# CLINICAL RESEARCH

# Meditation for Preterm Birth Prevention: A Randomized Controlled Trial in Udonthani, Thailand

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## ABSTRACT

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| **Accepted** | 24 August 2011 |
| **Introduction** | Preterm birth represents a major obstetric complication. This study aimed to assess the efficacy of a meditation programme in the prevention of preterm birth. |
| **Methods** | This study was a randomized controlled trial without blinding. The study was performed at Udonthani Hospital in Northeast Thailand. A total of 199 eligible participants were randomly assigned to a five-step mindfulness meditation programme (n=84) or a control group (n=115). The control group received routine prenatal care. The meditation and control group subjects did not differ on a wide variety of sociodemographic characteristics, or in terms obstetric history and prior meditation experience. The data were analyzed on an intention-to-treat basis after delivery, using less than 37 weeks as the criterion for a preterm birth. Other outcome variables included a subjective measure of symptoms of stress. |
| **Results** | The preterm birth rate for the meditation group was significantly less than that for the control group (6.0% vs. 15.7%, p=0. 037). The stress scores reported by the meditation group markedly decreased over time (p<0.001), while the control group scores showed no change (p=0.375). |
| **Conclusions** | The results confirm and strengthen the findings of past research indicating that participation in a meditation programme can reduce symptoms of stress. Meditation appears to be a promising technique for reducing the incidence of preterm birth. Recommendations are made for future research in this area. |
| **Keywords** | meditation programme - preterm birth – prevention - randomized controlled trial |

## INTRODUCTION

Preterm birth is defined as birth occurring before 37 completed weeks of gestation, or fewer than 259 days since the first day of the woman's last menstrual period. Preterm birth still represents a major obstetric complication, affecting between 5 and 10 percent of pregnancies, resulting in a variety of disorders and potential hazards to the child's development. The major cause of preterm birth is spontaneous preterm labor. The early diagnosis, mechanism, and management of preterm labor remain unresolved issues in obstetrics. Preterm labor often leads to hospitalization and tocolytic therapy in an attempt to stop preterm birth. The cost of such preventive measures is very high, their results remain controversial, their safety has been seriously questioned, and they may have harmful psychological consequences[1-4].

In Thailand, only a few population studies on preterm birth are available, mainly due to difficulties in obtaining information on gestational age. However, preterm labor can be indirectly determined from the incidence of low birth weight (LBW). The rates of LBW are relatively stable in Thailand, ranging from 8.4% to 9.9%.

The etiology of preterm birth is unknown. Empirical reports linking maternal psychosocial stress and preterm birth were published in the late 1970s[2, 3]. Since then, numerous reports have highlighted the role of stressful life events, anxiety, nervousness and depression as significant mediators of preterm labor[1, 5-7].

Stress may increase the likelihood of preterm birth by increasing corticotrophin-releasing hormone (CRH), a neuropeptide synthesized primarily in the paraventricular nucleus of the hypothalamus[4, 8].

During pregnancy, CRH is also synthesized by the placenta and membranes and increases exponentially in the final weeks before a full-term delivery. As CRH rises with the advancing pregnancy, there is a fall in concentrations of CRH-binding protein which leads to an increase in the levels of CRH available for the body to use. CRH release leads to increased adrenocorticotropin hormone and increased glucocorticoids, which in turn up-regulate CRH in the placenta and stimulate prostaglandin production and labor[4, 8].

CRH was found to be present at higher levels in women, who went on to deliver preterm, than in women, who had normal, full-term pregnancies. This finding supports the link between stress and preterm delivery[4, 8-11].

Several attempts have been made to reduce stress in pregnant women. Methods of promoting relaxation to self-regulate arousal and reduce stress, including various forms of meditation, make up one category of behavioral intervention of demonstrated utility across a spectrum of healthcare concerns. Derived from what were originally and primarily religious or spiritual practices, meditation has been adapted for secular purposes and is believed to bestow on its practitioners the subjective benefits of personal transcendence, equanimity, and tranquility in addition to purported health benefits[4, 8, 11].

There has been a resurgence of interest in more integrative stress reduction techniques, which attempt to address not only a person's mental and physical illness, but also their interpersonal, emotional, and spiritual needs. Integrative stress reduction techniques, such as mindfulness meditation, have been increasingly reported to be effective interventions for reducing stress symptoms in various patient populations[12, 13].

