evaluation of the effects of each method for inducing labor among women in the third trimester of pregnancy has been performed in the Cochrane systematic review (Kavanagh, Kelly, & Thomas, 2005) with details described below.

For the medication method, synthetic oxytocin is administered intravenously and is the most commonly used treatment in the USA (ACOG Committee on Practice Bulletins -- Obstetrics, 2009). Oxytocin activates phospholipase C which increases calcium concentration in uterine muscle cells, resulting in strong uterine contractions (Kamel, 2010; Sanborn, 2001). Administration of synthetic oxytocin increases the vaginal delivery rate of pregnant women within 24 hours compared with the control group of expectant management (53.8% vs. 8.4%, risk ratio (RR) 0.16 [95% confidence interval (CI) 0.10, 0.25], three trials, n = 399) (Alfirevic et al., 2009). Prostaglandin E2 (PGE2) is administered to the vagina or cervical canal before labor induction mainly for cervical ripening in case of an unfavorable cervix. Some women were reportedly induced by this procedure alone and most of them did not need synthetic oxytocin (Wing, 2014). The cervical ripening induced by PGE2 is due to the dissolution of collagen bundles and an increase in the water content of the cervical submucosa (Wing & Farinelli, 2012). PGE2 administration reportedly decreased the number of pregnant women who did not vaginally deliver within 24 hours compared with the control group of expectant management or with no treatment (PGE2: RR 0.61 [95% CI 0.47, 0.79], four trials, n = 198) (Boulvain, Kelly, & Irion, 2008). However, PGE2 administration is also reported to increase the risk of uterine hyperstimulation.

For the mechanical method, labor is induced as a result of increasing the production of prostaglandin in the decidua by mechanical stimuli from amniotomy and

membrane stripping (Wing & Farinelli, 2012). Notably, the specific effects of amniotomy have not yet been established owing to the limited number of research articles in this area (Bricker & Luckas, 2000). Women who underwent membrane stripping were reported to less likely continue their pregnancy than women who underwent no treatment (beyond 41 weeks: RR 0.59 [95% CI 0.46, 0.74], six trials, n = 937; 42 weeks: RR 0.28 [95% CI 0.15, 0.50], six trials, n = 722) (Boulvain, Stan, & Irion, 2005).

For the alternative method, it is suggested that labor is induced as a result of increasing oxytocin by breast stimulation (Amico & Finley, 1986; Christensson, Nilsson, Stock, Matthiesen, & Uvnäs-Moberg, 1989; Kavanagh et al., 2005). Women who underwent breast stimulation delivered within 72 hours compared with women in expectant management (62.7% vs. 93.6%, RR 0.67 [95% CI 0.60, 0.74], four trials, n = 437) (Kavanagh et al., 2005). Although the specific effects of other methods on inducing labor have not yet been fully clarified, women have also attempted using castor oil, bath and/ or enema (Kelly, Kavanagh, & Thomas, 2013), homeopathy (Smith, 2003), and sexual intercourse (Kavanagh, Kelly, & Thomas, 2001). The exact mechanisms of these methods were not clearly stated, although, the mechanisms of sexual intercourse and breast stimulation for inducing labor were assessed as similar. For women who are ready for labor induction and who have the maximum number of oxytocin receptors in the uterus, increasing the oxytocin level could induce labor (Buckley, 2015).

Hormones Related to Labor Induction

The prostaglandin level increases in the uterine lining, particularly in the decidual layer, in premature or term delivery. The prostaglandin level in the amniotic fluid starts to increase before labor onset and further increases in the early labor period (Romero et al., 1996). Prostaglandin helps induce labor by causing dissolution of the cervix and increasing the number of oxytocin receptors (Garrioch, 1978; Karim & Hillier, 1979).

Oxytocin activates the inflammation stream associated with labor induction in

the uterine muscle and amnion (Kim et al., 2015), as well as improves the production of prostaglandin in the chorion, decidua, and amnion (A. Fuchs, Fuchs, Husslein, Soloff, & Fernstrom, 1982; Kamel, 2010). There have been conflicting conclusions regarding changes in the oxytocin level throughout pregnancy, and a previous review of 20 research articles has suggested a very small change if the oxytocin level increased (Chard, 1995). However, a recent study has revealed that the plasma oxytocin level from the first trimester to the third trimester of pregnancy increased in 73.3% of women and decreased in 26.8% of women (N = 272) (Prevost et al., 2014).

Oxytocin is a peptide hormone mainly produced by the magnocellular neurosecretory cells of the paraventricular nucleus and supraoptic nucleus in the hypothalamus and is secreted in pulse from the posterior pituitary. It is also produced in the placenta, amnion, and fetus during pregnancy (Zingg et al., 1995) as well as in the heart, uterus, and corpus luteum (Gimpl & Fahrenholz, 2001; Kiss & Mikkelsen, 2005). Oxytocin produced in the fetus is transferred to the maternal blood (Dawood, Wang, Gupta, & Fuchs, 1978; Norwitz, Mahendroo, & Lye, 2014). The effects of oxytocin are observed when oxytocin binds to an oxytocin receptor. An oxytocin receptor is expressed in the uterine muscle, endometrium, ovary, breast (T Kimura, 1995), and brain (Gimpl & Fahrenholz, 2001). The concentration of oxytocin receptor in the uterine muscle reportedly increased 200- to 300-fold, and peaked at about 39 weeks of gestation and at the start of labor, suggesting that the oxytocin receptor concentration is associated with the initiation of labor (A. R. Fuchs & Fuchs, 1984).

Studies on pigs and rats have shown that stress during labor decreases the oxytocin level (Buckley, 2015; Lawrence et al., 1992; Leng et al., 1988). A randomized controlled trial of women who were breastfeeding has shown that the stress from arithmetic calculation or noise decreases the number of pulses for oxytocin secretion (n = 22) (Ueda, Yokoyama, Irahara, & Aono, 1994).

Aromatherapy for Labor Induction

Previous studies of aromatherapy for the induction and augmentation of labor are shown in **Table 1**. Among 13 women who had premature rupture of the membrane

Table 1

Aromatherapy for Induction and Augmentation of Labor

Reference	Purpose	Essential oil	Applied method	Timing
Samejima (1999)	IL	Palmarosa Sweet fennel Peppermint	ND	<ul style="list-style-type: none"> • Twice a day • Two or three weeks before delivery and during delivery
Omoto (2005)	IL	1) <u>Jasmine</u> , <u>clary sage</u> , and palmarosa 2) <u>Lavender</u> , geranium, and rosewood	<ul style="list-style-type: none"> • Massage (the plant oil is diluted with two drops of each selected essential oil from 1) and 2). • <u>Foot bath</u> 	<ul style="list-style-type: none"> • Pregnancy beyond due date
Musil (2013)	IL	<u>Clary sage</u> , <u>jasmine</u> , blend oil of rose, <u>jasmine</u> , and bergamot	<ul style="list-style-type: none"> • Inhalation • Topical application to the abdomen and inside of ankle 	The use of clary sage starts between 38 and 40 weeks of gestation or from 37 weeks of gestation in the case of women who have a history of post-term delivery
Kino (1999)	IL and AL	<u>Clary sage</u> (four drops) and <u>lavender</u> (two drops)	<ul style="list-style-type: none"> • <u>Foot bath</u> with hot water of 42°C above the sanyinjiao point for 20-30 minutes (the device used for the foot bath should have a temperature-maintaining capability) 	<ul style="list-style-type: none"> • Twice a day • Every other day in 40 weeks of gestation and every day in 41 weeks of gestation
Ibata et al. (2010)	IL and AL	<u>Lavender</u> (0.05 mL) and <u>clary sage</u> (0.1 mL)	<ul style="list-style-type: none"> • <u>Foot bath</u> with hot water of around 40°C under the knee 	ND
Burns et al. (2000)	AL	<u>Clary sage</u>	<ul style="list-style-type: none"> • Inhalation • Massage • <u>Foot bath</u> 	During labor
Zahra et al. (2013)	AL	<u>Lavender</u> (two drops)	<ul style="list-style-type: none"> • Massage 	During labor and delivery
Buckle (2014)	AL	<u>Clary sage</u>	ND	During active labor
Kaviani et al. (2014)	AL	Common sage (3 mL)	<ul style="list-style-type: none"> • Inhalation 	During labor
Fritz (2015)	AL	<u>Clary sage</u> (one drop)	<ul style="list-style-type: none"> • Topical application to pinky toes at the nail bed, inside the ankle bones on both feet, and on the lower abdomen. 	Every 15 to 20 minutes or until the strength of contractions has increased.
Clark (2015)	AL	<u>Jasmine</u>	ND	During labor

Note . IL, Induction of labor; AL, augmentation of labor; ND, No description; One drop of essential oil means 0.05 mL.

and used a foot bath infused with clary sage and lavender essential oils, labor was induced during the use of the foot bath in seven women (53.8%) and after six hours in four women (30.7%); labor was not induced after six hours in one woman (7.6%), and labor induction was unknown in one woman (7.6%). Among 22 women who were beyond their due dates, labor was induced during the use of a foot bath in 13 women (30.9%) and labor was classified to be in the other three categories in three women (7.1%) (Kino, 1999). The method of Musil (2013) was empirically stated to induce labor in pregnant women between three and ten days.

For augmentation of labor, Burns (2000) reported the use of aromatherapy during labor and delivery in a single delivery suite in the UK (N = 8058). Of all the women evaluated, 523 women (6%) used aromatherapy for augmentation of labor. Of these 523 women, 87% used clary sage essential oil: 36% evaluated clary sage essential oil as useful and 28% as useless. The authors pointed out that uterine contraction as induced by clary sage essential oil should have been examined using a control group, because 70% of multigravida pregnant women who were in dysfunctional labor with a spontaneous labor onset and who used clary sage essential oil did not need synthetic oxytocin infusion, and 92% of these women achieved spontaneous vaginal delivery. The methods of aromatherapy administration in the suite included the use of an aroma candle, a pillow with drops of essential oil, massage, and a foot bath.

