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Review

Complementary and alternative medicine (CAM) in reproductive-age women: a review of randomized controlled trials

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Abstract

Purpose: Complementary and alternative medicine (CAM) therapies are widely used in the general population. This paper reviews randomized controlled trials of CAM therapies for obstetrical and gynecologic conditions and presents therapies that are likely to be used by women of reproductive age and by pregnant women.

Data Sources: Sources included English-language papers in MEDLINE 1966–2002 and AMED (1985–2000) and the authors' extensive holdings.

Study Selection: Randomized controlled clinical trials of CAM therapies for obstetric and gynecologic conditions.

Data Extraction: Clinical information was extracted from the articles and summarized in tabular form or in the text.

Data Synthesis: Ninety-three trials were identified, 45 of which were for pregnancy-related conditions, 33 of which were for premenstrual syndrome, and 13 of which were for dysmenorrhea. Data support the use of acupressure for nausea of pregnancy and calcium for PMS. Preliminary studies indicate a role for further research on Vitamin B6 or ginger for nausea and vomiting of pregnancy; calcium, magnesium, Vitamin B6, or chaste-tree berry extract for PMS; and a low-fat diet, exercise, or fish oil supplementation for dysmenorrhea.

Conclusions: Limited evidence supports the efficacy of some CAM therapies. Exposure of women of reproductive age to these therapies can be expected.

Keywords: Complementary and alternative medicine; Reproductive-age women; Herbal medicine; Dietary supplements; Acupuncture; Mind–body therapies; Pregnancy; Premenstrual syndrome; Review

1. Introduction

Women are frequent users of complementary and alternative medicine (CAM) in many countries [1–5] including the US, where women use CAM more than do men (48.9% versus 37.8%) [6]. Pharmacologically active CAM treatments may be used by women at risk for pregnancy, or women who are trying to become pregnant. The current stage of knowledge is still inadequate to sufficiently inform clinicians, researchers, and the public about either benefits or potential risks. The following is a review of prospective, randomized controlled clinical trials of CAM therapies relevant to obstetrics and gynecology. Our purpose in this review is to identify exposures that can be expected in women of reproductive age. Possible reproductive effects of such exposures will be the subject of a future review.

Sources for this review included MEDLINE, (1966–2002), the Alternative and Complementary Database (AMED) of the British Library (1985–2000), and the authors' own extensive files. Databases were searched under the terms women's health, pregnancy, labor, postpartum, morning sickness, infertility, premenstrual syndrome, endometriosis, and fibroids; combined with alternative medicine, herbal medicine, herbs, traditional medicine, Traditional Chinese Medicine (TCM), Ayurveda, Ayurvedic medicine, naturopathy, chiropractic, osteopathy, massage, shiatsu, reiki, relaxation therapy, yoga, homeopathy, aromatherapy, and therapeutic touch. Most studies are summarized in the tables; conditions with two or fewer studies are summarized only in the text.

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2. Menstrual cycle

2.1. Premenstrual syndrome (PMS)

PMS is a spectrum of physical, emotional, and behavioral symptoms of unclear etiology. Women experiment extensively with self-medication in search of relief. Thirty-three randomized controlled trials have been performed on herbs, vitamins, minerals, manual therapies, diet and exercise, and mind–body approaches (Table 1) [7–38].

Vitamin B6 (pyridoxine) has been the subject of the most trials, and the majority of these trials show some benefit. Pyridoxine deficiency is one hypothesized cause of PMS, and in Europe, B6 supplementation is an accepted treatment. Most studies assessed an overall symptom score; studies of individual symptoms might be more instructive. Vitamin B6 doses ranged from 50 to 600 mg per day; no dose-response effects were seen. Many of the studies were not adequate methodologically, nor was there sufficient consistency in dose or outcome measures among them to enable specific clinical recommendations. Additional studies are warranted to establish optimal dosing. Vitamin B6 is a benign therapy, at least in doses $\leq$100 mg daily; sensory neuropathy has been reported in patients taking large doses of B6 (usually >2000 mg daily) [39].

Reducing dietary fat or increasing exercise also may benefit PMS; none of the studies reported here had placebo comparison groups, but these harmless interventions would be expected to have other health benefits as well. Disturbances in calcium or magnesium regulation may contribute to PMS; intracellular (but not plasma) magnesium levels have been found to be lower in women with PMS [40]. Some evidence suggests benefit for both calcium [21,22] and magnesium [23–25] as benign, effective treatments.