There are several forms of meditation. Mindfulness meditation, rooted in Buddhist Vipassana (translated as 'insight') meditation, encourages the cultivation of an intentional, non-reactive, non-judgmental, moment-to-moment, detached awareness and the observation of the continually changing field of perception and its contents. This form of meditation has been evaluated in a number of clinical settings[13].

Several studies found that, when delivered to a variety of adult populations, mindfulness-based interventions can reduce the impact of stress, improve psychological well-being and increase positive affect, alleviate anxiety and depression, prevent relapse or recurrence of major depressive disorder and substance abuse, and improve immune function[14-21].

In one randomized clinical trial of pregnant women found that Yoga practices, which included special physical postures and exercises, controlled breathing and meditation, improved birth weight, decreases preterm labor, and decreased isolated intrauterine growth retardation (IUGR) without any statistically significant adverse effects[22].

A mindfulness-based consciousness transformation programme was developed for Thai people by Krisanaprakornkit et al.[23] and was designed to teach patients with psychiatric disorders and other people how to live more peaceful, healthy, and adaptive lives. The programme is a clinical group intervention, which is patient-centered, experiential, and educational. The core of the programme involves intensive training in mindfulness meditation and its application to daily living and coping with stress. If mindfulness meditation can help pregnant women cope with stress more efficiently, make their thoughts more calm and peaceful, and help them learn to relax, while building their self-esteem and self-confidence, then it is possible that the resultant stress reduction will prevent preterm labor and ultimately decrease preterm birth rates. The aim of the present study was therefore to test the efficacy

of the mindfulness-based consciousness transformation in the prevention of preterm births.

## METHODS

This study is an unblinded randomized controlled trial and was conducted during May 2008 to May 2009 at the Antenatal Clinic of Udonthani Hospital, a tertiary medical center in Thailand. The research was approved by the Khon Kaen University Ethics Committee for Human Research (International Review Board Number IRB00001189; Reference No. HE501210).

### Participants and Random Assignment

A total of 330 pregnant women were approached by the first author, and deemed eligible to participate in the study if they met all the various criteria. The _inclusion criteria_ were: 1) singleton gestation, 2) between 18 and 35 years of ages, 3) irrespective of parity, 4) willing to participate in a weekly group meeting, and 5) between 12 to 20 weeks gestation. The last menstrual period and the earliest ultrasound assessment were used to date the pregnancy. The _exclusion criteria_ were: 1) had obstetric or medical risks, 2) had major fetal anomalies, and 3) did not plan to deliver at the study site. All eligible pregnant women were invited to sign a consent form after receiving detailed information about the study, and 131 refused to participate. The remainder (n=199) were randomly assigned either to the meditation intervention (n=84) or to a control group (n=115). The control group received routine prenatal care.

### Measures

Socio-demographics and medical history questionnaire

These questionnaires were completed by the participants before randomization and provided information about age, education, marital status, monthly family income, occupation, hours at work per day, height, BMI before pregnancy, smoke during pregnancy, passive smoking during pregnancy, alcohol and drug use during pregnancy, parity, inter-pregnancy interval, gravidity, previous stillbirth, previous abortions, previous preterm birth, pregnancy intent, and history of meditation experience.

Outcome variables

Gestational age (less than 37 weeks vs. 37 weeks or more), APGAR scores (1, 5 and 10 minute) and birth weight were recorded at the time of delivery, Symptoms of stress and anxiety were assessed at three points: (1) prior to starting the meditation programme or routine antenatal care, (2) five weeks later, and (3) two weeks after delivery. The instrument used for this was the Thai Self-Analysis Stress Test[24]. This is a 20-item scale in which respondents rate the frequency of experiencing various symptoms of stress over the past two months on a four-point Likert scale ranging from 0 (never) to 3 (always). The test is scored by summing all the item ratings to produce a maximum score of 60 with higher scores indicating higher levels of stress. The internal consistency of the test appears to be satisfactory with a reported Cronbach's alpha of 0.86[24].

### Intervention

The participants attended the meditation intervention programme in small groups (group size 8-10 participants). The programme was adapted from the Consciousness Transformations Programme for Stress Management originally developed by Krisanaprakornkit et al.[23] at the Faculty of Medicine, Khon Kaen University, but differed from the original programme in length. The duration of the programme in this study was shortened due to pregnancy time constrictions and difficulty of traveling to hospital. The adapted meditation programme consisted of two phases.