A randomized controlled trial using massage with lavender oil during labor and delivery resulted in a shorter active phase and the second stage of labor than with massage alone (active phase [hours]: massage with lavender oil, $M = 4.05$, $SD = 1.95$; massage only, $M = 5.21$, $SD = 2.52$, $p = .001$; Second stage: massage with lavender [minutes]: $M = 29$, $SD = 10.46$; massage only: $M = 42.36$, $SD = 13.86$, $p = .001$; N = 60) (Zahra, 2013).

Although some studies have reported on the use of aromatherapy for the induction and augmentation of labor, studies involving a comparison with a control group remain lacking, and conclusive scientific evidence regarding the effects of aromatherapy for labor induction has not yet been obtained.

Clary sage essential oil. Clary sage essential oil, which is used the most for the induction and augmentation of labor, is extracted from the buds and leaves of *Salvia sclarea*. The negative effects of using clary sage essential oil for aromatherapy have been unacknowledged (Posadzki, Alotaibi, & Ernst, 2012). The skin sensitization caused by clary sage essential oil is categorized as moderate and the use of clary sage essential oil has no contradictions (Tisserand & Young, 2013). The main aromatic ingredients of clary sage essential oil are linalyl acetate (45%-73%) and linalool (9%-19%). Linalyl acetate is expected to have anticonvulsant and sedative effects achieved by its balancing effect on the nervous and neuroendocrine systems. Monoterpene alcohol including linalool is expected to have anti-infection and sedative effects (Bowles, 2001; Tisserand & Young, 2013). Clary sage essential oil also includes sclareol whose structure is similar to that of estrogen, and is thus expected to have estrogen-like effects (Tisserand & Young, 2013). Estrogen can enhance the effect of oxytocin as it increases the release of oxytocin (Uvnas-Moberg & Petersson, 2005) and it indirectly increases the oxytocin receptor concentration (Tadashi Kimura, Ogita, Kumasawa, Tomimatsu, & Tsutsui, 2013).

Inhalation of the scent of clary sage essential oil by menopausal women using gauze dropped at 0.1 ml for five minutes resulted in a decrease in their plasma cortisol level compared with their preinhalation plasma cortisol level (μ g/100 ml) ($M = 9.97$, $SD = 0.14$, vs. $M = 7.28$ $SD = 0.09$; $p < .05$; $N = 22$) (K. B. Lee, Cho, & Kang, 2014).

Jasmine essential oil (jasmine absolute oil). Jasmine essential oil is extracted from the flower of *Jasminum officinale*. Some uses of jasmine essential oil in combination with other essential oils from various groups of plants (e.g., geranium, lavender, lemongrass, and peppermint; lavender, cananga, rose, ylang ylang, and geranium; and lavender, ylang ylang, and cypress) have been reported in one case of contact dermatitis with no adverse effects for the single use (Posadzki et al., 2012). Skin sensitization of jasmine essential oil is categorized as moderate, and there are no contraindications with its usage. The main aromatic ingredients of jasmine essential oil are benzyl acetate (15%-24%), benzyl benzoate (8%-20%), and phytol (7%-12%)

(Tisserand & Young, 2013). Jasmine essential oil is expected to have anticonvulsant and sedative effects (Bowles, 2001; Tisserand & Young, 2013). Although the mechanism of labor induction by jasmine essential oil has not yet been fully clarified, it is one of the essential oils used for labor induction (Musil, 2013; Omoto, 2005).

Lavender essential oil. The number Lavender essential oil is extracted from the flower and leaves of *Lavandula officinalis*. Acute eczema and dermatitis after the use of lavender essential oil and erythema and lichenization after the combination use of lavender and tee tree essential oils have been reported. In contrast, although skin sensitization after the use of lavender essential oil has been reported, it is categorized as moderate and there are no contraindications with its use (Tisserand & Young, 2013). The main aromatic ingredients of lavender essential oil are linalyl acetate (25%-46%) and linalool (20%-45%). Linalyl acetate is expected to have anticonvulsant and sedative effects achieved by balancing the nervous and neuroendocrine systems. Monoterpene alcohol including linalool is expected to have anti-infection and sedative effects (Bowles, 2001; Tisserand & Young, 2013).

With regard to hormonal changes, a crossover trial which compared the effects of lavender essential oil before and after inhalation for 30 minutes showed a significant lower serum cortisol level after inhalation (before inhalation: $M = 8.4$, $SD = 3.6$ mg/dL; after inhalation: $M = 6.3$, $SD = 3.3$ mg/dL; $p < .05$, $n = 30$) (Shiina et al., 2008). A comparison of the effects of five-minute inhalation of propylene glycol diluted with lavender essential oil, rosemary essential oil, or no essential oil showed that the salivary cortisol level was significantly decreased in the lavender and rosemary essential oil dilution groups by either 10-fold or 100-fold dilution compared with the control group. For the secretory IgA and amylase levels in the saliva, significant differences were not found ($N = 22$) (Atsumi & Tonosaki, 2007).

Regarding foot baths, a previous crossover research compared the effects of a foot bath containing lavender essential oil with a foot bath containing no lavender essential oil. When used for ten minutes, both foot baths showed no significant differences in the heart and respiratory rates. However, the blood flow was significantly

increased at ten minutes after using the foot bath without lavender essential oil ($p < .05$), and at 5, 10, and 15 minutes after using the foot bath with lavender essential oil ($p < .05$) ($N = 10$) (Saeki, 2000). A randomized controlled trial that compared the effects of a warm sitz bath with lavender essential oil with a warm sitz bath without any substances found that the pain intensity four hours postepisiotomy was significantly lower in the lavender group than in the no substances group (visual analog scale: $M = 2.7$, $SD = 1.7$ vs. $M = 4.2$, $SD = 1.5$; $p = .001$), and that the perineal healing five days postepisiotomy was better in the lavender group than in the no substances group (REEDA score: $M = 1.9$, $SD = 0.9$ vs. $M = 3.6$, $SD = 1.2$; $p = .000$; $N = 60$) (Sheikhan et al., 2012).

Therefore, lavender essential oil is expected to lessen the stress response, which could result in an increase in the oxytocin level and the subsequent induction of labor.

Effects of aromatherapy on body. Aromatherapy exerts its effects on the human body through percutaneous or nasal absorption. In percutaneous absorption, some oil components enter the bloodstream through the dermal capillaries within 20-40 minutes (Buckle, 2014). A previous review on baths infused with essential oils that included 12 studies (Büssing et al., 2008) found that terpene was absorbed into the bloodstream in 30 minutes as referred to by Römmelt (1974, 1978). In nasal absorption, the effects occur when odorant molecules start binding with odor receptors of olfactory sensory neurons in the membrane of olfactory cilia behind the bridge of the nose by scent inhalation. The axon of olfactory sensory neurons reaches the olfactory bulb including mitral cells and tufted cells. The axons of mitral cells and tufted cells reach the anterior olfactory nucleus, olfactory tubercle, piriform cortex, amygdala, or entorhinal cortex. From these regions, odorant information travels directly into the frontal cortex, or indirectly into the orbitofrontal cortex through the thalamus. It is suggested that the route through the amygdala is related to the emotional response to the odor, whereas the route through the entorhinal cortex is related to the memory of the odor (Barrett, Barman, Boitano, Brooks, & Ganong, 2012; Hall, 2015). Behavior

response to the scent of aromatherapy is immediately seen (Herz, 2009). A systematic review of the association of aromatherapy with mood, physiology, and behavior that included 18 studies (Herz, 2009) and with sleep that included 15 studies (Lillehei & Halcon, 2014) suggested that aromatherapy has positive effects on mood, physiology in terms of less heart and respiratory rate abnormalities, and behavior, as well as on sleep. The hormone changes after aromatherapy were commonly studied 30 minutes after starting the intervention (Atsumi & Tonosaki, 2007; K. B. Lee et al., 2014; Yamaguchi, Tahara, & Kosaka, 2009). Regarding other outcomes, parasympathetic nerve activity increased and heart rate decreased 45 minutes after inhalation of the scent of lavender essential oil for five minutes, but parasympathetic nerve activity decreased after 51 minutes, compared with the inhalation of the scent of distilled water ($n = 12$) (Kuroda et al., 2005).

Research articles that specifically examined the association between aromatherapy and changes in the oxytocin level could not be found.

Summary and Implications of the Study

The process of labor induction using the medication, mechanical, and alternative methods depends on prostaglandin and oxytocin. The number of oxytocin receptors reaches the maximum in 39 weeks of gestation and early labor; therefore, uterine oxytocin is considered to play an important role in labor induction.

The essential oils that are mainly used for labor induction include clary sage and jasmine essential oils, and in some cases clary sage is used with lavender. Clary sage essential oil is also used for the augmentation of labor; therefore, it can mimic the action of oxytocin which increases the uterine contraction and shortens the labor period. The scent of lavender essential oil is expected to have a relaxing effect to lessen the stress response. Under stress, the oxytocin level was shown to be reduced in some studies, and lavender could increase the oxytocin level by reducing stress. There is a scarcity of research articles about jasmine essential oil, thus the processes and mechanisms of its effects have not yet been fully clarified. However, jasmine essential oil has been used, and its use is suggested empirically. The above-mentioned essential

oils are considered to initiate labor induction by increasing the oxytocin level through inhalation of the scent of or by skin absorption of clary sage, lavender, and jasmine.

Accordingly, the effects of the essential oils of clary sage and lavender, and jasmine on labor induction need to be examined in relation to the oxytocin level as the index.

Methods

Study Design

This study used a quasi-experimental design with three arms. Each arm involved the use of a foot bath (1) with the essential oils of clary sage and lavender (Experimental group, clary sage and lavender group), (2) with the essential oil of jasmine (Experimental group, jasmine group), and (3) with no essential oil (Control group, no essential oil group) for 20 minutes (**Figure 1**). Salivary oxytocin level before and after the use of a foot bath was descriptively compared.

