

Acupuncture To Treat Nausea and Vomiting in Early Pregnancy: A Randomized Controlled Trial

Caroline Smith, PhD, MSc, BSc, Lic Ac, Caroline Crowther, MD, FRCOG, FRANZCOG, CMFM, and Justin Beilby, MBBS, FRACGP, MPH

ABSTRACT: Background: Nausea and vomiting in early pregnancy are troublesome symptoms for some women. We undertook a single blind randomized controlled trial to determine whether acupuncture reduced nausea, dry retching, and vomiting, and improved the health status of women in pregnancy. **Methods:** The trial was undertaken at a maternity teaching hospital in Adelaide, Australia, where 593 women less than 14 weeks' pregnant with symptoms of nausea or vomiting were randomized into 4 groups: traditional acupuncture, pericardium 6 (p6) acupuncture, sham acupuncture, or no acupuncture (control). Treatment was administered weekly for 4 weeks. The primary outcomes were nausea, dry retching, vomiting, and health status. Comparisons were made between groups over 4 consecutive weeks. **Results:** Women receiving traditional acupuncture reported less nausea ($p < 0.01$) throughout the trial and less dry retching ($p < 0.01$) from the second week compared with women in the no acupuncture control group. Women who received p6 acupuncture ($p < 0.05$) reported less nausea from the second week of the trial, and less dry retching ($p < 0.001$) from the third week compared with women in the no acupuncture control group. Women in the sham acupuncture group ($p < 0.01$) reported less nausea and dry retching ($p < 0.001$) from the third week compared with women in the no acupuncture group. No differences in vomiting were found among the groups at any time. **Conclusion:** Acupuncture is an effective treatment for women who experience nausea and dry retching in early pregnancy. A time-related placebo effect was found for some women. (BIRTH 29:1 March 2002)

Nausea and vomiting are common troublesome symptoms experienced by some women in the first trimester of pregnancy, and affect 50 to 80 percent of all pregnant women (1–3). These symptoms can have

a profound impact on women's general sense of well-being and day-to-day lives (4). Women often seek help from professionals and try numerous strategies to alleviate their symptoms, few of which suppress symptoms to their satisfaction.

In recent years the use of complementary medicine has become popular in many Western countries (5). Application of complementary therapies is more common among women of reproductive age, with almost one-half (49%) reporting use (6). It is possible that a significant proportion of women try these therapies during pregnancy. Interest in the antiemetic effect from using acupressure or acupuncture point pericardium 6 (p6) is increasing. Stimulation of point p6 has been proposed to have a specific effect on the upper digestive tract. The Cochrane systematic review of interventions to treat nausea and vomiting includes studies of acupressure point p6. The current Cochrane review contains no trials of acupuncture, and it concluded that acupressure may be helpful (7).

Caroline Smith is a postdoctoral research officer and Caroline Crowther is Associate Professor in the Department of Obstetrics & Gynaecology, Adelaide University; Justin Beilby is a Senior Lecturer in the Department of General Practice, Adelaide University, Adelaide, Australia.

The study was financially supported by the Department of Obstetrics and Gynaecology, Adelaide University, and the Women's and Children's Hospital Research Foundation, Adelaide, Australia. Needles were donated by Cathy Herbal Products, Sydney.

Address correspondence to Dr. Caroline Smith, PhD, MSc, BSc, Lic Ac, Department of Obstetrics & Gynaecology, Adelaide University, Women's & Children's Hospital, 72 King William Road, North Adelaide, SA 5006, Australia.

However, the quality of the three acupuncture trials (8–10) included in the meta-analysis was not high. Data from a fourth trial contained data not in a form that could be included in the meta-analysis (11). The methodology of this trial was good; however, the trial found no beneficial effect from acupressure.

Case reports describe the effectiveness of traditional acupuncture for treating nausea and vomiting when applied in a traditional Chinese medicine framework (12,13). Such application may give improved results compared with use of the single antiemetic point p6.

One randomized controlled trial from the United Kingdom evaluated the use of acupuncture in early pregnancy (14). This trial, which randomized 55 women to receive acupuncture or sham acupuncture, reported no evidence that acupuncture was more effective than sham acupuncture to reduce nausea.

In the absence of high-quality randomized trials, skepticism remains with respect to the benefits of acupuncture to treat nausea and vomiting in early pregnancy. We undertook a single blind randomized controlled trial of acupuncture to determine whether acupuncture (both traditional acupuncture and p6 acupuncture) was better than sham (placebo) acupuncture or no acupuncture in reducing the frequency, duration, amount, and distress from nausea, dry retching, and vomiting, and improved the health status of women in early pregnancy.