Phase 1 involved five steps over five weeks: (week 1) breathing meditation, recognition and awareness, (week 2) body sensation awareness, (week 3) recognition, acceptance, and contemplation of emotions, (week 4) awareness of thoughts and conditioning, and (week 5) absolute self-acceptance, loving-kindness. For each of the steps participants were required to attend a weekly session lasting approximately two hours with the meditation instructor (first author), and every participant was given a 56-page booklet containing information pertinent to each of the weekly sessions.

In addition to the weekly sessions, participants were also expected to engage in daily practice at home. This consisted of mini-meditations (each of about two to three minutes duration) at 8 a.m., 10 a.m., 12 a.m., 2 p.m., and 4 p.m. and longer meditations of about 30 minutes at 8 p.m. or before sleeping and at 5 a.m. or after waking up.

In phase 2 participants were required to continue with the schedule of daily practice at home until delivery, and they were contacted by telephone once a week by the meditation instructor to discuss progress.

### Statistical Analysis

The results were analyzed after delivery on an intention-to-treat basis using the last-observation-carried-forward method for missing data. The analyses involved the use of descriptive statistics, chi-square and Fisher's exact tests, independent t-tests, and a repeated measures analysis of variance. The computations were performed with STATA Version 10, and all tests were two-sided with statistical significance defined as $p < 0.05$.

## RESULTS

The flow of participants through the various stages of this study is summarized in Figure 1. The meditation and controls were not significantly different on any of the socio-demographic or history variables. These results are summarized in Table 1.
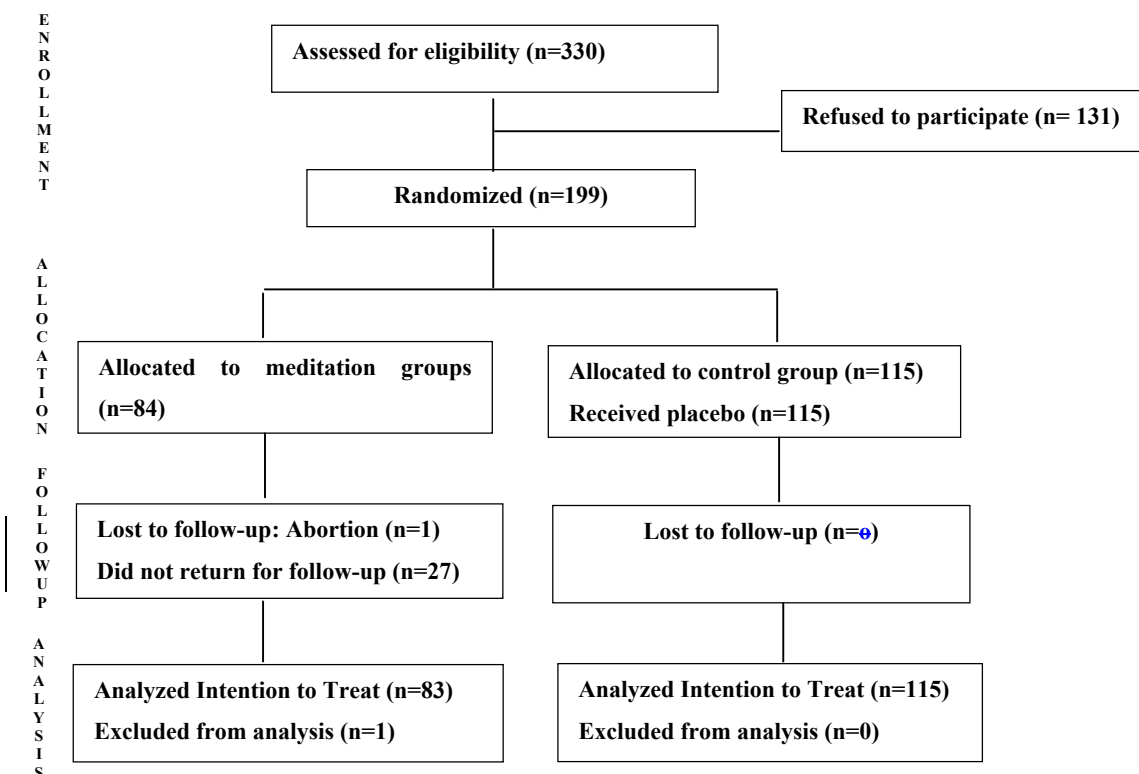