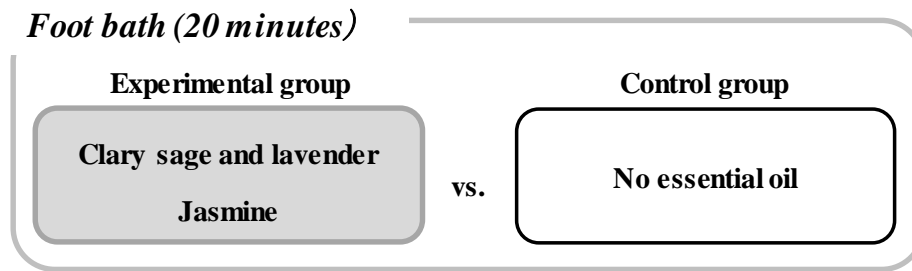


Figure 1. Comparison of experimental group and control group.

Participants used one of the foot baths of the two experimental groups or the foot bath of the control group on the first day of the intervention and used a different foot bath on the second day of the intervention or on the day closest to the first day of intervention. The combination of foot baths was evenly set to six orders, and the participants were successively allocated to one of the six orders on the first day of the intervention by the author or a research assistant. After five participants in each order finished the intervention, the rest of the participants were allocated to the orders to ensure balance in the number of participants in each order, taking into account the number of participants who could not collect 1.5 ml or more of saliva for oxytocin measurement.

Participants were masked so that they would not know their orders until the end of the intervention on the second day. However, most of the participants could guess

whether they were in the experimental or control group from the start of the foot bath intervention because of the nature of the experiment.

	Day 1	Day 2
Order NC	No essential oil	Clary sage and lavender
Order NJ	No essential oil	Jasmine
Order CJ	Clary sage and lavender	Jasmine
Order CN	Clary sage and lavender	No essential oil
Order JC	Jasmine	Clary sage and lavender
Order JN	Jasmine	No essential oil

Participants and Setting

The participants included low-risk pregnant women of singleton cephalic presentation pregnancies who were planning vaginal delivery; who were between 38 and 40 gestation weeks before labor onset; who were between 20 and 40 years old; and who could communicate, read, and write in Japanese. The exclusion criteria included obstetric history (post-term delivery, cesarean section, recurrent miscarriage, recurrent pregnancy loss, and abnormalities during pregnancy); planning for labor induction; medical history (mental disorder, endocrine disease, dermatitis, or olfaction disorder); alcohol addiction; smokers; and breastfeeding and allergy to some foods, medicine, plants, and aromatherapy. All the participants were tested for allergy to any essential oils used in the intervention at least one day before the intervention.

The recruitment of participants and the intervention were conducted during the weekdays at a single birth center in Tokyo, Japan, between February and July 2016 by the author and two research assistants who were certified nurse midwives < **Appendices 1-3**>.

Interventions

Interventions were conducted between 12:00 and 14:00 and lasted for 1.5 hours in a quiet room (17.8 m³) under a controlled humidity of 50% and a temperature of 25°C

by air conditioning. The participants were given instructions regarding the saliva collection procedure at the start of the intervention and collected saliva samples before and after the use of a foot bath. The time for using a foot bath was 20 minutes. The foot bath temperature was maintained at 42°C using a warm sustainable foot bath device (FB-C80, Koyo-sha, Gifu, Japan). The depth of the foot bath containing 10.7 liters of water was about 15 cm, which was above the sanyinjiao point (SP6 of acupuncture point) (Kino, 1999; Omoto, 2005; M. Shimizu & Nagaya, 2015). A foot bath was used until the second saliva collection was completed. To obtain sufficient volume of saliva for oxytocin measurement, the participants were instructed to rinse their mouth at the beginning of the intervention and to drink 100 ml of water ten minutes before each saliva collection (Horiuchi, Tadokoro, & Takahata, 2016; Tadokoro, Horiuchi, Takahata, Shuo, Yamanaka, et al., 2016). A silent movie featuring trains (Sekai no Shasho kara [See the World by Train], Australia railway, JAN 4988021151528, VAP Inc., Tokyo, Japan) was shown to ensure that the condition of the participants was calm and without additional stress (Figure 2) <Appendix 4>.

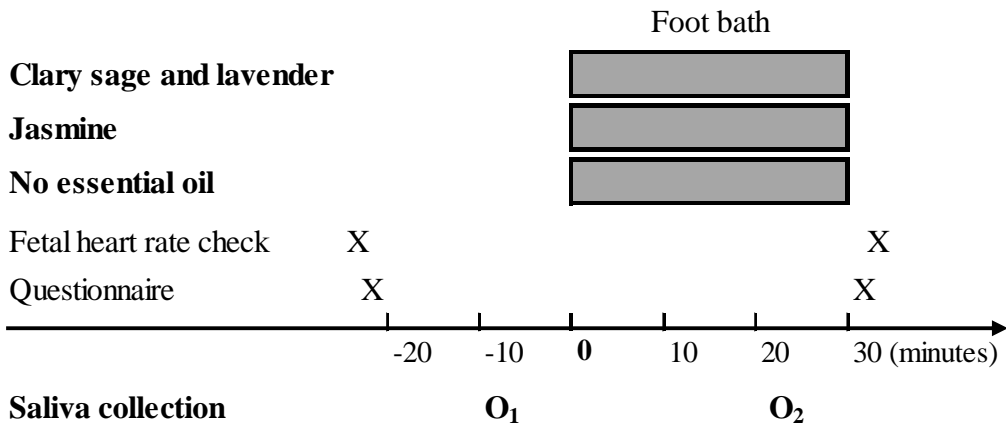


Figure 2. Intervention protocol and saliva collection for measuring oxytocin level.

To avoid discrepancies in oxytocin and cortisol level measurement, the participants were asked to abstain from visiting a dentist two days before the intervention; alcohol, spicy dishes, and sexual intercourse on the day before the experiment; caffeine intake 12 hours before the intervention; lunch one hour before the

intervention; doing activities other than the protocol during the intervention.

Experimental group. Each essential oil was diluted with salt (6 g) to emulsify the oil and water in the foot bath. In the clary sage and lavender group, 0.2 ml of clary sage essential oil (0.0019% of water) and 0.1 ml of lavender essential oil (0.0009% of water) were used. In the jasmine group, 0.25 ml of jasmine essential oil (0.0023% of water) was used. Five nonpregnant women confirmed that the scent of the oil in each group was the strongest, but they felt comfortable using the foot baths.

Clary sage essential oil, which is extracted by steam distillation of the whole plants of *Salvia sclarea* (Lamiaceae, Lot No. 57, Tree of life Co. Ltd., Tokyo, Japan), contains linalyl acetate (55.8%), linalool (23.5%), alpha-terpineol (3.3%), beta-caryophyllene (2.1%), geranyl acetate (2.1%), germacrene D (1.1%), and sclareol (0.6%) (Tree of Life Co. Ltd., 2015).

Lavender essential oil, which is extracted by steam distillation of the flowers and leaves of *Lavandula officinalis* (Lamiaceae, Lot No. 57, Tree of life Co. Ltd.) contains linalyl acetate (37.9%), linalool (31.4%), cis-beta-ocimene (3.8%), terpinen-4-ol (2.7%), trans-beta-ocimenes (2.6%), acetic acid lavandulyl ester (2.0%), 3-octanone (1.1%), 1,8-cineole + p-mentha-1(7), 2-diene (1.0%), alpha-terpineol (0.9%), lavandulol (0.6%), and camphor (0.4%) (Tree of Life Co. Ltd., 2016b).

Jasmine absolute oil, which is extracted by solvent extraction of *Jasminum officinale* (Oleaceae, Lot No. 39, Tree of life Co. Ltd.) contains benzyl acetate (23.9%), benzyl benzoate (17.3%), linalool (6.7%), isophytol (5.3%), epoxy dihydrosqualene (2.8%), phytol (2.8%), methyl linolenate (2.6%), eugenol (2.3%), acetic acid (2E,7R,11R)-3,7,11,15-tetramethyl-2-hexadecenyl ester (2.1%), methyl hexadecanoate (1.8%), benzyl alcohol (1.74%), indole (1.63%), squalene (1.4%), cis-3-Hexenyl benzoate (1.3%), jasmone (1.3%), geranyl linalool (1.1%), and alpha-farnesene (0.8%) (Tree of Life Co. Ltd., 2016a).

Essential oils are categorized as sundries and anyone can buy and use them in Japan.

Control group. Only salt (6 g) for dilution was used in the foot bath.

Outcome Measures

Primary outcome. The primary outcome was salivary oxytocin level. The preliminary study of this research, which has been conducted recently, showed that the effect of the scent of clary sage essential oil was immediately diminished (Tadokoro, Horiuchi, Takahata, Shuo, Sawano, et al., 2016). Therefore, the oxytocin level was measured after finishing the foot bath for 20 minutes, and continued during the saliva collection.

To measure the oxytocin level, saliva was collected before and after using the foot bath by passive drool following the instructions of a saliva collection manual (Salimetrics LCC., 2015). The participants attempted drooling their saliva in a prechilled polypropylene tube (Eppendorf, NY, USA) after accumulating saliva in the mouth for three minutes. The participants attempted drooling their saliva three times in each saliva collection point (Horiuchi et al., 2016). When the saliva volume was less than 1.5 ml after three attempts, a fourth attempt was made. The tubes were kept in ice between saliva poolings and the salivary samples were immediately frozen in a box containing dry ice or in a -80°C freezer (Cryo Porter CS-80C, Scinics Corp., Tokyo, Japan) after each collection point. Following completion of each intervention, all the samples were stored at a -80°C freezer in the Research Center of St. Luke's International University, Tokyo Japan.

Salivary oxytocin level was measured by enzyme-linked immunosorbent assay (ELISA; ENZO Life Sciences, NY, USA) in duplicates by a biochemist of the Research Center of St. Luke's International University, Tokyo Japan. Samples from individual participants were measured at the same ELISA plate. The measurements followed the protocol of Carter et al. (2007) but with the addition of 500 KIU/μL aprotinin (Sigma-Aldrich Corporation, MO, USA). Carter et al. used 250 μL of a sample concentrated from 1000 μL of the supernatant; therefore, the concentration rate was the same as that of the current protocol because 125 μL of the samples was concentrated from 500 μL of the supernatant with aprotinin. When the % coefficient of variation (%CV) of the intra assay was more than ten, the data was removed because the %CV of

less than ten was acceptable (Salimetrics, n.d.).