Chaste-tree berry (*Vitex agnus-castus*) extract may also be promising. Two studies, each using a different dose and different outcome measures, reported a benefit of *Vitex* over the comparison (placebo or Vitamin B6), but only relative to baseline [29,30]. In two of three small trials, evening primrose (*Oenethera biennis*) oil does not appear to be effective [26,27]. Trials of manual therapies (reflexology, chiropractic, massage) [35–37] and mind–body treatments [38] are few and have been hampered by small sample sizes, high dropout rates, and lack of placebo controls; but perhaps should be explored further based on initial beneficial outcomes.

2.2. Dysmenorrhea

Thirteen, mostly small, studies have examined CAM treatments for menstrual pain (Table 2) [32,41–52]. Further research is indicated on the promising effects of diet and exercise on dysmenorrhea. Specific dietary components may be important; oily fish, for example, are rich in the polyunsaturated fatty acids eicosapentaenoic acid and docosahexaenoic acid, which may modulate prostaglandin production.

Exercise (not necessarily aerobic) also appears to help menstrual pain; women who exercise appear to have fewer menstrual symptoms than women who do not exercise [47–50]. These studies were not blinded. Although an appropriate placebo control for exercise trials is difficult to imagine, treatment-controlled trials are a viable option, and are warranted given the encouraging outcomes reported previously.

Only one randomized controlled study of acupuncture was located [51]. Some benefit was demonstrated, and additional studies should be initiated.

3. Infertility

There is little evidence that CAM therapies are effective for female infertility. Only two studies were identified. Cognitive behavioral therapy or a support group intervention as adjuncts to conventional treatment were compared to routine care in a year-long, randomized, single-blind controlled trial in 184 infertile women, all receiving fertility drugs [53]. Intervention groups met weekly for two hours. Cognitive-behavioral treatment included relaxation techniques, cognitive restructuring, methods for emotional expression, and nutrition and exercise information. The support group talked about personal issues, relationships, and self-esteem, among other subjects. Dropout rates were high: 9/56 (16%) in the cognitive behavioral group, 16/65 (25%) in the support group, and 38/63 (60%) among controls. Among study completers, 55% in the cognitive-behavioral group, 54% in the support group, and 20% of controls had viable pregnancies. Although time to viable pregnancy using survival analysis indicated a significantly higher viable pregnancy rate in both treatment groups compared to control, the large and unequal dropout rates render these data uninterpretable.

A randomized, double-blind, controlled trial of a homeopathic preparation of chaste tree berry *(Vitex agnus-castus)* tested placebo against 50 drops three times daily of Phyto Hypophyson L (Steirl-Pharma GmbH, Herrsching, Germany) for 3 months or three cycles in 67 women with infertility associated with amenorrhea or oligomenorrhea. There was no significant difference between groups in spontaneous menstruation, pregnancy, or take-home baby rates during the treatment or 6 months later [54]. *Vitex* may have hormonal effects: a randomized double-blind placebo-controlled trial of 52 women with luteal phase defect due to latent hyperprolactinemia found that *Vitex* extract (20 mg daily) reduced prolactin levels, normalized luteal phase length, and normalized luteal phase progesterone levels [55]. Additionally, a case of ovarian hyperstimulation was attributed to *Vitex* [56].