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L            │  Assessed for eligibility (n=330)   │
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M                                │          ┌──────────────────────────────────┐
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| **Allocated to meditation groups (n=84)** | **Allocated to control group (n=115)** <br> **Received placebo (n=115)** |
| **Lost to follow-up: Abortion (n=1)** <br> **Did not return for follow-up (n=27)** | **Lost to follow-up (n=0)** |
| **Analyzed Intention to Treat (n=83)** <br> **Excluded from analysis (n=1)** | **Analyzed Intention to Treat (n=115)** <br> **Excluded from analysis (n=0)** |

(Left margin labels: ENROLLMENT, ALLOCATION, FOLLOWUP, ANALYSIS)

**Figure 1** CONSORT Flowchart for participant progress though the stages of the randomized trial.

**Table 1** Comparison of baseline characteristics in meditation and control groups.

| Variables | Meditation group (n=83) | Control group (n=115) | p-value |
|---|---|---|---|
| **Maternal age (years)** | 24.7±4.5 | 25.2±5.0 | 0.43 |
| **Maternal education (years)** | 9.7±2.7 | 9.4±3.1 | 0.48 |
| **Monthly family income (USD)** | | | |
| No | 3 (3.6%) | 2 (1.7%) | 0.40 |
| <145 | 11 (13.3%) | 24 (20.9%) | |
| 145-300 | 44 (53.0%) | 53 (46.1%) | |
| >300 | 25 (30.1%) | 36 (31.3%) | |
| **Maternal occupation** | | | |
| Housewife | 56 (67.5%) | 70 (60.9%) | 0.54 |
| General worker | 20 (24.1%) | 36 (31.3%) | |
| Officer | 7 (8.4%) | 9 (7.8%) | |
| **Hours at work per day** | | | |
| ≤8 | 58 (69.9%) | 66 (57.4%) | 0.07 |
| >8 | 25 (30.1%) | 49 (42.6%) | |
| **Maternal height (cm)** | 156.9±6.8 | 156.9±5.9 | 0.96 |
| **BMI before pregnancy (kg/m$^2$)** | | | |
| <20 (Under weight) | 30 (36.2%) | 37 (32.2%) | 0.12 |
| 20-24.9 (Normal weight) | 42 (50.6%) | 47 (40.9%) | |
| 25-29.9 (Over weight) | 9 (10.8%) | 22 (19.1%) | |
| ≥30 (Obesity) | 2 (2.4%) | 9 (7.8%) | |

| | | | |
|---|---|---|---|
| **Passive smoker during pregnancy** | | | |
| No | 41 (49.4%) | 66 (57.4%) | 0.27 |
| Yes | 42 (50.6%) | 49 (42.6%) | |
| | | | |
| **Parity** | 39 (47.0%) | 45 (39.1%) | 0.27 |
| Nulliparous | 44 (53.0%) | 70 (60.9%) | |
| Multiparous | | | |
| **Interpregnancy interval** | 2.86±3.3 | 3.50±3.9 | 0.22 |
| **Gravidity** | | | |
| Primigravidarum | 33 (39.8%) | 40 (34.8%) | 0.47 |
| Multigravidarum | 50 (60.2%) | 75 (65.2%) | |
| **Previous abortion** | | | |
| No | 66 (79.5%) | 96 (83.5%) | 0.48 |
| Yes | 17 (20.5%) | 19 (16.5%) | |
| **Previous preterm birth** | | | |
| No | 77 (92.8%) | 107 (93.0%) | 0.94 |
| Yes | 6 (7.2%) | 8 (7.0%) | |
| **Pregnancy intent** | | | |
| No | 15 (18.1%) | 33 (28.7%) | 0.085 |
| Yes | 68 (81.9%) | 82 (71.3%) | |
| **History of meditation** | | | |
| No | 55 (66.3%) | 90 (78.3%) | 0.06 |
| Yes | 28 (33.7%) | 25 (21.7%) | |

In terms of outcome variables (Table 2), the proportion of preterm births in the mothers assigned to the meditation programme (6.0%) was significantly (p=0.037) less than that for the controls (15.7%). However, there were no significant differences between the meditation and control groups in terms of type of delivery, the three APGAR scores, birth weight or the three scores on the Thai Self-Analysis Stress Test. The birth weights were higher in the meditation groups than in the controls, but the difference narrowly failed to reach significance.