Methods

Participants

Women were eligible for the trial if they were less than 14 weeks' pregnant with symptoms of nausea or vomiting. Women were excluded if they had clinical signs of dehydration, or if there was reason to suspect their symptoms were not due to pregnancy, for example, a recent episode of gastroenteritis. The previous use of antiemetics or any other comfort measure did not preclude entry into the trial. Women were able to continue with any existing measures during the trial, and a record of use was recorded at the start, during, and at the end of the trial.

Women were recruited to the trial at the Women's and Children's Hospital in Adelaide, Australia, between January 1997 and July 1999. The trial was promoted within the community using the media, and referrals were made by general practitioners and other hospital health practitioners. The study was approved by the hospital's research and ethics committee, and all women gave written informed consent before enrolling in the trial.

Procedure

Demographic information, history of nausea and vomiting, health status assessment, and a traditional Chinese medicine diagnosis were obtained from each woman before randomization. Women were randomly assigned to a study group controlled by a telephone randomization service at Adelaide University, Clinical Trials Unit. The randomization schedule used balanced variable blocks, and was prepared by a researcher not involved in the trial. Women were allocated into 1 of 4 study groups: traditional acupuncture, p6 acupuncture, sham acupuncture, or no acupuncture (control).

Acupuncture diagnosis and treatment were performed by the study investigator (CS) using a standardized protocol guiding the interaction with women, including diagnosis, acupuncture and sham acupuncture treatment, and needling techniques. The diagnosis included a tongue diagnosis (examination of color, shape, and coating) and an assessment of the quality of the pulse and a history of symptoms. Participation in the trial was for 4 weeks to provide information on the effectiveness of acupuncture and the nature of spontaneous remission of symptoms.

Women allocated to the 2 acupuncture groups and sham acupuncture group were advised to attend for treatment twice during the first week and then to attend weekly. The decision on treatment frequency was pragmatic, given the constraints of feeling unwell, traveling to the hospital, making provision for child care, and scheduling appointments around women's work commitments.

Serin (Japan) 0.2 × 30 mm needles were inserted using a guide tube. A maximum of 6 needles were used during a treatment session. Needles were stimulated after insertion by rotating them anticlockwise through 45 to 90 degrees, or by rotating clockwise through 180 degrees; further stimulation was minimal. Needles were inserted to a depth 0.5 to 1 cun (cun is a proportional unit of measurement relative to the subject), with *de qi*, a sensation associated with correct needling. Needles were retained over a 20-minute period.

Women allocated into the traditional acupuncture group were administered a treatment based on their traditional Chinese medicine diagnosis. A classically trained acupuncturist may treat individuals with nausea and vomiting in very different ways, according to the diagnosis made. Treatment was guided by the approach described by Maciocia (15). Treatment used acupuncture points on the mid and upper abdomen, located on the energy pathways (meridians) in this area; for example, stomach meridian on

acupuncture points stomach 19, 20, 21; kidney meridian, kidney points 21 and 20; and conception vessel points 14, 13, 12, 11, or 10. Acupuncture points were also selected to treat the traditional Chinese medicine diagnosis: *liver qi stagnation* (conception vessel 12 on the mid abdomen, p6 on the medial surface of forearm, gallbladder 34 below the knee, conception vessel 13 mid abdomen, kidney 21 upper abdomen, stomach 34 superior to the patella, stomach 36 below the knee); *stomach or spleen qi deficiency* (stomach 36, p6, conception vessel 12); *stomach heat* (stomach 44 on top of the foot, conception vessel 11 mid abdomen, stomach 34, stomach 21 mid abdomen, p6 and pericardium 3 on the forearm); *phlegm* (stomach 40 lateral to tibia, spleen 9 medial surface of lower leg, stomach 19 mid abdomen, bladder 20 [on the back] kidney 21); *heart qi deficiency* (heart 5 forearm, p6, stomach 36, conception vessel 14 mid abdomen); or *heart fire* (p6, conception vessel 14, bladder 15 on the back).

Women allocated to the p6 study group received this single point only. This point is located on the anterior surface of the forearm. Women allocated to the sham acupuncture group received acupuncture needles inserted into an area close to, but not on, acupuncture points. Specific points were located on the upper limb between the pericardium and lung meridian at 6 cun, a point on the ankle area between the stomach and gallbladder meridians, a point on the foot between the third and fourth metatarsals, and a point on the lower leg between gallbladder and stomach channel 3 cun below stomach 36.