Table 1
CAM treatments for premenstrual syndrome

Reference	Subjects	Study design and duration	Intervention	Outcome measures	Results
Vitamins					
[7]	60 women (56 completed, 44 analyzed) with moderate-severe PMS	Randomized, double-blind, placebo controlled trial; duration: 4 months (treatment for three menstrual cycles)	Optivite-12 (including 600 mg per day B6); Optivite-6 (including 300 mg per day B6); placebo (Optivite is a multivitamin/multimineral supplement)	Luteal phase symptom score using London's 27 symptom menstrual symptom questionnaire (MSQ) (4 symptom category groups)	Optivite-12: significant reduction in every symptom category ($P < 0.004$–0.014); Optivite-6: significant reduction in 3 of 4 symptom categories ($P < 0.005$–0.013); placebo: significant reduction in 2 symptom categories ($P < 0.017$–0.022)
[8]	63 women (32 completed) with moderate-severe PMS	Randomized, double-blind, placebo-controlled crossover trial; duration: 7 cycles (3 cycles treatment, 3 cycles placebo)	Vitamin B6 (50 mg per day) vs. placebo	9 symptoms in 3 groups (emotional, somatic, menstrual), assessed by postal survey	Emotional symptoms improved significantly more in drug vs. placebo months ($P < 0.05$). There was no effect on somatic or menstrual symptoms
[9]	76 women with PMS	Randomized, double-blind, placebo-controlled trial; duration: 4 cycles	Vitamin B6 (120 mg per day) vs. placebo	47 symptom scale	No differences between groups
[10]	74 women (55 completed) with moderate-severe PMS	Randomized, double blind, placebo-controlled trial; duration: 3 cycles (1 cycle baseline, 2 cycles treatment)	Vitamin B6 (150 mg per day) vs. placebo	Moos Menstrual Distress Questionnaire (47 symptoms in 8 subgroups)	Positive effect only in 2/8 symptom subgroups (autonomic reactions and behavior change) ($P < 0.01$); no improvement in depression, anxiety, or other symptoms
[11]	175 women (119 completed) with PMS	Randomized, double-blind, placebo-controlled trial; duration: 3 months	Optivite (a multivitamin-multimineral generally containing 50 mg B6/tablet) 4 tablets per day, 1st half of cycle; 8 tablets per day, 2nd half of cycle) vs. placebo	Self assessment (worse, no better, slightly better, substantially better, cured)	Significantly more women in treatment group improved (71% of treatment group vs. 55% in placebo group "substantially better" or "cured") ($P < 0.05$)
[12]	143 women (104 completed) with PMS	Randomized, double-blind, placebo controlled trial; duration: 4 months	Optivite (a multivitamin-multimineral generally containing 50 mg B6/tablet) 2 tablets/ day first half of cycle, 4 tablets per day second half of cycle vs. placebo	Self assessment (worse, no better, slightly better, substantially better, cured)	No difference between groups (63% of treatment group and 60% of placebo group "substantially better" or "cured")
[13]	32 women with PMS	Randomized, double-blind, placebo- controlled, crossover trial; duration: 8 cycles (each phase lasted 4 cycles)	Vitamin B6 (300 mg per day) vs. placebo	14 symptom scale	Treated group significantly better than placebo for 8/14 symptoms
[14]	42 women with mastalgia	Randomized, double-blind, placebo-controlled, crossover trial; duration: 2 cycles	Vitamin B6 (Benadon) (200 mg per day) vs. placebo	Breast pain and breast tenderness on visual analogue scale Analgesic consumption	No significant difference between B6 and placebo on any measure