**Table 2** Outcomes in meditation and control groups.

| Variables | Meditation group (n = 83) | Control group (n = 115) | Mean difference (95% CI) | p-value |
|---|---|---|---|---|
| Gestational age | | | | 0.037* |
| < 37 weeks | 5 (6.0%) | 18 (15.7%) | 2.89 | |
| ≥ 37 weeks | 78 (94.0%) | 97 (84.3%) | (1.03 to 8.15) | |
| 1 minute APGAR scores | 8.92±0.42 | 8.89±0.41 | -0.03 (-0.15 to 0.09) | 0.632 |
| 5 minute APGAR scores | 9.94±0.33 | 9.90±0.38 | -0.04 (-0.15 to 0.06) | 0.396 |
| 10 minute APGAR scores | 9.95±0.31 | 9.91±0.36 | -0.04 (-0.14 to 0.06) | 0.432 |
| Birth weight (gm) | 3121.93±374.75 | 2,997.74±478.94 | -124.19 (-248.71 to 0.33) | 0.051 |
| Thai Self-Analysis Stress Test 1st Assessment | 12.93±7.00 | 12.43±6.62 | -0.49 (-2.42 to 1.43) | 0.614 |
| Thai Self-Analysis Stress Test 2nd Assessment | 10.94±6.12 | 11.81±6.38 | 0.87 (-0.91 to 2.65) | 0.337 |
| Thai Self-Analysis Stress Test 3rd Assessment | 11.16±6.81 | 11.70±7.15 | 0.51 (-1.48 to 2.51) | 0.594 |

When scores on the Thai Self-Analysis Stress Test were examined over the three points in time from baseline to follow-up (Table 3), significant changes in scores over time were found for those assigned to the meditation programme ($p<0.001$), but no significant changes were found for the controls ($p=0.375$). The results of a further analysis of the changes in stress scores (Table 4) showed that for those assigned to the mediation programme there were significant decreases in scores between Time 1 (baseline) and Time 2 (five weeks after beginning meditation training) ($p=0.003$) and between Time 1 and Time 3 (follow up, two weeks after delivery) ($p=0.021$), but no significant difference was found between Time 2 and Time 3.

**Table 3** Comparison of changes in scores in meditation and control groups on the Thai Self-Analysis Stress Test.

| Measure | 1st Assessment | | 2nd Assessment | | 3rd Assessment | | Repeated measures ANOVA | |
|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | Mean | SD | F | p-value |
| Meditation group (n=83) | 12.93 | 7.00 | 10.94 | 6.12 | 11.16 | 6.81 | 7.458 | 0.001* |
| Control group (n=115) | 12.43 | 6.62 | 11.81 | 6.38 | 11.70 | 7.15 | 0.949 | 0.375 |

**Table 4** Pair-wise comparison of stress scores on the Thai Self-Analysis Stress Test in meditation and control groups.

| Group | Time | Mean Difference | Standard Error (SE) | 95% Confidence Interval for Difference | p-value |
|---|---|---|---|---|---|
| **Meditation** | 1 and 2 | 1.98 | 0.59 | 0.55 to 3.43 | 0.003* |
| **(n=83)** | 1 and 3 | 1.74 | 0.63 | 0.21 to 3.29 | 0.021* |
| | 2 and 3 | -0.24 | 0.46 | -1.37 to 0.89 | 1.000 |
| **Control** | 1 and 2 | 0.63 | 0.53 | -0.65 to 1.90 | 0.707 |
| **(n=115)** | 1 and 3 | 0.74 | 0.69 | -0.95 to 2.43 | 0.868 |
| | 2 and 3 | 0.11 | 0.49 | -1.09 to 1.31 | 1.000 |

**Note:** Time 1 = first assessment (baseline); Time 2 = second assessment (after five weeks); Time 3 = third assessment (two weeks after delivery)

## DISCUSSION

The current study was performed in Thailand on a population of pregnant women similar in ethnic background. There have been no previous randomized trials specifically designed to prevent preterm birth in this population. Our study provides further information and understanding about the prevention of preterm birth.

The results confirm and strengthen the findings of past research indicating that participation in a meditation programme can reduce symptoms of stress. The stress appraisal of an event, such as the transition to parenthood, prompts the coping process and produces affective responses. These responses are associated with physiological reactivity and are linked to patterns

of chronic physiological arousal, which are in turn related to poor health.

A number of researchers have written extensively about the physical benefits of meditation. Research on mindfulness supports the idea that cultivating greater attention[25], awareness and acceptance through meditation practice is associated with lower levels of psychological distress, including less anxiety, depression, anger, and worry[15, 25, 26]. Mindfulness may also promote better health. For instance, some of the studies to date have found that people trained in mindfulness show a better ability to quit smoking[27], and reduce alcohol and illicit substance use[28].