A no acupuncture control group was included to control for the effect of spontaneous remission of symptoms. To reduce disappointment when women were allocated to this group, a standardized information sheet was made available about advice on diet, lifestyle, and the use of vitamin B6 during the 4-week study period. Women in this group received a weekly 10-minute telephone call from the study investigator to assess their general sense of well-being and to encourage compliance with participating in the trial.

The primary outcomes were experience from nausea, dry retching, and vomiting at days 7, 14, 21, and 26 measured by the Rhodes Index of Nausea and Vomiting Form 2 (16), a 5-point Likert scale. Women's health status was measured by the MOS 36 Short Form Health Survey (SF36) (17). The SF36 is a general outcome measure consisting of an 8 multi-item scale measuring physical functioning, physical role functioning, emotional role functioning, social functioning, bodily pain, mental health, vitality, general health perceptions, and a rating of their health compared with a year ago. The responses to each SF36 domain are summed to provide 8 scores,

and transformed into a multi-item scale between 0 and 100, with 0 indicating poor health and 100 suggesting good health. An assessment of health status was made at days 1, 14, and 28.

Statistical Analysis

Sufficient women were randomized to provide reliable evidence of the effect of acupuncture on nausea and vomiting. It was an entry requirement that women experienced nausea at trial entry. A trial of 114 women would have an 80% power to detect a treatment effect of a 35 percent reduction in the number of women reporting nausea from 99 to 64 percent ($p=0.05$, beta 0.2). The prevalence of vomiting is reported at 50 percent (18), and to detect a treatment effect of a 35 percent (10,11) reduction in vomiting from 50 to 32.5 percent ($p=0.05$, beta 0.2), a sample size of 592 women was required. The sample size allowed for a 10 percent loss to follow-up (pregnancy loss or withdrawal from the trial).

To detect changes in health status, sample size calculations were made for each SF36 domain, and were based on an improvement of 25 percent for each score. Sample size varied from 29 women per group for the mental health domain to 143 women for the vitality domain. At the time of designing the trial, no data were available to guide a sample size calculation to demonstrate a difference between acupuncture and a placebo effect.

Women recorded their own primary outcome scores, and data were entered by an experienced data entry operator blinded to study group allocation. Analysis was by intention to treat using SPSS 9.0 for Windows (19). Each symptom of nausea, dry retching, and vomiting was summed into a subscale describing women's experience (based on a recording of the frequency or amount, duration, and distress). Differences in the mean experience subscales were examined using analysis of variance (ANOVA) for normally distributed data, and the Kruskal-Wallis 1-way ANOVA by ranks for data not normally distributed. Mean SF36 domain scores were explored using ANOVA for repeated measurements between traditional acupuncture and p6 acupuncture and the two control groups. Multiple comparisons among study groups were adjusted using the Tukey means comparisons. The chi-square test was used for binary variables. A p value of less than 0.05 was used to demonstrate differences in primary outcomes. Relative risks and 95% confidence intervals (CI) and the number needed to treat with 95% confidence intervals were reported for the primary outcomes. The number needed to treat is based on the number

of people who will benefit within a certain period of time who otherwise would not benefit (it is calculated as $1/\text{control event rate} - \text{experimental event rate}$).

Results

A total of 593 women were randomized to the trial. Figure 1 summarizes recruitment and return of data forms. We received data from 534 (90%) of women at the end of the first week of the trial, and data from 443 (75%) at the end of the fourth week of the trial (Fig. 1). No differences in baseline characteristics, including demographic characteristics (Table 1), nausea, dry retching, and vomiting experience scores (Table 2) and SF36 domain scores (Table 3), were found among study groups. A lower response rate to the SF36 was obtained from women in the no acupuncture control group at baseline ($p < 0.05$) compared with other groups; however, no differences were found in SF36 scores among groups at baseline (Table 3).

Effect of Acupuncture on Nausea

Women’s experience of nausea differed among study groups at the end of the first week in the trial ($p < 0.05$) (Table 2). Women receiving traditional

acupuncture reported less frequent and shorter periods of nausea, which caused less distress, compared with women in the no acupuncture group ($p < 0.05$). Women in the traditional acupuncture group (13, 9%) were more likely to be free from nausea compared with women in the no acupuncture control group (4, 3%) (relative risk 0.93, 95% CI 0.88–0.99) at the end of their first week of treatment. Fifteen women (95% CI 8–166) receiving traditional acupuncture would need to be treated for 1 woman to report complete relief from nausea at the end of the first week of the trial.