[15]	31 women (31 completed) with moderate-severe PMS	Randomized, double-blind, placebo controlled, crossover; duration: 3 cycles	Optivite (including 300 mg per day B6) (300 mg per day) 1 vs. placebo	PMS Symptom Questionnaire (19 symptoms) in 4 subgroups	Mean luteal phase symptom scores significantly lower for 2 of 4 PMS subgroups
[16]	617 women (434 completed) with PMS	Randomized, double-blind, placebo- controlled trial; duration: 3 cycles	Vitamin B6 (100 mg per day) vs. placebo (subjects were permitted to increase dose to 200 mg if no effect or decrease to 50 mg if side effects)	11 symptom scale	Significantly greater improvement in treated group compared with placebo for depression, irritability, tension, breast tenderness, oedema and bloating, headache, and acne
[17]	42 women (34 completed) with PMS	Randomized, placebo-controlled, crossover trial; duration: 4 cycles (each phase lasted two cycles)	Vitamin B6 (100 mg per day) vs. placebo	Global symptoms (VAS); 6 individual symptoms ranked blood magnesium	No difference between phases in global symptoms or ranking of individual symptoms; significant increase in blood magnesium in B6 group
[18]	48 women with PMS	Randomized, double-blind, placebo-controlled, crossover trial; duration: 2 months	Vitamin B6 (100 mg per day) vs. placebo	Symptom diary card (8 symptoms)	Treated group improved significantly more than placebo group ($P < 0.001$)
[19]	25 women with PMS	Randomized, placebo-controlled, double-blind crossover trial; duration 6 cycles (each phase lasted 3 cycles)	Vitamin B6 (500 mg per day) vs. placebo	19 symptom scale	Treatment improved symptoms significantly better than placebo in 21 subjects
[20]	13 women with PMS	Randomized, placebo-controlled, double-blind, multiple crossover trial; duration: 8–12 cycles	Vitamin B6 (50 mg per day for 18 days before and during menses) vs. placebo	47 symptoms	No benefit for treatment; only one patient improved significantly
[21]	46 women (41 completed)	Randomized, double-blind placebo-controlled trial; duration: 3 cycles	Vitamin E (D-alpha-tocopherol 400 IU per day) vs. placebo	Luteal phase premenstrual syndrome symptom scores (Abraham classification)	No significant difference between groups (although a positive effect is claimed by authors)
Minerals					
[22]	60 women (33 completed) with PMS	Randomized double-blind placebo-controlled crossover trial; duration: 7 months (each phase lasted 3 cycles)	Calcium carbonate (Oscal, providing 1000 mg elemental calcium per day) vs. placebo	Mean scores on a 14 symptom index during luteal phase	Total scores decreased significantly more in treated group (↓ 50%) than placebo group (↓ 20%) ($P = 0.011$)
[23]	497 (466 analyzed) women with moderate to severe PMS	Randomized, double-blind, placebo-controlled, multi-center trial; duration: 5 cycles (2 cycles baseline, 3 cycles treatment)	Calcium carbonate (two TUMS E-X tablets twice daily, providing 600 mg elemental calcium) vs. placebo	Mean 17-symptom complex scores during luteal phase PMS diary score	Scores ↓ significantly more (48%) in the calcium group than the placebo group (↓30%) ($P = 0.001$)