There is increasing scientific evidence to support the therapeutic effect of mindfulness meditation training in pain management[29, 30], and also in enhancing the body's immune system[31]. Study on the long-term mental benefit of meditation show that meditation reduces stress and increases reported levels of happiness, self-confidence, and general effectiveness[13, 15, 26, 31]. Mind-body interventions have shown promise for reducing stress and improving mood in many populations, including pregnant women. An integrative approach to stress reduction, which infuses mind-body practices into developmentally-appropriate behavioral interventions administered during the perinatal period, may help promote healthier pregnancies and better birth outcomes. This approach may also encourage qualities beneficial for promoting healthy parenting and, as a result, enhance the social-emotional development and physical health of children.

Pregnant mothers have found that mindfulness training is beneficial for their emotional well-being, for the quality of their relationship with their baby and partner, and for promoting a sense of calm[32, 33].

We conducted the current study to adapt an existing mindfulness meditation programme for pregnant women and to test the hypothesis that participation in this intervention would reduce stress and improve mood during pregnancy by increasing the ability to regulate negative affect. We further hypothesized that this would result in a reduced likelihood of a preterm birth. Both these hypotheses were supported by our findings.

Although fundamentally a normal, healthy process for most women, pregnancy itself has inherently challenging elements, which may be perceived as stressful. It is a time of rapid physical and emotional change with an irreducible element of uncertainty regarding the outcome of the birth process for the mother, the baby, the family, and life beyond. Depending on the physical and psychological health of a particular woman and the unfolding normalcy of a particular pregnancy and fetus, the pregnant state is more or less stressful. The same can be said of the birth and postpartum experience. To have inner resources to navigate the physiological changes of pregnancy and birth, and emotional tools to navigate the developmental change in the life course may have benefit for both expectant parents and their care providers.

We found that our meditation programme was feasible when women attended sessions with their infants, it might have been better to provide the programme during both the prenatal and postnatal periods to sustain its beneficial effects and improve the possibility of it having a favorable impact on mother-infant interactions. Future studies should evaluate the relationship between preconception stress and pregnancy stress, the role of prenatal stress and fetal programming, and effects of meditation on maternal indices of pregnancy outcomes. Based on this study, we advocate randomized control trials for the definitive demonstration of the beneficial effects of meditation on pregnancy outcomes.

## Study limitations and implications

The study described in this paper was the first randomized controlled trial of a meditation programme conducted in Thailand with pregnant women. It provided health professionals with a research-based and empirically tested protocol for providing an apparently effective meditation intervention for reducing the preterm birth rate. However, the sample was small when compared with the preterm birth population in Thailand, and participants were recruited from only one geographical region, namely Udonthani in Northeast Thailand. The results, although promising, may not generalize to populations of other nations or ethnic groups, to participants living in different socio-economic situations or to women with health problems. A further clinical trial needs a larger sample with subjects drawn from different areas of Thailand and encompassing women living in a wider variety of socioeconomic circumstances and with a range of concurrent health problems. Secondly, the recruitment of participants to the study by health care workers may have led to the enrolment of a biased sample of especially well-motivated participants. Furthermore, participants in meditation studies often refuse to be randomized to the study group. People who do not want to undergo meditation training will drop out immediately. Even worse, those participants, who were randomized to the control group and initially wanted to participate in the meditation programme, may meditate assiduously on their own. Thirdly, the study involved only a short follow-up period of two weeks following completion of the intervention and delivery. There is therefore very limited information about the effects of the intervention on maternal stress. Fourthly, the remarkably good results may be due to the ethnic background of our participants. Thai people seem

especially likely to respond positively to performance expectations. The intervention participants may have perceived themselves as having received more attention than their control counterparts and felt more obligated to perform. This may, in turn, have influenced their responses to the intervention and especially their scores on the subjective measure of stress. A related point is that some participants in a group intervention may have given socially desirable responses to the outcome measures, because they did not want to be perceived as difficult clients. All of this suggests the need for a placebo-control group with features as credible to participants as the meditation programme.

## CONCLUSIONS

This research represents the first attempt in Thailand to explore the efficacy of meditation for the reduction of preterm births. To our knowledge, it is the first attempt anywhere to investigate the benefits of mindfulness in this regard using a randomly controlled design. The findings indicate that mindfulness meditation training reduces prenatal stress and, possibly as a consequence of this, the preterm birth rate. Further studies are needed to demonstrate whether these findings can be generalized to other populations in Thailand and elsewhere.

## ACKNOWLEDGEMENT

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