During the second week of the trial, women who received traditional acupuncture ($p < 0.001$), and p6 acupuncture ($p < 0.05$) reported lower nausea scores compared with women in the no acupuncture control group. This improvement in nausea continued for women receiving traditional acupuncture ($p < 0.001$) and p6 acupuncture ($p < 0.01$) into the third week compared with women in the no acupuncture control group. From the third week, women in the sham acupuncture group ($p < 0.01$) also reported lower nausea scores compared with women in the no acupuncture control group. In the final week of the study, improvements in nausea continued for women in the traditional acupuncture ($p < 0.001$), p6 acupuncture

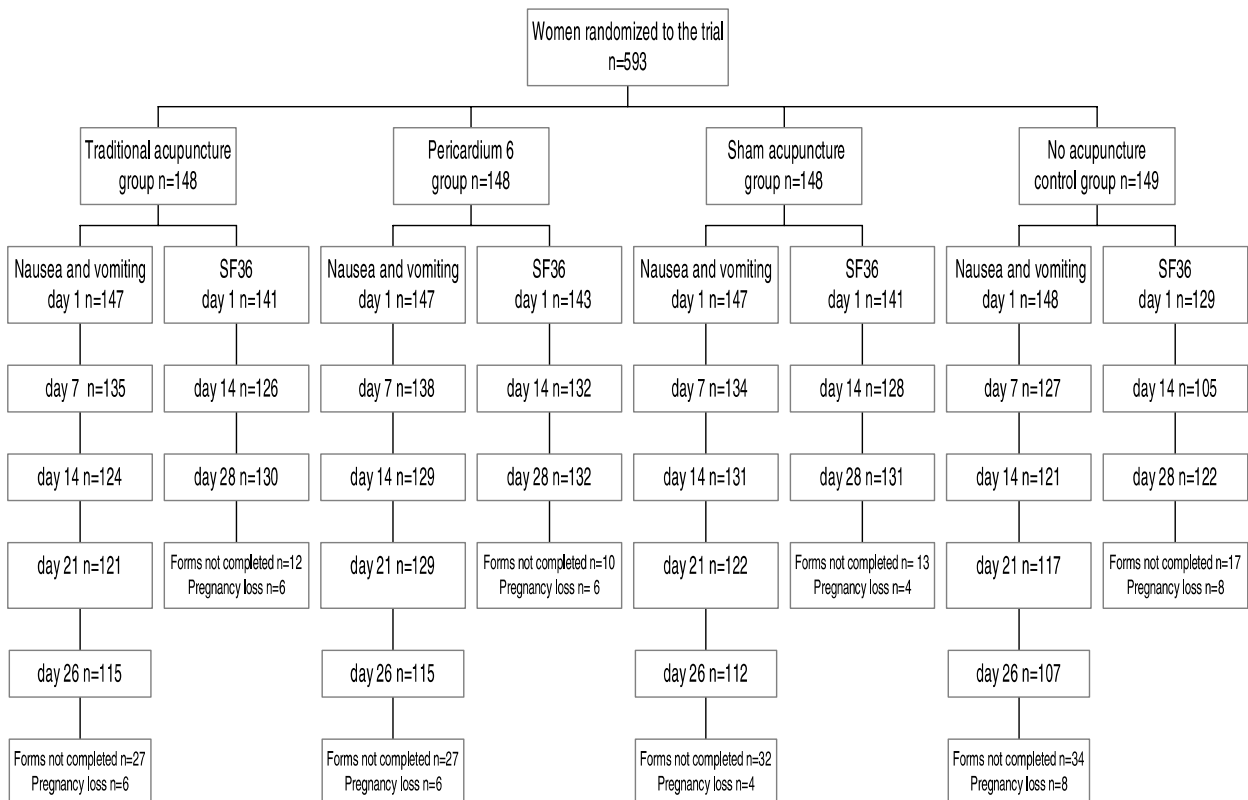


Fig. 1. Trial profile: Return of nausea and vomiting and SF36 questionnaires at days 1, 7, 14, 21, and 26.