Secondary outcomes. The secondary outcomes were subjective uterine contraction, salivary cortisol level, and delivery outcomes.

The frequency of subjective uterine contraction before and after using a foot bath was evaluated using a self-administered questionnaire after using the foot bath (i.e., unchanged, increasing, or decreasing) <Appendix 5>.

Salivary cortisol level was measured to examine whether the intervention induced stress (Clements, 2013) and whether the intervention procedure affected the hormone system (K. B. Lee et al., 2014). To measure salivary cortisol level, 50 μ L of saliva was drooled and collected into a separate polypropylene tube after collecting saliva for oxytocin level measurement. The saliva samples were stored similarly as the saliva samples for oxytocin level measurement. Salivary cortisol level was measured by ELISA (Salimetrics, PA, USA) in duplicate assays by a biochemist of the Research Center of St. Luke's International University, Tokyo, Japan, following the manufacturer's instruction. The cortisol level in the samples from individual participants was measured at the same ELISA plate. When the %CV of the inter assay was more ten, such cortisol data was not used.

Delivery outcomes, which included data on gestational weeks of delivery, duration from intervention to delivery, induction and augmentation of labor, and mode of delivery, were obtained using medical records.

Feasibility. The feasibility of the intervention was examined in terms of limited efficacy, acceptability, and practicality of the intervention for the participants (Bowen et al., 2009; Eldridge et al., 2016).

Limited efficacy was descriptively examined on the basis of changes in the oxytocin level, uterine contraction, and cortisol level and delivery outcomes.

Acceptability was examined on the basis of burden to the participants (e.g., saliva collection, foot bath use, intervention participation for two days, and answering the self-administered questionnaire) using a self-administered questionnaire with a

five-point Likert scale (i.e., light, a little light, moderate, a little heavy, and heavy) after using a foot bath.

Practicality was examined on the basis of the volume of the obtained saliva checked visually during the intervention, the number of samples in which oxytocin level could be measured, the procedure which could not be carried out following the intervention protocol, the temperature of the foot bath water judged by the participants (i.e., hot, moderate, and lukewarm), and negative effects on the participants or their babies (e.g., skin symptoms and fetal heart rate less than 110 bpm or more than 160 bpm checked during the intervention after using a foot bath; premature rupture of membrane (PROM), low Apgar score at five minutes, and neonatal intensive care unit admission using medical records) <Appendix 6>.

Characteristics of participants. Changes in the oxytocin level as induced by various stimuli were reported to be unstable among depressed women (Cyranowski et al., 2008). Healthy married couples with a high depression score on the Center for Epidemiologic Studies Depression Scale (CES-D) were shown to have a high plasma or saliva oxytocin level (Holt-Lunstad, Birmingham, & Light, 2011). In contrast, university students with a high depression score had less plasma oxytocin level (Gordon et al., 2008). A low oxytocin level was reported among the subjects who had clinical symptoms of anxiety (Heim et al., 2009), who had a high body mass index (BMI) (Light et al., 2004), who were married (Gordon et al., 2008), who had less social support from their partner (Gordon et al., 2008; Light et al., 2004), and who had strenuous exercise (Hew-Butler et al., 2008). Regarding the oxytocin level in primipara and multipara women, conflicting results have been reported (Light et al., 2004; Prevost et al., 2014).

Basic information related to oxytocin level was also collected using the self-administered questionnaire. This included states of depression and anxiety, BMI, history of delivery, number of children being taken care of, marriage, living with their partner, and exercise for the last one week. Depression and anxiety were assessed using the Japanese version of CES-D (Radloff, 1977; Shima, 1998) and State-Trait Anxiety Inventory (STAI), which were confirmed in terms of validity and reliability (H. Shimizu

& Imae, 1981; Spielberger, Gorsuch, & Lushene, 1970). CES-D consists of 20 items with a 4-point Likert scale, and a normal condition is evaluated as < 16 scores. STAI has two scales, namely, trait (A-trait) and state (A-state) of anxiety, each consisting of 20 items with a 4-point Likert scale <Appendix 7>.

Data which were considered to have an effect on oxytocin and cortisol level measurement included anxiety over their pregnancy (Obel et al., 2005); physical complaints; accuracy of the due date (confirmation of the due date by ultrasonography before 12 weeks of gestation); scent perception (preference, recognition, and strength of the scent of the foot bath; experience of smelling the scent of a foot bath; memory evoked by the scent of a foot bath); country of origin; race (Herz, 2009); mouth injury; taking supplements and medicine. The sex of the baby is reported to have an effect on gestational weeks until delivery (Divon, Ferber, Nisell, & Westgren, 2002). These data were collected using a self-administered questionnaire or the medical records. The face validities of all the self-administered questionnaires were confirmed by three researchers having a master's degree in nursing.

Sample Size

As this was a feasibility study, the sample size was not strictly calculated and 15 subjects were considered sufficient for initially examining changes in the oxytocin level. The proportion of salivary samples (≥ 1.5 ml) that could be collected was 72.7% in our previous preliminary research (Tadokoro, Horiuchi, Takahata, Shuo, Yamanaka, et al., 2016). Therefore, 20 subjects in each group and 30 participants in the entire groups were needed.

Taking account of the preliminary study, the sample size was considered to be rational. The changes in the salivary oxytocin level before and after 15 minutes of intervention in the preliminary study were 12.2 pg/ml (*SD* 4.5) in the experimental group, 5.1 pg/ml (*SD* 22.3) in the control group, and 8.19 pg/ml (*SD* 16.42) in both groups. Based on the results, when the detected change in the oxytocin level was set to 7 pg/ml, the numbers of subjects in each group were calculated as 15.6 (*SD* was set to 7 pg/ml) and 11.5 (*SD* was set to 6 pg/ml).

Analysis

Data were analyzed using descriptive statistics. The primary outcomes of the changes in the salivary oxytocin level in the experimental groups were compared within groups. For the comparison of groups, the change in the oxytocin level between before and after using the foot bath was compared using change volume ([oxytocin level after using the foot bath] – [oxytocin level before using the foot bath]) and change rate (oxytocin level after using the foot bath/oxytocin level before using the foot bath $\times 100$ [%]). The rates of participants whose oxytocin level increased after using the foot bath in the experimental groups were compared with that in the control group. The secondary outcomes were also compared among the groups. Feasibility was assessed in terms of limited efficacy, practicality, and acceptability of the intervention for the participants.

This feasibility study aimed to compare the outcomes before and after using a foot bath between groups descriptively as limited efficacy. However, changes in the mean oxytocin and cortisol levels before and after using the foot bath within the group were compared using the paired *t*-test after graphical review of the normal distribution. Oxytocin and cortisol level changes between groups were compared using *t*-test. If Levene's test for equality of variances was not confirmed, Welch's test was used. Categorical data was compared using the chi-square test and the *p*-value was interpreted using Cramer's *V* or Fisher's exact test. Ordinal data were compared using the Kruskal-Wallis test. Statistical analyses were conducted using SPSS version 24.0J, except for Fisher's exact test which was conducted using R version 3.3.2, with a two-sided 5% level of significance.

Ethical Consideration

This study was approved by the Research Ethics Committee of St. Luke's International University (No. 15-084). The participants provided written informed consent before study participation. After finishing the intervention, all the participants received monetary compensation for their time (¥3,500 or ¥2,500 if they could not participate on the second day of the intervention because of delivery) and a travel fee < **Appendices 8-10**>. This study was registered in the Clinical Trials Registry of

University Hospital Medical Information Network in Japan before participant recruitment (February 8, 2016, UMIN000020933).

Results

Retention and Characteristics of Participants

Recruitment and retention. Of the 106 women who met the inclusion criteria, 94 women were contacted and 63 women agreed to participate (67.0%). Of these 63 women, 22 women were not included according to the exclusion criteria. On the first day of intervention, 41 women were allocated to each of the six orders and all the women completed the intervention on the first day. Before the intervention on the second day, three women delivered and one woman withdrew. Consequently, 37 women completed the intervention on the second day (**Figure 3**).

The total numbers of subjects on both days of interventions were 27 in the clary sage and lavender group, 26 in the jasmine group, and 25 in the no essential oil group (**Figure 4**).

Characteristics of participants. The characteristics of the participants are shown in **Table 2**. There were no specific differences in the characteristics of the participants among the orders. Although some women had physical complaints such as low back pain, these were mild cases. There were no women who had any mouth injury. All the women's due data were estimated by ultrasonography before 12 weeks of gestation. Most women took folic acid or iron for supplement, used an iron pill or a cathartic for medicine, and walked for 30 to 120 minutes for exercise.

Primary Outcome: Changes in Oxytocin Level

The oxytocin levels before and after using the foot baths are shown in **Table 3** under '**Including all subjects**'. The oxytocin level (pg/ml) increased after using the foot bath compared with the oxytocin level before using the foot bath in the clary sage and lavender group and jasmine group. In particular, a significant difference was observed in the clary sage and lavender group (before: $M = 139.5$, $SD = 106.5$; after: $M = 152.0$, $SD = 115.2$; $MD = 12.5$, $SD = 23.9$, 95%CI for MD [1.0, 24.1]; $t(18) = 2.29$, $p = .035$). In contrast, the oxytocin level decreased after using the foot bath in the no essential oil group.