Table 1 (*Continued*)

Reference	Subjects	Study design and duration	Intervention	Outcome measures	Results
[24]	32 women (28 completed) with PMSl	Randomized, double-blind, placebo-controlled trial; duration: 4 cycles (2 cycles treatment or placebo, then all get 2 months treatment)	Magnesium pyrrolidone carboxylic acid (360 mg three times daily during last half of cycle × 2 months) vs. placebo. All subjects then received magnesium for additional 2 months	Changes in 6 symptom clusters (pain, inability to concentrate, behavioral changes, autonomic reactions, water retention, negative affect, arousal) and total Menstrual Distress Questionnaire (MDQ) scores	Compared to baseline, magnesium, but not placebo, significantly reduced MDQ scores ($P < 0.5$). For symptom clusters, magnesium reduced only 1/5 symptom clusters (negative affect) ($P < 0.05$). It is not stated whether or not differences between groups was significant. Additional 2 months magnesium significantly decreased scores in both groups, compared to 2-month time point ($P < 0.05$)
[24]	40 women (35 completed) with PMS	Double-blind, randomized, placebo-controlled trial; duration: 6 cycles	Sillix Donna®, 2 tablets twice daily (containing a total of magnesium 400 mg, pyridoxine 1.5 mg, Vitamin E 12 mg, folic acid 0.2 mg, iron 20 mg, copper 4 mg, *S. cerevisiae* 1 g) vs. placebo	Scores on the MOOS MDQ (differences between premenstrual and follicular phases), assessed at 2, 4, and 6 months	At all time points, treated group was significantly better than placebo group ($P < 0.02$ by analysis of variance)
[25]	54 women (38 completed ≥2 cycles) with PMS	Randomized, double-blind, placebo-controlled crossover trial; duration: 2 cycles	Magnesium oxide (200 mg per day) vs. placebo	22-symptom Menstrual diary	No significant changes in symptom score totals; treated group, compared to placebo group, improved in fluid retention symptoms ($P < 0.01$)
Herbs					
[26]	38 women with PMS	Randomized, double-blind, placebo-controlled, crossover trial; duration: 6 cycles (3 treatment cycles)	Evening primrose oil (Efamol, 8 capsules per day, 45 mg gamma linolenic acid/capsule) vs. placebo	10 PMS symptoms (4 psychological, 6 physical), menstrual pain and blood loss	No significant difference between groups
[27]	38 women with PMS (27 completed)	Randomized, double-blind, placebo controlled, crossover trial; duration: 8 cycles (4 treatment cycles)	Evening primrose oil (12 capsules Efamol per day, containing 4.32 g linoleic acid and 0.54 g gamma-linolenic acid/capsule) vs. placebo	Daily self rating of Hammarback 16 symptom scale and global scores	No significant difference between groups (both groups improved)
[28]	30 women with severe PMS	Randomized, single (possibly double)-blind, placebo controlled, crossover trial; duration: 4 cycles	Evening primrose oil (6 capsules per day Efamol 500 mg, (daily dose contained 2.16 g *cis*-linoleic acid and 0.27 g gamma linolenic acid) vs. placebo	19-symptom scale Global symptom score	Treatment reduced symptom scores significantly more than controls ($P < 0.05$); more patients (62%) improved in treatment group (62%) than in placebo group (40%)
[29]	178 women (170 completed)	Randomized, double-blind, placebo-controlled trial; duration: 3 cycles	*Vitex agnus-castus* fruit, One 20 mg tablet daily dry extract ZE440 (standardized to casticin, 60% ethanol m/m, extract ratio 6–12: 1) vs. placebo	Visual analog scale of symptoms (irritability, mood alteration, anger, headache, bloating, and breast fullness)	Compared to baseline, mean combined symptom scores ↓ and individual symptoms (except for bloating) decreased significantly more in treated group than placebo group (all P $P = 0.001$)
[30]	175 patients (105 analyzed)	Randomized, controlled multicenter trial; duration: 3 cycles	Chaste tree (*Vitex agnus-castus*) extract (Agnolyt: 3.5–4.2 mg) vs. Pyridoxine (200 mg per day on days 16–35 of menstrual cycle)	Scores on a modified Pre-Menstrual Tension Scale (PMTS) (36 symptoms)	Symptom scores were significantly reduced from baseline in both groups ($P < 0.05$). Mean reduction in PMTS scores significantly greater for *Vitex* than B6 ($P < 0.05$, 95% CI −6.43 to −0.17)
[31]	165 women (143 analyzed)	Randomized, double-blind, placebo-controlled multicenter trial; duration: 2 cycles	*Ginkgo biloba* extract (Egb 761) 80 mg twice daily from cycle day 16 to cycle day 5. Dosage could be doubled after first cycle if subject found treatment ineffective	Diary recording of congestive symptoms of breasts, abdomen, and extremities, and "neuro-psychological symptoms" (mood and headache)	Symptoms (including tender and painful breasts, mood, and headaches improved in both groups, but there was not a significant difference between groups at 2 months
Diet					
[32]	51 women (33 completed)	Randomized crossover trial; duration: 4 months (each phase lasted 2 months)	Low-fat vegetarian diet vs. regular diet plus a placebo pill	Menstrual symptom diary (a modification of MOOS)	Compared to baseline, mean duration of symptoms ↓ significantly only during intervention phase for water retention symptoms ($P < 0.01$); behavioral changes ($P < 0.05$); and concentration symptoms ($P < 0.01$)
[33]	37 women (31 completed)	Randomized, controlled trial; duration: 9 cycles (1 cycle baseline; each phase lasted 4 months)	Women were randomized to a diet with different ratios of polyunsaturated: saturated fatty acids (P:S) (either 1.0 or 0.3). Each group then ate a high-fat diet (40% fat) for four cycles, followed by a low-fat diet (20%) for four cycles	The MOOS Menstrual Distress Questionnaire (MMDQ)	P:S ratio did not affect symptoms; significant decreases in symptoms associated with water retention were seen during the low-fat phase, compared to the high-fat phase ($P = 0.01$)