Table 1. Comparison of Women by Treatment Group

<i>Characteristics</i>	<i>Traditional Acupuncture (n = 148)</i>	<i>P6 Acupuncture (n = 148)</i>	<i>Sham Acupuncture (n = 148)</i>	<i>No Acupuncture Control (n = 149)</i>
Age (yr) (mean ± SD)	29.5 (4.7)	30.1 (4.8)	29.6 (4.6)	30.0 (5.2)
BMI (kg.m ²) (mean ± SD)	24.7 (4.6)	24.0 (4.4)	24.2 (4.6)	23.7 (4.4)
Gestational age (wk) (median and range)	8.3 (5–13)	8.3 (4–14)	8.0 (4–13)	8.4 (5–14)
Parity (≥ 20 wk) (No. and %)				
0	59 (40)	51 (35)	51 (34)	50 (34)
1 or more	89 (60)	97 (65)	97 (66)	99 (67)
Smoked at trial entry (No. and %)	7 (4)	7 (4)	4 (12)	5 (3)
Previous use of acupuncture* (No. and %)	28 (19)	29 (20)	17 (12)	32 (21)
Private patient† (No. and %)	34 (24)	47 (32)	39 (26)	52 (35)
Employed outside the home (No. and %)	97 (66)	95 (64)	102 (69)	105 (70)

*Not significant ($p > 0.12$).

†Not significant ($p > 0.13$).

BMI = body mass index.

Table 2. Experience of Nausea, Dry Retching and Vomiting by Treatment Group

<i>Experience of Symptoms</i>	<i>Traditional Acupuncture (n = 148)</i>	<i>P6 Acupuncture (n = 148)</i>	<i>Sham Acupuncture (n = 148)</i>	<i>No Acupuncture Control (n = 149)</i>	<i>p</i>
Nausea (range 0–12) (mean ± SD)					
Baseline	8.3 (2.5)	8.2 (2.6)	8.6 (2.5)	8.4 (2.3)	ns
Day 7	5.0 (3.0)	5.4 (3.3)	5.7 (2.8)	6.1 (2.9)	0.05
Day 14	4.6 (3.1)	4.8 (3.6)	5.0 (3.0)	6.0 (3.1)	0.01
Day 21	3.8 (3.1)	4.3 (3.3)	4.4 (2.7)	5.8 (3.1)	0.001
Day 26	3.4 (3.0)	4.0 (3.3)	3.7 (2.8)	5.0 (3.0)	0.001
Dry retching (range 0–8) (mean ± SD)					
Baseline	2.5 (1.9)	2.5 (2.2)	2.4 (2.1)	2.6 (1.8)	ns
Day 7	1.3 (1.4)	1.6 (1.7)	1.5 (1.8)	1.7 (1.7)	ns
Day 14	0.9 (1.3)	1.3 (1.5)	1.3 (1.7)	1.6 (1.7)	0.01
Day 21	0.9 (1.4)	0.9 (1.3)	0.9 (1.3)	1.6 (1.7)	0.001
Day 26	0.8 (1.4)	0.9 (1.3)	0.9 (1.4)	1.6 (1.7)	0.001
Vomiting (range 0–12) (mean ± SD)					
Baseline	2.3 (2.7)	2.1 (2.8)	2.4 (2.8)	2.1 (2.7)	ns
Day 7	1.4 (2.0)	1.2 (2.0)	1.5 (2.2)	1.5 (2.1)	ns
Day 14	1.1 (1.8)	1.3 (2.2)	1.4 (2.1)	1.6 (2.2)	ns
Day 21	0.9 (1.6)	1.2 (2.1)	1.0 (1.7)	1.1 (2.1)	ns
Day 26	0.9 (1.5)	0.9 (1.8)	1.0 (1.6)	1.4 (2.0)	ns