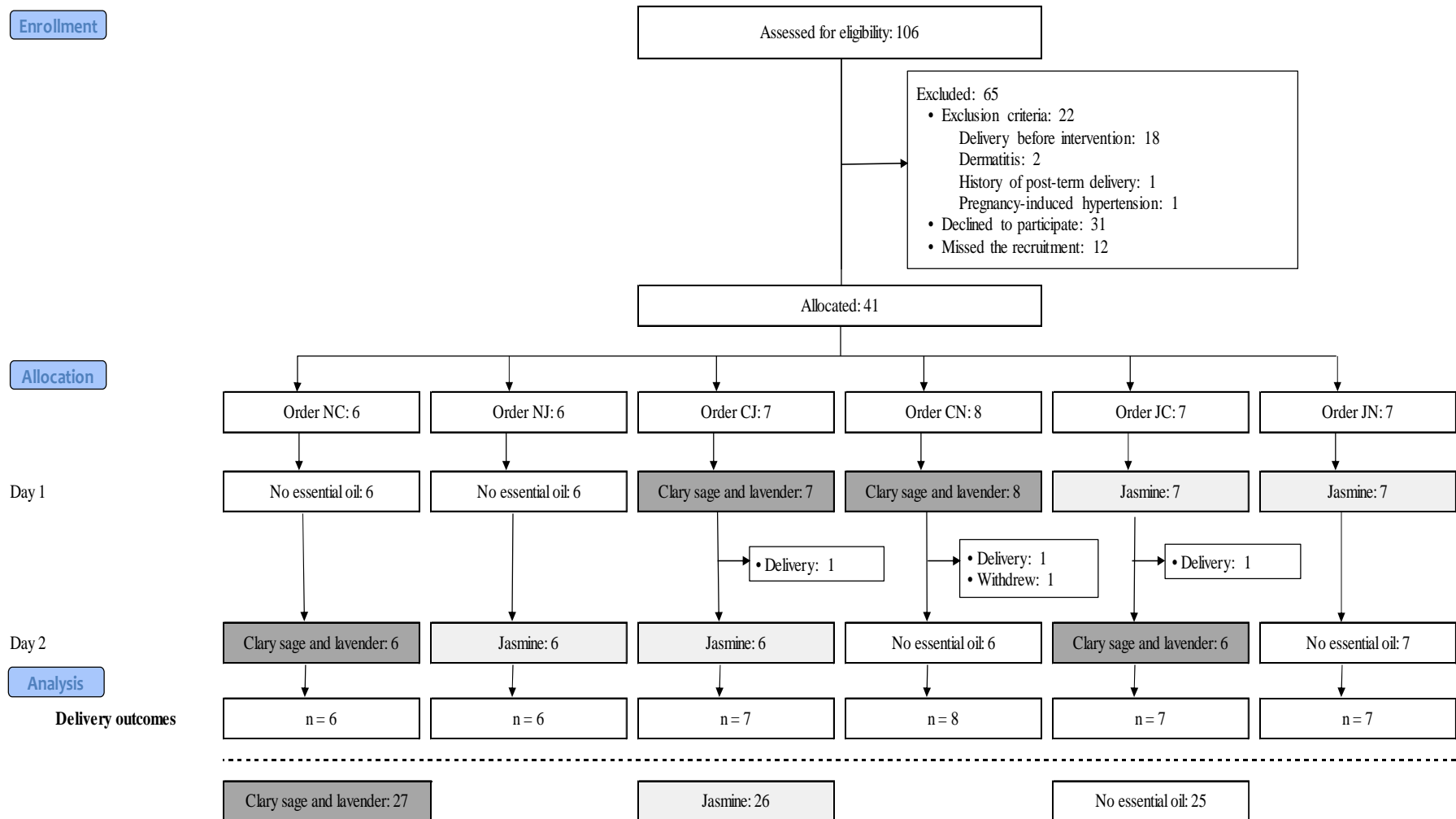


Figure 3. Intervention profile of foot bath based on orders.

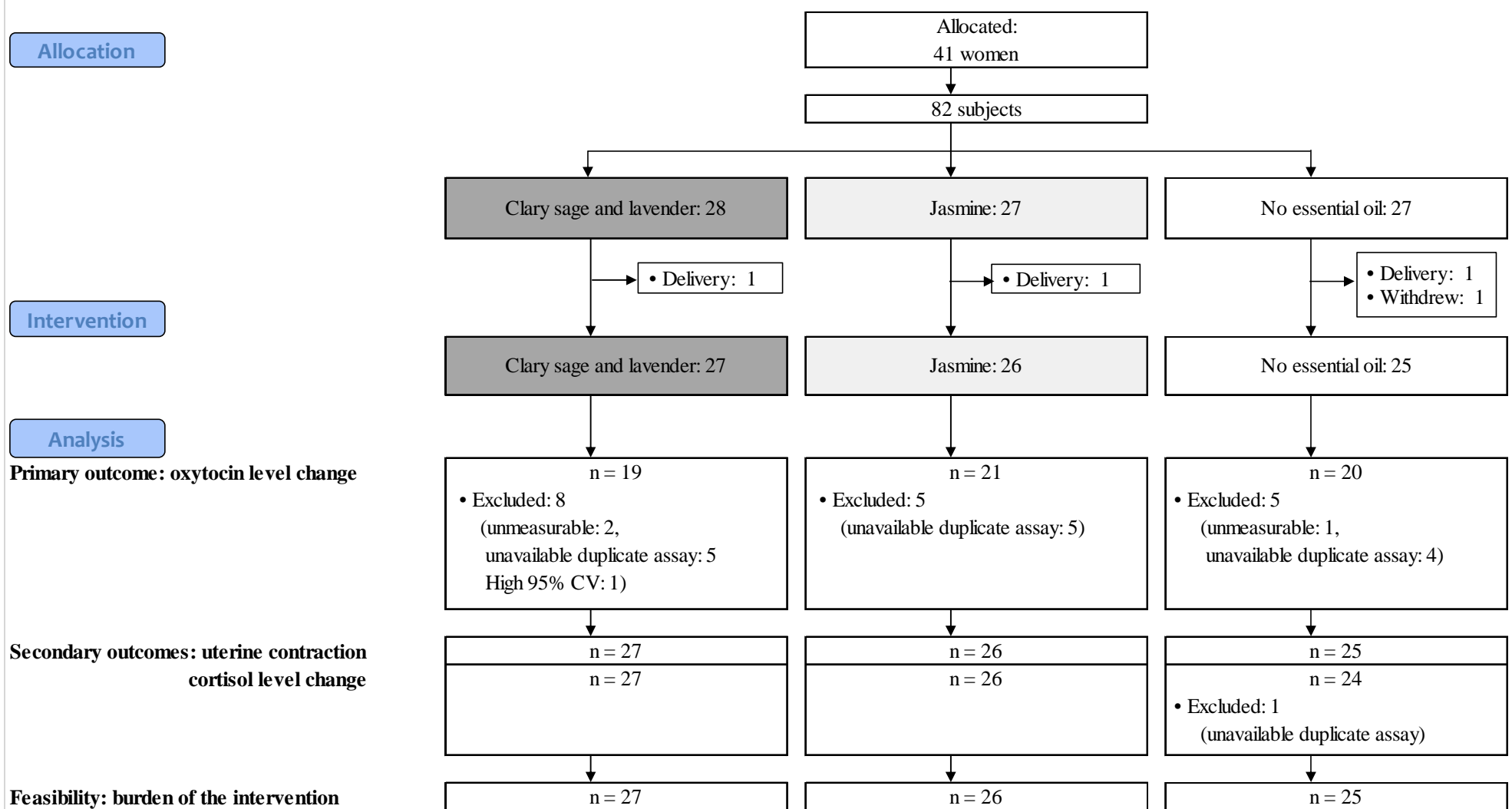


Figure 4. Intervention profile of foot bath based on groups.

Table 2***Characteristics of Participants***

	Order NC n = 6 No essential oil	Order NJ n = 6 No essential oil	Order CJ n = 7 Clary sage and lavender Jasmine	Order CN n = 8 Clary sage and lavender No essential oil	Order JC n = 7 Jasmine Clary sage and lavender	Order JN n = 7 Jasmine No essential oil	<i>df</i>	<i>F</i> <i>or</i> χ^2	<i>p</i> -value
Day 1									
Day 2	Clary sage and lavender	Jasmine	Jasmine	No essential oil	Clary sage and lavender	No essential oil			
Age (years) (<i>SD</i>)	32.2 (2.5)	32.7 (3.3)	30.7 (3.6)	32.4 (4.2)	33.1 (6.0)	33.7 (3.5)	5	0.45	.812
Gestation weeks (weeks) (<i>SD</i>)									
Day 1	38.3 (0.2)	38.4 (0.3)	38.6 (0.4)	38.2 (0.2)	38.6 (0.5)	38.7 (0.5)	5	1.08	.378
Day 2	38.6 (0.3)	38.8 (0.6)	39.1 (0.5)	38.5 (0.3)	38.9 (0.6)	38.9 (0.4)	5	1.13	.367
Primiparas	6	1	4	6	3	4	5	2.40	.795
Infertility treatment	0	0	1	0	0	1	5	4.05	.795
Living with partner	6	6	6	6	7	7	5	6.24	.283
Married	6	6	7	8	7	7	—	—	—
Having children	0	5	3	2	4	3	5	10.20	.070
Having interaction with children	3	5	4	2	4	3	5	10.20	.070
Education \geq 12 years	6	5	7	8	7	6	5	5.07	.444
Japanese	6	6	7	8	7	7	5	—	—
Exercise	0	1	2	0	1	1	—	4.57	.499
Weight increase during pregnancy > 12 kg	1	0	1	0	0	0	5	3.87	.630
BMI before pregnancy < 18.5	1	0	4	2	0	2	5	4.57	.499
BMI before pregnancy \geq 25	1	0	0	0	0	0	5	9.04	.118
Taking supplements	2	1	2	2	2	4	5	5.98	.293
Taking medicine	0	2	2	2	2	2	5	2.96	.768
Having anxiety about their pregnancy									
Day 1	0	1	2	0	1	1	5	0.78	.992
Day 2	2	1	2	0	2	1	5	30.42	.696
CES-D score \geq 16									
Day 1	0	0	0	0	1	0	5	4.98	.805
Day 2	0	0	0	0	1	0	5	4.98	.805
Trait anxiety score (STAI) (<i>SD</i>)									
Day 1	34.5 (5.9)	35.7 (5.0)	37.9 (9.4)	36.4 (4.3)	40.0 (8.7)	37.9 (5.7)	4	2.19	.107
Day 2	35.5 (7.0)	35.7 (4.8)	38.7 (8.2)	34.0 (3.0)	40.2 (8.8)	37.6 (6.8)	5	0.66	.660
State anxiety (STAI) (<i>SD</i>)									
Day 1	32.5 (7.9)	33.2 (7.4)	32.6 (11.4)	32.3 (4.9)	34.3 (7.2)	34.4 (8.4)	5	0.10	.992
Day 2	32.3 (10.0)	33.5 (8.2)	35.2 (9.8)	31.2 (5.0)	33.0 (7.1)	32.9 (8.3)	5	0.29	.915

Note . The numbers of subjects on the second day of intervention were 6 in the orders CJ, CN, and JC because of delivery or withdrawal after the first day; BMI, Body Mass Index; wks, weeks of gestation; CES-D, Center for Epidemiologic Studies Depression Scale; STAI, State-Trait Anxiety Inventory.