Other CAM therapies					
[34]	23 women (all completed)	Randomized, controlled trial; duration: 12 weeks	Aerobic exercise vs. Strength training (1 h 3× per week)	23 item Menstrual Symptom Questionnaire	Compared to baseline, total MSQ scores significantly decreased in the aerobic group ($P < 0.05$) but not the strength exercise group
[35]	50 women (35 completed)	Randomized, controlled study; duration: 8 weeks	Ear, hand and foot reflexology, 30 min treatment once a week vs. reflexology at incorrect points	PMS scale including 19 somatic and 19 psychological symptoms	Significantly greater decrease in premenstrual symptom scores in the treated group compared to the placebo group ($P < 0.01$)
[36]	45 women (25 completed)	Randomized, placebo-controlled crossover trial; duration: 3 cycles (treatment or placebo for 1st and 3rd, no treatment for 2nd cycle)	Chiropractic spinal adjustment and soft tissue therapy vs. Sham treatment (minimal force at incorrect points) 2–3 times during the week before menses	Moos premenstrual symptom questionnaire and total daily scores from daily symptom monitoring	Mean global scores after treatment were significantly improved over baseline or sham treatment ($P < 0.01$ for both). Both groups improved significantly over baseline ($P < 0.01$)
[37]	24 women	Randomized controlled trial; duration: 5 weeks	Massage therapy (30 min twice weekly) vs. progressive muscle relaxation (twice-weekly for 30 min on own; first and last session with a therapist)	Center for Epidemiological Depression Scale, Menstrual Distress Questionnaire, State Trait Anxiety Inventory, Profile of Mood States, and visual analog scale on pain intensity. Tests administered before and after intervention on first and last day of study	Massage therapy significantly decreased scores on STAI, POMS, and VAS from pre-massage levels on first and last days (all $P < 0.05$). Compared to baseline, MDQ scores, but not CES-D, significantly improved in the massage group from the first to the last day of the study. Relaxation only decreased anxiety on the first day; no other measures were affected
[38]	107 women (46 completed)	Randomized, controlled trial; duration: 3 months	"Relaxation response" vs. two controls: a symptom-charting group and a reading group	Premenstrual Assessment form, and Daily Rating Form	All groups improved in most measures. The relaxation group improved significantly more than other groups only on 1/4 subtypes (physical symptoms) on the Premenstrual Assessment Form ($P < 0.025$)

Table 2
CAM treatments for dysmenorrhea

Reference	Subjects	Study design and duration	Intervention	Outcome measures	Results
Diet					
[32]	51 women (33 completed)	Randomized controlled crossover study; duration: 4 months (each phase lasted 2 months)	Low-fat vegetarian diet vs. regular diet plus a placebo pill	Duration of dysmenorrhea; pain intensity	Duration of dysmenorrhea significantly ↓ from baseline (days) during diet phase but not placebo phase. Differences in pain intensity between the placebo and diet phases were significant for only one of three days with pain
Dietary supplements					
[41]	100 high school students (age 16–18)	Randomized placebo-controlled trial; duration: 2 cycles	Vitamin E 500 IU per day 2 days before expected menses, until third day of menses	Severity of pain by visual analog scale	Both groups experienced significant decrease in median pain scores at 2 months, but Vitamin E was significantly better than placebo ($P = 0.02$)
[42]	100 university students (ages 18–21); 83 completed	Randomized, double-blind, placebo-controlled trial; duration: 3 months (and 2 months follow-up)	Vitamin E 50 mg tds (tid) from 10 days before expected menses, until fourth day of menses	Pain severity during menses (also discomfort during premenstrual phase)	Significantly more women in the treated group (34/50, 68%) improved, compared to 9/50 (18%) of controls. 76% of treated women vs. 29% of controls improved during menses. Comment: this trial was not truly randomized (alternation allocation). Statistical analysis not presented
[43]	556 young women (ages 12–21); 530 completed	Randomized, double-blind, placebo-controlled, crossover trial; duration: 5 months (unequal phases: 2 months, then 3 months)	Vitamin B_1 (Thiamine hydrochloride) 100 mg per day (2 or 3 times in months, depending on treatment assignment)	Improvement in pain	In group that started with thiamin, >90% improved, compared to <1% of those who started on placebo; improvement persisted 3 months through placebo phase.>90% of group that started with placebo reported improvement after 2 months of thiamine. Comment: these results appear too good to be true and generally implausible
[44]	42 adolescents (37 completed)	Randomized placebo-controlled crossover study; duration: 4 months (each phase lasted 2 months)	Fish oil (daily dose contained eicosapentanoic acid 1080 mg, docosahexaenoic acid 720 mg, and Vitamin E 1.5 mg) vs. placebo	Cox Menstrual Symptom scale	Compared with baseline, fish oil but not placebo significantly ↓ symptom scores ($P = 0.0004$)
[45]	78 women	Randomized, double-blind placebo-controlled trial; duration: 3 cycles	Fish oil, fish oil with B12, seal oil, or placebo (containing fat); 5 capsules daily for 3 cycles	Menstrual Symptom Questionnaire and visual analog scale for pain	Compared to baseline, only fish oil with B12 significantly ↓ symptom scores ($P < 0.01$) and VAS for pain ($P < 0.02$). Reduction in symptoms lasted 3 months after treatment ended
Herbs					
[46]	40 women with dysmenorrhea and a traditional Chinese medicine diagnosis of "deficiency", "yin", "stagnated blood" and "cold"	Double-blind, placebo-controlled trial; duration: 2 cycles, with 2 cycle baseline assessment and 2-month follow-up	Chinese herbal formula (Danggui-Shao-Yao-San in Chinese transliteration, or Toki-shakuyaku-san in Japanese transliteration)	Pain severity by visual analog scale	Compared to placebo, treatment significantly reduced pain throughout two treatment months and two follow-up months ($P < 0.05$ for first treatment month, $P < 0.005$ for subsequent months). No serious adverse effects were reported
Exercise					
[47]	36 college women	Randomized controlled, non-blinded trial; duration: 3 cycles	Aerobic training for three menstrual cycles vs. sedentary control	Moos Menstrual Distress Questionnaire	Training group had significantly lower MDQ scores during menstruation than controls ($P < 0.05$)