Table 3. Change in Mean SF36 Domain Over Trial Period

SF36 Domain	Traditional Acupuncture (n = 148)	P6 Acupuncture (n = 148)	Sham Acupuncture (n = 148)	No Acupuncture Control (n = 149)	p
Social function					
Day	48.3 (28.6)	45.1 (30.3)	42.9 (28.5)	45.3 (28.5)	0.01*
Day 14	51.9 (29.0)	50.7 (28.4)	48.5 (28.1)	45.1 (28.7)	0.01†
Day 28	54.0 (27.1)	51.4 (32.0)	48.9 (28.0)	37.8 (22.5)	0.001‡
Vitality					
Day 1	23.4 (18.0)	21.6 (17.7)	22.6 (18.3)	24.1 (15.4)	ns*
Day 14	30.0 (19.7)	27.4 (23.1)	25.8 (18.0)	22.8 (15.1)	0.001†
Day 28	31.9 (20.4)	27.0 (18.9)	27.0 (19.0)	26.0 (17.0)	0.05‡
Physical function					
Day 1	63.7 (24.0)	58.7 (26.5)	63.1 (25.0)	63.0 (25.2)	ns*
Day 14	68.5 (26.1)	63.3 (23.1)	66.0 (24.5)	59.4 (27.3)	0.01†
Day 28	68.0 (21.0)	64.0 (23.5)	66.0 (21.0)	63.3 (25.0)	0.05‡
Physical role function					
Day 1	12.6 (26.4)	11.7 (27.0)	11.4 (26.8)	9.3 (23.0)	ns*
Day 14	7.3 (14.6)	6.3 (13.5)	6.0 (11.9)	4.1 (10.4)	0.001†
Day 28	8.7 (15.5)	6.6 (14.1)	5.0 (11.7)	11.9 (25.0)	0.05‡
Bodily pain					
Day 1	60.0 (24.5)	60.7 (26.7)	59.0 (26.1)	64.3 (24.7)	ns*
Day 14	65.9 (22.5)	66.5 (24.7)	60.0 (24.5)	65.9 (23.0)	0.001†
Day 28	65.2 (22.8)	68.0 (23.0)	65.0 (25.1)	66.6 (22.7)	ns‡
Mental health					
Day 1	59.2 (18.0)	56.6 (18.4)	57.3 (18.1)	58.0 (19.7)	0.05*
Day 14	66.2 (20.2)	60.0 (20.1)	62.0 (17.7)	58.2 (19.9)	0.001†
Day 28	64.7 (18.8)	62.0 (19.1)	64.6 (17.7)	58.6 (20.0)	0.01‡
Emotional role function					
Day 1	54.9 (45.5)	47.4 (44.5)	54.0 (46.6)	52.7 (45.4)	ns*
Day 14	61.4 (44.7)	49.1 (45.8)	59.7 (45.8)	54.7 (45.3)	0.001†
Day 28	68.7 (43.0)	57.2 (52.0)	60.7 (44.4)	53.2 (45.0)	ns‡
General health perception					
Day 1	67.9 (19.1)	64.1 (21.0)	67.7 (20.9)	67.7 (7.5)	ns*
Day 14	65.3 (19.4)	62.6 (19.0)	64.7 (19.4)	63.4 (18.7)	0.001†
Day 28	67.0 (20.6)	63.8 (20.3)	66.1 (19.5)	65.3 (21.6)	ns‡

Figures are mean and standard deviation (SD).

*Group: differences in SF36 scores across groups.

†Time observation of the SF 36 score at days 1, 14, 28.

‡Differences in SF 36 scores across all groups over time.

($p < 0.05$), and sham acupuncture ($p < 0.01$) groups compared with women in the no acupuncture group.

Effect of Acupuncture on Dry Retching

Differences in women's experience of dry retching were first demonstrated among study groups by the end of the second week of the trial ($p < 0.01$) (Table 2). Women receiving traditional acupuncture experienced fewer periods and less distress from dry retching compared with women in the no acupuncture control group ($p < 0.01$). During the third week of the trial, differences in women's experience from dry retching were evident again among study groups ($p < 0.001$).

Women in the traditional acupuncture ($p < 0.001$), p6 acupuncture ($p < 0.01$), and sham acupuncture

($p < 0.001$) groups all experienced fewer periods of, and less distress from, dry retching compared with women in the no acupuncture control group. Sixty eight (56%) women in the traditional acupuncture group were free from dry retching compared with 46 (39%) women in the no acupuncture control group by the end of the third week (relative risk 0.72, 95% CI 0.56–0.93, $p < 0.01$; number needed to treat = 6, 95% CI 3–22). In the sham acupuncture group, 72 (59%) women were free from dry retching compared with 46 (39%) women in the no acupuncture control group (relative risk 0.68, 95% CI 0.52–0.87, $p < 0.001$; number needed to treat = 6, 95% CI 3–13). These improvements continued to the end of the trial. In the p6 acupuncture group, no difference occurred in women free from

dry retching compared with women in the no acupuncture control group.

Effect of Acupuncture on Vomiting

No differences in women's experience from vomiting were found among study groups at any stage in the trial (Table 2).

Effect of Acupuncture on Women's Health Status

At the end of the trial, evidence was seen of a study group effect on the social function ($p < 0.01$) and mental health ($p < 0.05$) SF36 domains. A time effect was seen on all SF36 domains and a study group time effect on five SF36 domains. Women in the traditional acupuncture group showed an improved health status on five SF36 domains over time (Table 3) compared with improvements on two domains for women receiving p6 or sham acupuncture, and an improvement on one domain for women in the no acupuncture control group.