Table 3***Oxytocin Levels before and after Using the Foot Baths and Level Changes (pg/ml)***

	Mean	<i>SD</i>	95% CI	Median	Range	<i>MD</i>	<i>SD</i>	95% CI	Range	<i>t</i>	<i>df</i>	<i>P</i> -value
Including all subjects												
Clary sage and lavender (n = 19)												
Before	139.5	106.5	[88.1 , 190.8]	108.6	[23.2 , 399.3]	12.5	23.9	[1.0 , 24.1]	[-34.5 , 57.3]	2.29	18	.035
After	152.0	115.2	[96.5 , 207.5]	121.1	[27.3 , 427.5]							
Jasmine (n = 21)												
Before	166.2	136.7	[104.0 , 228.4]	124.0	[35.5 , 581.6]	4.8	51.8	[-18.8 , 28.4]	[-127.9 ,142.3]	0.43	20	.676
After	171.0	141.4	[106.6 , 253.4]	134.9	[43.1 , 536.7]							
No essential oil (n = 20)												
Before	141.6	118.3	[86.3 , 197.0]	119.9	[28.9 , 538.5]	-3.3	71.0	[-36.5 , 29.9]	[-270.2 ,123.0]	-0.21	19	.839
After	138.4	91.4	[95.6 , 181.1]	112.1	[31.6 , 581.6]							
Excluding subjects whose absolute oxytocin volumes were above 100												
Jasmine (n = 19)												
Before	156.9	139.8	[89.5 , 224.2]	124.0	[35.5 , 581.6]	4.6	31.0	[-10.4 , 19.5]	[-48.5 , 73.0]	0.64	18	.529
After	161.4	142.8	[92.6 , 230.3]	134.9	[43.1 , 536.7]							
No essential oil (n = 18)												
Before	117.0	74.9	[79.8 , 154.3]	96.9	[28.9 , 317.4]	4.5	20.9	[-5.8 , 14.9]	[-47.7 , 43.0]	0.92	17	.369
After	121.6	79.4	[82.1 , 161.1]	100.2	[31.6 , 310.6]							

Note . Paired t -test; SD, standard deviation; MD, mean difference; CI, confidence interval. In the clary sage and lavender group, there were no subjects whose absolute oxytocin change volume was above 100.

Regarding the ratio of women whose oxytocin level increased after using the foot bath, more than half of the women showed an increase in the oxytocin level after using the foot bath in each group. In terms of a comparison among the groups, the ratio was higher in the clary sage and lavender group (15 of 19 subjects, 78.9%) than in the jasmine group (12 of 21 subjects, 57.1%) and the no essential oil group (11 of 20 subjects, 55.0%) ($\chi^2(2, N = 60) = 2.93, p = .230$).

Oxytocin change volume. In the comparison of the oxytocin change volumes (pg/ml) between the experimental groups and the no essential oil group ($M = -3.3, SD = 71.0, 95\%CI [-36.5, 29.9], n = 20$), higher volumes were found in both experimental groups, particularly in the clary sage and lavender group (clary sage and lavender group: $M = 12.5, SD = 23.9, 95\%CI [1.0, 24.1], n = 19$; jasmine group: $M = 4.8, SD = 51.8, 95\%CI [-18.8, 28.4], n = 21$). However, there were no significant differences between the experimental groups and the no essential oil group (clary sage and lavender group vs. no essential oil group: $MD = -15.8, 95\%CI \text{ for } MD [-50.6, 18.9], t(37) = -0.92, p = .363$; jasmine group vs. no essential oil group: $MD = -8.1, 95\%CI \text{ for } MD [-47.2, 31.0], t(39) = -0.42, p = .679$).

The oxytocin change volume showed a large range, that is, between -270.2 and 142.3 in all the groups ($M = 4.6, SD = 52.4, 95\%CI [-9.0, 18.1], \text{Median} = 5.2, n = 60$) and it was strongly affected in four subjects in the jasmine group ($n = 2$) and the no essential oil group ($n = 2$). Their absolute oxytocin change volumes were above 100 (127.9 and 142.3 in the jasmine group and 270.2 and 123.0 in the no essential oil group). The four subjects were not the same women. When the four subjects were excluded, the range became small, that is, between -48.5 and 73.0 ($M = 7.3, SD = 25.5, 95\%CI [0.4, 14.1], \text{Median} = 5.2, n = 56$).

In the data, the oxytocin change volume was mostly unchanged in the jasmine group ($M = 4.6, SD = 31.0, 95\%CI [-10.4, 19.5], n = 19$) compared with the data including all the subjects. In contrast, the oxytocin change volume showed an increasing oxytocin level after using the foot bath in the no essential oil group ($M = 4.5, SD = 20.9, 95\%CI [-5.8, 14.9], n = 18$), although oxytocin change volume calculated using the data

including all the subjects showed a decreasing oxytocin level after using the foot bath. In the comparison between the experimental groups and the no essential oil group, the difference in the oxytocin change volume between the jasmine group and the no essential oil group became unapparent. However, the oxytocin change volume was still higher in the clary sage and lavender group than in the no essential oil group (See **Table 3, Excluding subjects whose absolute oxytocin change volumes were above 100**).

Specific differences in the characteristics of the subjects were not found between those who had absolute oxytocin change volumes above 100 and those who had absolute oxytocin change volumes below 100, such as age, gestational weeks, history of delivery, infertility treatment, living with partner, having children, having interaction with children, education, exercise, weight increase during pregnancy, BMI before pregnancy, taking supplements and medicine, having anxiety about pregnancy, CES-D score, and STAI scores.

Incidentally, a woman who was judged as depressed according to the CES-D scale used the foot baths in the clary sage and lavender group and the jasmine group. Oxytocin change volumes showed a decreasing trend (- 11.4 pg/ml and - 10.2 pg/ml, respectively), although these change volumes were shown as increasing trends in the means of each group.

Oxytocin change rate. The oxytocin change rate (%) was higher in the clary sage and lavender group ($M = 114.1$, $SD = 28.0$, 95%CI [100.6, 127.6]) than in the no essential oil group ($M = 105.4$, $SD = 27.2$, 95%CI [92.7, 118.2]), although the difference was not significant ($MD = 8.7$, 95%CI for MD [- 26.6, 9.2], $t(37) = - 0.98$, $p = .332$). In contrast, the oxytocin change rates were not significantly different between the jasmine group ($M = 104.9$, $SD = 26.0$, 95%CI [93.0, 116.7]) and the no essential oil group ($M = 105.4$, $SD = 27.2$, 95%CI [92.7, 118.2]) ($MD = 0.6$, 95%CI for MD [- 16.3, 17.4], $t(39) = - 0.07$, $p = .946$).

Secondary Outcomes

Subjective uterine contraction. The number of women with increased

subjective uterine contractions after using the foot bath was larger in the jasmine group (7 of 26 women, 26.9%) than in the clary sage and lavender group (3 of 27 women, 11.1%) and the no essential group (4 of 25 subjects, 16.0%). This remained unchanged or decreased in more than 70% of the subjects in each group (**Table 4**).

Table 4

Changes in Uterine Contraction before and after Using the Foot Bath (%)

	Clary sage and lavender (n = 27)	Jasmine (n = 26)	No essential oil (n = 25)	χ^2	p - value
Increase	3 (11.1)	7 (26.9)	4 (16.0)		
Unchanged	22 (81.5)	17 (65.4)	20 (80.0)	2.80	.591
Decrease	2 (7.4)	2 (7.7)	1 (4.0)		

Note . Fisher's exact test.

Cortisol level change. The cortisol level (ng/ml) significantly decreased in each group after using the foot bath compared with the cortisol level before using the foot bath (clary sage and lavender group: before, $M = 3.84$, $SD = 1.36$, after $M = 3.41$, $SD = 1.15$, $MD = - 0.42$, $SD = 0.48$, 95% CI for MD [- 0.62, - 0.24], $p = .000$; jasmine group: before, $M = 3.80$, $SD = 1.01$, after, $M = 3.39$, $SD = 0.80$, $MD = - 0.41$, $SD = 0.53$, 95% CI for MD [- 0.63, - 0.19], $p = .001$; no essential oil group: before $M = 3.85$, $SD = 1.13$, after, $M = 3.46$, $SD = 1.01$, $MD = - 0.40$, $SD = 0.39$, 95% CI for MD [- 0.56, - 0.24], $p = .000$; **Table 5**). In the comparison of cortisol change volume between either the clary sage and lavender group or the jasmine group and the no essential oil group, no significant differences were found.

Correlations of cortisol and oxytocin change volume. The correlations of the cortisol and oxytocin change volumes in each group were very weak and showed no significant differences (clary sage and lavender group: $r (17) = -.138$, $p = .572$; jasmine group: $r (19) = .164$, $p = .476$; no essential oil group: $r (18) = .046$, $p = .553$). These correlations were unchanged when the subjects who had absolute oxytocin change volumes above 100 were excluded.

Delivery outcomes. The delivery outcomes in terms of order are shown in **Table 6**. Induction of labor was performed owing to oligohydramnios and a nonreassuring fetal heart rate pattern in one woman of each of the orders CN and JN; post due date pregnancy in one woman of the order CN; and premature rupture of the membrane without labor pain, a nonreassuring fetal heart rate pattern, and meconium-stained amniotic fluid in one woman of the order JN. There were no consistent differences in the delivery outcomes among the orders.