[48]	302 junior high school students	Randomized, controlled, non-blinded trial; duration: 3 years	Daily Golub exercise (Golub exercises involve twisting and bending)	Frequency of premenstrual difficulties and dysmenorrhea	39% of exercise group reported dysmenorrhea, compared to 61% of controls ($P < 0.05$)
[49]	101 college students	Randomized, controlled, non-blinded trial; duration: 15 weeks	Billig exercises vs. non-Billig exercises	Dysmenorrhea symptoms	Both types of exercise significantly decreased dysmenorrhea symptoms
[50]	53 college students	Randomized, controlled, non-blinded trial; duration: 20 weeks	Billig vs. Mosher vs. series exercises	Dysmenorrhea symptoms	All exercises significantly decreased dysmenorrhea symptoms
Acupuncture					
[51]	43 women	Randomized, controlled trial with three different controls; duration: 3 menstrual cycles	True acupuncture vs. three controls: sham acupuncture (at non-acupuncture points); "standard" controls (usual treatment); and "visit controls" (usual treatment and extra office visits). Acupuncture groups were treated three times per month	Pain score	There was no significant difference between groups in mean monthly pain scores. The proportion of women whose average pain scores were halved after treatment (10/11) was significantly higher in the real acupuncture group than the other groups ($P < 0.05$)
Chiropractic					
[52]	45 women with primary dysmenorrhea	Randomized controlled trial; duration: single treatment on first day of menses	Spinal manipulative therapy (SMT) vs. sham manipulation	Menstrual Distress Questionnaire and a visual analog pain scale	Compared with baseline, the SMT group had significantly less abdominal pain ($P = 0.019$) and lower MDQ scores than the sham-treated group ($P = 0.003$)