Women receiving traditional acupuncture reported higher vitality ($p < 0.05$), social function ($p < 0.001$), physical function ($p < 0.01$), mental health ($p < 0.01$), and emotional role function ($p < 0.05$) scores compared with women in the no acupuncture control group at the end of the trial. Women in the traditional acupuncture group also reported higher vitality scores compared with women in the p6 acupuncture ($p < 0.05$) and sham acupuncture ($p < 0.05$) groups. Improvements were also reported midway through the study on the vitality ($p < 0.01$), physical function ($p < 0.001$), and mental health ($p < 0.01$) domains for women receiving traditional acupuncture compared with women receiving no acupuncture. An improvement was also observed midway through the study for women receiving traditional acupuncture compared with women receiving p6 acupuncture ($p < 0.05$) for the emotional role functioning domain. At the end of the study, women receiving p6 acupuncture and sham acupuncture reported improved scores on the social function domain ($p < 0.001$) and mental health domain ($p < 0.01$) compared with women in the no acupuncture control group. Women in the latter group reported higher physical role function scores compared with women in the p6 ($p < 0.05$) and sham acupuncture ($p < 0.001$) groups. No other differences among study groups and SF36 domains were found.

Discussion and Conclusions

Women who took part in this trial reported a range of health benefits. Traditional acupuncture was

shown to be an effective treatment for women who experience nausea and dry retching in early pregnancy. Pericardium 6 acupuncture reduced nausea and dry retching, although the therapeutic response occurred a week later compared with women receiving traditional acupuncture, and a time-related placebo effect occurred for some women receiving sham acupuncture.

Findings from our trial cannot easily be compared with those of other trials that used acupressure for nausea and vomiting in early pregnancy. Acupuncture and acupressure are different treatment modalities and cannot be compared directly. One trial that compared acupuncture with sham acupuncture among women presenting with nausea showed that acupuncture had no effect (14). The data collection tools used in our trial and the trial by Knight et al (14) were different, and the data were not comparable. Our sample size was sufficiently large to detect changes in nausea, vomiting, and health status, and it included a control group to take account of spontaneous remission of nausea and vomiting, which may explain the difference in results.

Acupuncture failed to reduce vomiting at any time—a lack of beneficial treatment response that some might consider to be disappointing. The observation of a time difference in the efficacy of traditional acupuncture to reduce nausea and dry retching suggests that the frequency of treatments might need to be greater than two treatments in the first week followed by weekly treatments. In trials of acupressure, bands are worn continuously. Two trials of acupressure described its beneficial effect on reducing vomiting during pregnancy (8,9). However, two trials failed to show any therapeutic effect on vomiting (9,11). The optimum frequency of acupuncture treatments for vomiting has not been documented in the literature, but it is possible that increasing the frequency of treatment may reduce the frequency and severity of vomiting. Daily treatments of acupuncture have been recommended for women with severe vomiting (15). Future research may consider evaluating the impact of daily acupuncture treatments to assess its efficacy with reducing vomiting.

No published research has measured the effect of acupuncture for nausea and vomiting on women's health status during early pregnancy. Our results showed that women's health status improved with time. In addition, there was strong evidence of a treatment effect over time that differed between study groups. This time effect was greater for women receiving traditional acupuncture with improvements on five SF36 domains, improvements on two domains for p6 acupuncture and sham acupuncture, and improvements on one domain for

no acupuncture. These results again demonstrate the efficacy of traditional acupuncture in improving women's physical and emotional well-being compared with women receiving no acupuncture, and improving women's vitality compared with the use of p6 and sham acupuncture. Evidence of a placebo effect was demonstrated with sham acupuncture, which improved women's emotional well-being and social function.

The use of traditional acupuncture as a treatment for nausea and vomiting provided an opportunity to practice acupuncture in a traditional Chinese medicine framework compared with the use of a single acupuncture point p6. The study findings support the validity of the traditional Chinese medicine approach compared with the sole use of p6 acupuncture point.

The existence of a placebo effect in health care is well established, multifaceted, and composed of several nonspecific effects. Recent work by Hrobjartsson and Gotzsche found little evidence that placebo effects had any powerful clinical influence (20). We suggest that the placebo effect demonstrated in our trial may have been affected by women finding the trial a source of support. Moreover, the weekly treatments provided an opportunity for the development of a relationship between study participants and the practitioner. It would not be unreasonable to assume that these nonspecific effects would become greater with time and contribute toward a placebo effect. No external observation of the treatment administered between study participants and practitioner was performed, and practitioner bias cannot be excluded. However, women were asked to comment on the "credibility of the treatment" to assess the effectiveness of blinding. Women were blinded to their group allocation, and these findings will be reported elsewhere. With increasing evidence of a time-related placebo effect (14), further research is warranted to understand the placebo effect and to recognize its contributions to an individual's sense of well-being.