Effects of Perception of Scent on Changes in Oxytocin and Cortisol Levels

The oxytocin and cortisol change volumes before and after using the foot baths by perception of the scent are shown in **Tables 7 and 8**. All the memories evoked by the scent were judged as positive images by the subjects, except one memory judged as a negative image by a subject in the jasmine group.

Table 5*Cortisol Levels before and after Using the Foot Baths and Level Changes (ng/ml)*

	Mean	<i>SD</i>	95% CI	Median	Range	<i>MD</i>	<i>SD</i>	95% CI	Range	<i>t</i>	<i>df</i>	<i>p</i> -value
Clary sage and lavender (n = 27)												
Before	3.84	1.36	[3.30 , 4.38]	3.51	[2.28, 7.67]	-0.42	0.48	[- 0.62, - 0.24]	[-2.13 , 0.27]	- 4.61	26	.000
After	3.41	1.15	[2.96 , 3.87]	3.13	[2.03, 6.35]							
Jasmine (n = 26)												
Before	3.80	1.01	[3.39 , 4.21]	3.72	[2.17, 7.17]	-0.41	0.53	[- 0.63, - 0.19]	[-1.72 , 0.52]	- 3.91	25	.001
After	3.39	0.80	[3.07 , 3.71]	3.40	[1.89, 5.86]							
No essential oil (n = 24)												
Before	3.90	1.14	[3.42 , 4.38]	3.97	[2.10, 6.67]	-0.40	0.39	[-0.56, -0.24]	[-1.10 , 0.21]	- 5.03	23	.000
After	3.50	1.01	[3.07 , 3.93]	3.36	[2.04, 6.41]							

*Note . Paired *t*- test; SD, standard deviation; CI, confidence interval; MD, mean difference.*

Table 6***Delivery Outcomes***

	Order NC n = 6	Order NJ n = 6	Order CJ n = 7	Order CN n = 8	Order JC n = 7	Order JN n = 7	<i>F</i> or χ^2	<i>p</i> -value
Day 1	No essential oil	No essential oil	Clary sage and lavender	Clary sage and lavender	Jasmine	Jasmine		
Day 2	Clary sage and lavender	Jasmine	Jasmine	No essential oil	Clary sage and lavender	No essential oil		
Gestational weeks of delivery, Mean (<i>SD</i>)	40.1 (0.7)	39.5 (0.4)	39.9 (0.6)	40.1 (1.1)	39.6 (0.7)	40.3 (0.8)	1.17	.346
Delivery within 72 hours after using the foot bath	0	1	1	0	2	1	3.87	.630
Gestational weeks of delivery ≥ 41	1	0	1	2	0	2	4.03	.546
Induction of labor	0	0	0	2	0	2	7.46	.189
Augmentation of labor	0	1	1	3	0	0	7.70	.173
Mode of delivery								
Spontaneous vaginal birth	6	6	6	6	6	6		
Instrumental vaginal birth	0	0	0	0	1	0	9.27	.506
Caesarean section	0	0	1	2	0	1		
Baby boy	2	4	4	5	5	3	2.84	.725

Note . Fisher's exact test except one-way ANOVA in gestational weeks of delivery. Delivery within 72 hours after using the foot bath was calculated from the second day of the intervention and the numbers of the participants were 6 in the orders C, D, and E because of delivery or withdrawal before the second day. Induction and augmentation of labor were induced by synthetic oxytocin infusion.

Table 7***Oxytocin Change Volumes before and after Using the Foot Baths by Perception of Scent (pg/ml)***

	Clary sage and lavender (n = 19)			Jasmine (n = 21)		
	Mean	SD	n	Mean	SD	n
Preference of the scent						
Dislike	6.4	—	1	-19.6	54.6	3
Like	12.9	24.6	18	8.8	22.3	18
Recognition of the scent						
Did not recognize	29.2	—	1	30.8	—	1
Recognized	11.6	24.3	18	3.5	52.8	20
Strength of the scent						
Weak	31.9	36.0	2	-18.0	43.1	2
Moderate	10.3	22.6	17	7.8	54.6	18
Strong	—	—	0	-2.7	—	1
Experience of smelling the scent						
No experience	12.7	30.8	4	33.4	53.9	7
With experience	12.5	23.1	15	-9.5	46.2	14
Memory evoked by the scent						
Evoked	17.3	25.5	5	18.7	40.3	6
Not evoked	10.8	24.1	14	-0.7	56.1	15

Table 8***Cortisol Change Volumes before and after Using the Foot Baths by Perception of Scent (ng/ml)***

	Clary sage and lavender (n = 27)			Jasmine (n = 26)		
	Mean	SD	n	Mean	SD	n
Preference of the scent						
Dislike	-0.10	—	1	-0.24	0.51	5
Like	-0.44	0.48	26	-0.45	0.55	21
Recognition of the scent						
Did not recognize	-0.39	0.05	2	-0.61	1.57	2
Recognized	-0.43	0.50	25	-0.39	0.45	24
Strength of the scent						
Weak	-0.30	0.18	3	-0.02	0.48	3
Moderate	-0.44	0.52	23	-0.47	0.54	22
Strong	-0.45	—	1	-0.29	—	1
Experience of smelling the scent						
No experience	-0.10	0.37	5	-0.35	0.73	10
With experience	-0.50	0.48	22	-0.45	0.39	16
Memory evoked by the scent						
Evoked	-0.51	0.41	6	-0.32	0.53	18
Not evoked	-0.40	0.50	21	-0.61	0.52	8

In the clary sage and lavender group, the changes in the oxytocin and cortisol levels after using the foot bath were not specific regardless of the perceptions of the scent. Nevertheless, a subject who disliked or did not recognize the scent showed an increase in the oxytocin level and a decrease in the cortisol level similarly to the subjects who liked or recognized the scent.

In the jasmine group, similar trends in changes in the cortisol level were found regardless of the perceptions of the scent. In contrast, opposite trends in changes in the oxytocin level were found in the preference of the scent, strength of the scent, experience of smelling the scent, and memory evoked by the scent. The oxytocin level increased after using the foot bath in the subjects who liked the scent, who judged the scent as moderate, who had not experienced smelling the scent, and who had memory evoked by the scent. Conversely, the oxytocin level decreased in the subjects who disliked the scent, who judged the scent as weak or strong, who had experienced smelling the scent, and who did not have memory evoked by the scent.

In the no essential oil group, three women inaccurately recognized the foot bath as containing an essential oil. Their oxytocin level decreased after using the foot bath compared with their oxytocin level before using the foot bath (oxytocin change volume: $n = 2$, $M = -4.2$ pg/ml, $SD = 3.7$), although the oxytocin level increased in the subjects who recognized the scent in the clary sage and lavender group and jasmine group. The cortisol level decreased in the subjects ($n = 3$, $M = -0.63$ ng/ml, $SD = 0.37$) similarly in the other groups and the subjects in the control group.

Feasibility of Intervention for Participants

Acceptability. The rating of each burden by participating in the intervention is shown in **Table 9**. More than 90% of the women rated each burden as light or moderate.

There were no women who rated answering the self-administered questionnaire as a heavy burden. In terms of collecting saliva, two of 41 women rated this step as heavy on the first day of the intervention. One of the two women also made a similar rating on the second day. The other woman could not participate in the intervention on

the second day because of delivery. With regard to using the foot bath, three of 41 women rated this step as a heavy burden on the first day. Two of three women rated the step as moderate on the second day. The other woman withdrew on the second day because the foot bath was very hot for her. Regarding participation in the intervention, the same woman rated this step as heavy on the first and second days. She rated collecting saliva and using the foot bath as moderate on the first day but as heavy on the second day. Participation in the interventions for two days was rated by two of 41 women as heavy.

The burden of saliva drooling was rated higher when this step was attempted in four trials instead of three trials. Among 13 subjects who attempted four saliva drooling trials, four rated the burden as light (30.8%), six as moderate (46.2%), and four as heavy (23.1%). Among 65 subjects who attempted three saliva drooling trials, 46 rated the burden as light (70.8%), 17 as moderate (26.2%), and two as heavy (3.1%) ($\chi^2(1, N = 78) = 8.99, p = .003$).

Table 9

Burden of the Intervention (%)

	Light	Moderate	Heavy
Collecting saliva			
Day 1	25 (61.0)	14 (34.1)	2 (4.9)
Day 2	25 (67.6)	9 (24.3)	3 (8.1)
Using the foot bath			
Day 1	33 (80.5)	5 (12.2)	3 (7.3)
Day 2	29 (78.4)	7 (18.9)	1 (2.7)
Answering the self-administered questionnaire			
Day 1	38 (92.7)	3 (7.3)	0 (0.0)
Day 2	34 (91.9)	3 (8.1)	0 (0.0)
Conducting all the interventions on the day			
Day 1	31 (75.6)	9 (22.0)	1 (2.4)
Day 2	29 (78.4)	7 (18.9)	1 (2.7)
Participating in the interventions for two days	25 (67.6)	10 (27.0)	2 (5.4)

Note . n = 41 on day 1 and n = 37 on day 2.

Practicality. All interventions were conducted following the study protocol. One woman declined the intervention on the second day because the water of the foot

bath was very hot for her. The temperature of the water was judged as hot by 20 of 41 women for either one or two days. Of these women, eight women judged the temperature of the water differently by the day, and two women did not perform the intervention on the second day because of delivery and withdrawal. The rest of the 21 women judged the water temperature as moderately hot. There were no women who judged the water as lukewarm.

The temperature of the water had no effect on the burden regarding the use of the foot bath. Among 30 subjects who judged the water as hot, 23 subjects rated the burden as light (76.7%), four subjects as moderate (13.3%), and three subjects as heavy (10.0%). Among 48 subjects who judged the water as moderately hot, 39 rated it as light (81.3%), 12 as moderate (16.7%), and one as heavy (2.1%) ($\chi^2(1, N = 78) = 0.40, p = .530$).

Regarding negative effects, there were no women who had skin symptoms after the intervention. PROM was observed in 10 of 41 women (24.4%) after 7.5 days ($SD = 4.4$) from the second day of intervention: three women in Order NC, one woman in order CJ, two women in order JC, and four women in order JN. However, nine of ten women had spontaneous labor onset. For the babies, a fetal heart rate of less than 110 bpm or more than 160 bpm was not observed after the intervention. All the babies had an Apgar score of more than 9 at 5 minutes. A newborn in the order NC required neonatal intensive care unit admission because of transient tachypnea.

Regarding saliva sampling and oxytocin level measurement, a total of 156 specimens from 78 subjects were collected. Of these specimens, 145 (92.9%) had 1.5 ml or more saliva volume. Oxytocin level could be measured in 131 of the 156 specimens (83.1%). The unmeasurable oxytocin levels were due to the lack of saliva volume after centrifugation. With regard to saliva volume and oxytocin measurement, oxytocin level could be measured in 93 of 100 samples (93.0%) with a saliva volume of 2.0 ml or more, in 35 of 44 samples (79.5%) with a saliva volume between 1.5 ml and 1.9 ml, and in 3 of 11 samples (27.3%) with a saliva volume between 1.0 ml and 1.4 ml.

Discussion

Primary Outcome: Changes in Oxytocin Level

This study showed that salivary oxytocin level significantly increased after using the foot bath infused with the clary sage and lavender essential oils. A similar trend showing an increase in salivary oxytocin level after using the foot bath was shown with the jasmine essential oil, although a significant difference was not observed. Oxytocin level change before and after using the foot bath showed a higher volume and rate of salivary oxytocin after using the foot bath with the clary sage and lavender essential oils (12.5 pg/ml and 114.1%, respectively) and with the jasmine essential oil (4.8 pg/ml and 104.9%) than the foot bath with no essential oils (- 3.3 pg/ml and 105.4%).

Notably, some studies have shown a significant increase in the oxytocin level using nonmedical methods (Grewen, Girdler, Amico, & Light, 2005; Holt-Lunstad, Birmingham, & Light, 2008; Morhenn, Beavin, & Zak, 2012; Rapaport, Schettler, & Bresee, 2012; Tsuji et al., 2015). However, studies showing an immediate and significant increase in oxytocin level after one intervention session remain scarce. Holt-Lunstad et al. (2008), Papaport et al. (2012), and Tsuji et al. (2015) found significant effects after a long period of intervention from four weeks to three months by a warm touch of a partner or massage. Only Grewen et al. (2005) and Morhenn et al. (2012) reported a significant increase in oxytocin level after one session involving a warm contact with a partner for ten minutes in 38 women (plasma oxytocin level was measured by radioimmunoassay) and Swedish massage for 15 minutes in 65 healthy young adults (plasma oxytocin level was measured by enzyme immunoassay). The oxytocin change rate was 117.0% after the Swedish massage. This change rate was similar to the present finding with the use of the foot bath with clary sage and lavender essential oils.

Breast stimulation which has a significant effect on delivery within 72 hours (Kavanagh et al., 2005) was also reported to increase the plasma oxytocin level as measured by radioimmunoassay (Amico & Finley, 1986; Christensson et al., 1989). The

oxytocin change rates were not described in these previous studies, and these rates were calculated in the present study. Amico et al. (1986) reported an increase in the oxytocin level in 18 of 19 women during their third trimester of pregnancy, and the change rate was estimated as 166.7% calculated from the means before and after breast stimulation. Christensson et al. (1989) reported an increase in uterine contraction in nine of ten women between 39 and 40 gestation weeks, and their estimated mean oxytocin change rate calculated from individual data was 145.3%. The oxytocin change rate induced by the foot bath with the clary sage and lavender essential oils in the present study was lower than this previously reported rate. However, it cannot be concluded that the present lower oxytocin change rate is less effective for labor induction. This is because the amounts of increase in the volume and rate of oxytocin level that are needed for labor induction by nonmedical methods have not yet been fully clarified.

The oxytocin and cortisol change volumes were larger in the women who liked the scent in the clary sage and lavender group. These changes were also observed in the women who disliked the scent. The oxytocin and cortisol changes had a similar direction despite the difference of perception. These findings suggest that the effects of the foot bath diluted with the clary sage and lavender essential oils were not affected by the perception of the scent by the women.

Altogether, the present findings showing that the oxytocin level was increased after using the foot bath with the clary sage and lavender essential oils incrementally add knowledge into developing methods for increasing oxytocin level in nonmedical settings. Foot baths with the clary sage and lavender essential oils are worth further examining particularly with regard to their effects on increasing oxytocin level in aid of labor induction.

Secondary Outcomes

This study showed that the cortisol level was significantly decreased by all the foot baths. Differences in the cortisol change volume among the foot baths were not observed. These findings suggest that the intervention had effects on physiological marker.

Studies examining the effects of jasmine essential oil and foot bath on changes in the cortisol level remain scarce. For clary sage essential oil, its scent has been reported to decrease the plasma cortisol level in 22 women in their 50s (K. B. Lee et al., 2014). The scent of lavender essential oil has also been reported to decrease the salivary cortisol level in 22 healthy young adults (Atsumi & Tonosaki, 2007). However, a bath without any essential oil has also been observed to decrease salivary cortisol level in 12 healthy men. Altogether these previous findings showed similarity to the present findings. The present study showed that a foot bath can be used for stress reduction whether or not it contains any essential oils.

Acute stress suppresses the release of oxytocin (Buckley, 2015; Lawrence et al., 1992; Leng et al., 1988; Ueda et al., 1994). As described earlier, aromatherapy was shown to decrease the cortisol level. Accordingly, it was supposed that a decrease in the cortisol level would lead to an increase in the oxytocin level. However, such a relation was not found in the present study. Clary sage essential oil contains sclareol which is expected to have estrogen-like effects (Tisserand & Young, 2013). Estrogen in turn can increase the release of oxytocin (Uvnas-Moberg & Petersson, 2005). Therefore, the increase in the oxytocin level with the use of clary sage and lavender essential oils in the foot bath may follow this mechanism route.

Regarding subjective uterine contraction, the frequency was unchanged in most of the women in each group. There are three possible reasons for this. First is the small number of samples which prevented the detection of increased frequency. Second is the not so large oxytocin change such that subjective uterine contraction could not be induced immediately. Third is the subjective examination of uterine contraction. In future studies, monitoring of objective uterine contraction must be considered.

Feasibility of Intervention for Participants

Acceptability of intervention. More than 90% of the subjects rated the burden of the intervention as moderate or light. The decreased salivary cortisol level after using the foot baths also indicate that stress was not induced by the intervention among the

participants. This confirms the acceptability of the intervention.

Practicality of intervention. All the interventions were conducted in accordance with the study protocol. Negative effects considered to be caused by the intervention were not observed in the women and their babies.

Regarding salivary oxytocin level measurement, 83.1% of the specimens could be measured. This rate depended on the saliva samples with a volume of more than 2.0 ml in which oxytocin level could be measured in 93.0%. However, the obtained rate of 83.1% showed no significant improvement from the rate of 81.8% reported in a recent preliminary study (Horiuchi et al., 2016). Nevertheless, the protocol was improved in terms of drinking water ten minutes before each saliva collection and the routine of carrying out three saliva drooling trials. To improve the measurement rate of oxytocin level, obtaining saliva samples with a volume of 2.0 ml or more is considered vital. This entails a fourth saliva drooling trial in more women. However, a fourth trial is inevitably related to a higher burden of saliva collection. Therefore, it is better to firstly improve the method of oxytocin level measurement than carrying out a fourth saliva pooling trial. To measure oxytocin level with a higher accuracy in salivary samples with a volume of less than 2.0 ml, optimized measurement methods should be used. One of these methods is performing an oxytocin extraction step in the measurement process. Grewen, Davenport, & Light et al. (2010) were able to optimally measure oxytocin level in 90.0% of 1.0 ml saliva samples from pregnant or breastfeeding women by performing an extraction step in duplicate assays. Other methods of oxytocin level measurement in addition to this oxytocin extraction step need to be further evaluated in future studies.

Limitations and Future Study

The main limitation of this study is related to the large variance of oxytocin change volume. This may have resulted in the absence of significant differences between the use of the foot bath with clary sage and lavender essential oils and the use of the foot bath with no essential oil. Two causes were considered to underlie the large variance of oxytocin change volume.

The first possible cause is the method of oxytocin assay. The present study used ELISA without an extraction step based on Carter's (2007) method for oxytocin level measurement. Carter's method can be performed more easily than the method with an extraction step and it has been used in many studies. However, some researchers have criticized the validity of Carter's method (McCullough, Churchland, & Mendez, 2013; Szeto et al., 2011) for excluding an extraction step. The level measured without an extraction step was suggested to be interfered by any other unknown substances because the measured level without an extraction step had two or three digits and a larger variance than the measured level with an extraction step which had one or two digits.

The second possible cause is any event or interpersonal differences. There are scarce studies regarding the cause of a large variance of oxytocin change volume. The present study could not find any differences in the characteristics between those who had and those who had no large oxytocin change volumes. Each subject had two oxytocin change volumes along with the study protocol, and the other oxytocin change volumes were not very large in the subjects who had large oxytocin change volume. Therefore, any event which happens occasionally might cause a large oxytocin change volume. Notably, there are few studies which have shown interpersonal longitudinal oxytocin level changes. There is always a possibility that the large variance might be due to interpersonal differences.

As for other limitations, delivery outcomes could not be evaluated simply by one of the interventions because of the study design.

In future studies, these limitations must be addressed by taking important steps. *First*, the precision and accuracy of an oxytocin assay with an extraction step should be examined and considered. *Second*, any event that may affect oxytocin change volume or interpersonal differences should be clarified and managed appropriately to control the study setting. *Third*, a simple study design should be used to examine delivery outcomes.

Conclusion

This study confirmed an increase in the oxytocin level in pregnant women after using a foot bath with the clary sage and lavender essential oils with a limited efficacy. There was, however, no significant difference in the oxytocin level between the foot baths with the clary sage and lavender essential oils and with no essential oil. The feasibility of the intervention was confirmed in terms of acceptability and practicality for the participants. In future studies, the precision and accuracy of oxytocin measurement and evaluation need to be improved.