Evidence from trials using pharmacological and nonpharmacological methods to treat nausea and vomiting in early pregnancy suggest that many effective interventions reduce the severity of symptoms rather than relieve symptoms completely (21).

Nausea and vomiting in early pregnancy remains a significant public health problem that results in physiological, emotional, social, and economic consequences on women, their families, and society. For women looking for relief from these symptoms and desiring an overall improvement in well-being, the use of acupuncture in early pregnancy will reduce or resolve symptoms earlier than simply waiting for

them to improve spontaneously. Based on these findings, acupuncture can be considered an effective, nonpharmacological treatment option for women who experience nausea and dry retching in early pregnancy.

Acknowledgments

We thank the women for participating in this trial; the general practitioners, obstetricians, and midwives at the Women's and Children's Hospital for referring women to the trial; and the staff in the Maternal and Perinatal Clinical Trials Unit.

References

1. Tierson FD, Olsen CC, Hook EB. Nausea and vomiting of pregnancy: An association with pregnancy outcome. *Am J Obstet Gynecol* 1986;155:1017-1022.
2. Soules MR, Hughes CL, Garcia JA, et al. Nausea and vomiting of pregnancy: Role of human chorionic gonadotropin and 17 hydroxyprogesterone. *Obstet Gynecol* 1980; 55:696-700.
3. Lacroix R, Eason E, Melzack R. Nausea and vomiting during pregnancy: A prospective study of its frequency, intensity and pattern of change. *Am J Obstet Gynecol* 2000; 182:931-937.
4. Smith C, Crowther C, Beilby J, Dandeaux J. The impact of nausea and vomiting on women: A burden of early pregnancy. *Aust N Z J Obstet Gynaecol* 2000;4:397-401.
5. MacLennan A, Wilson DH, Taylor AW. Prevalence and cost of alternative medicine in Australia. *Lancet* 1996;347: 569-573.
6. Eisenberg DM, Kessler RC, Foster C, et al. Unconventional medicine in the United States: Prevalence, costs and patterns of use. *N Engl J Med* 1993;328:246-352.
7. Jewell MD, Young G. Interventions for nausea and vomiting in early pregnancy. In: *The Cochrane Library*. Issue 2. Oxford: Update Software, 2001.
8. Dundee JW, Sourial FB, Ghaly RG, Bell PF. P6 acupressure reduces morning sickness. *J R Soc Med* 1988;81:456-457.
9. Belluomini J, Litt RC, Lee KA, Katz M. Acupressure for nausea and vomiting in pregnancy: A randomized blinded study. *Obstet Gynecol* 1994;84:245-248.
10. De Aloysio D, Penacchioni P. Morning sickness control in early pregnancy by Neiguan point acupressure. *Obstet Gynecol* 1992;80:852-854.
11. O'Brien B, Relyea MJ, Taerum T. Efficacy of P6 acupressure in the treatment of nausea and vomiting during pregnancy. *Am J Obstet Gynecol* 1996;174:708-715.
12. Rongjun Z. 39 Cases of morning sickness treated with acupuncture. *J Trad Chin Med* 1987;7:25-26.
13. Changxin Z. Acupuncture treatment of morning sickness. *J Trad Chin Med* 1988;8:228-229.
14. Knight B, Mudge C, Openshaw S, White A. Effect of acupuncture on nausea of pregnancy: A randomized, controlled trial. *Obstet Gynecol* 2001;9:184-188.
15. Maciocia G. *Obstetrics and Gynecology in Chinese Medicine*. New York: Churchill Livingstone, 1998:451-463.
16. Rhodes VA, Watson PM, Johnson MH. Development of a reliable and valid measure for nausea and vomiting. *Cancer Nurs* 1984;7:33-41.

17. Ware JE, Sherbourne CD. The MOS 36 Item Short Form Health Survey (SF-36): Conceptual framework and item selection. *Med Care* 1992;30:473–483.
18. Klebanoff MA, Koslowe PA, Kaslow R, Rhoads GG. Epidemiology of vomiting in early pregnancy. *Obstet Gynecol* 1985;66:612–616.
19. SPSS, Inc. *Statistical Package for the Social Sciences [Version 10.0]*. Chicago: 1988.
20. Hrobjartsson A, Gotzsche PC. Is the placebo powerless? An analysis of clinical trials comparing placebo with no treatment. *N Engl J Med* 2001;344:1594–1602.
21. O'Brien B, Zhou Q. Variables related to nausea and vomiting during pregnancy. *Birth* 1995;22:93–100.