Table 3
Alternative therapies for pregnancy and lactation-related conditions

Reference	Subjects	Study design and duration	Intervention	Outcome measures	Results	Comments
Nausea and vomiting						
[57]	$N = 593$ women <14 weeks pregnant (443 completed) with N/V	Single-blind randomized controlled trial; duration: 4 weeks	4 groups: Individualized acupuncture vs. P6 acupuncture vs. sham acupuncture vs. no acupuncture (treatments given twice the first week, then once weekly)	Nausea, vomiting, dry retching	There was no difference among groups in vomiting. Compared to no-acupuncture control, traditional, P6 and sham acupuncture were significantly more effective for nausea and retching at 3 and 4 weeks. Compared with no acupuncture, benefits were seen in the traditional acupuncture group at one week, in the P6 group at 2 weeks, and in the sham acupuncture group at 3 weeks	
[58]	$N = 97$ women (8–12 weeks pregnant; 84 completed); with nausea ≥1 week	Randomized, double-blind, placebo controlled trial; duration: 12 days (4 days run-in, 4 day treatment, 4 day follow-up)	P6 acupressure wrist bands vs. placebo bands (no buttons) on both wrists	Intensity, duration and nature of nausea and vomiting	No significant difference between proportion of each group reporting less intensity or shorter duration of symptoms	63% of active and 90% of placebo groups reported problems with wristbands including pain, numbness, soreness
[59]	$N = 138$ women (110 completed) in the first trimester	Randomized, single-blind controlled trial; duration: 4 days (and 3 days follow-up)	Acupressure bands vs. placebo bands (no buttons), worn on both wrists)	Frequency and severity of N/V by daily log	Treatment group had significantly less frequency and severity of N/V compared with women using placebo bands ($P < 0.0005$)	
[60]	$N = 60$ women 9–11 weeks pregnant (40 analyzed)	Randomized, placebo-controlled trial; duration: 14 days	3 groups: P6 acupressure band vs. placebo acupressure bands (inappropiately placed) vs. no treatment (control group) Unilateral		Compared to placebo and control, P6 acupressure reduced both nausea and vomiting ($P < 0.05$). Placebo acupressure reduced nausea between days 1 and 6 ($P < 0.05$); between days 6–14 there was no difference between placebo acupressure and control	
[61]	$N = 31$ women with morning sickness, 6–12 weeks pregnant	Randomized controlled trial; duration: 7 days	Acupressure bands vs. placebo bands (no button)	Level of nausea by questionnaire (no further details given)	Significantly greater reduction of nausea in the placebo group, compared to the treatment group ($P = 0.052$)	
[62]	55 pregnant women with morning sickness (6–10 weeks gestation); 50 completed 3 treatments, 44 completed 4 treatments	Double-blind, randomized controlled trial; duration: 3 weeks	Traditional acupuncture (one of 3 sets of points) or sham treatment (3–4 treatments over 3 weeks)	Nausea score by visual analog scale by daily diary	No significant difference between groups (nausea scores decreased in both groups)	This is an unusual study because it used traditional Chinese medical diagnosis and a semi-individualized treatment
[63]	33 women hospitalized with hyperemesis gravidarum)	Randomized controlled crossover trial; duration: 6 days (each phase lasted 2 days, with 2 days washout between phases)	P6 acupuncture vs. superficial acupuncture (each given three times daily)	Degree of nausea by VAS Episodes of emesis	Significantly fewer women were vomiting after first phase in the active treatment group (7/17) than placebo (12/16) $P \leq 0.05$. Active acupuncture resulted in faster ↓ in nausea	Initial VAS estimates for nausea differed between groups, so speed of VAS reduction was calculated
[64]	350 pregnant women (202 completed) at first prenatal visit	Randomized controlled trial; duration: 4 days	Self-applied pressure at P6 point vs. self-applied pressure at "dummy" point (near the elbow) vs. filling out a form	Incidence and severity of morning sickness, assessed by mail-back questionnaire	Significantly less severe symptoms for P6 acupuncture compared to both other groups ($P < 0.001$)	No baseline assessment performed. High and unequal dropout rate (significantly lower rate of completed returns for both acupressure groups compared to no-treatment control). P6 group was significantly further along in pregnancy
[65]	60 women (54 completed) 7–12 weeks pregnant, with morning sickness	Randomized, controlled, double-blind crossover trial; duration: 12 days (each phase lasted 3 days)	Bilateral use of acupressure bands and placebo bracelet in 4 different combinations	Symptom scale (Slight, moderate, troublesome, severe)	Unilateral or bilateral P6 pressure significantly reduced or eliminated symptoms in acupressure group, compared to placebo group ($P < 0.05$)	
[66]	22 women (16 completed) with morning sickness	Randomized, controlled crossover trial; duration: 10 days (each phase lasted 5 days)	Acupressure bands vs. no therapy	5-point nausea and vomiting scale	Compared to no therapy, acupressure significantly reduced nausea and/or vomiting in 12/16 subjects ($P < 0.025$)	No sham control

[67]	90 women with morning sickness (60 completed)	Randomized controlled trial; duration: 10 days	Acupressure bands on P6 or placebo point × 10 days	Rhodes index of nausea and vomiting	P6 group improved significantly more than control group for nausea ($P = 0.002$) but not emesis. Both groups improved significantly from baseline	
[68]	161 pregnant women (149 completed)	Randomized controlled trial; duration: 7 days	P6 acupressure bands vs. placebo point vs. no treatment	Rhodes index of nausea and vomiting	No significant difference between groups (all groups improved significantly over baseline	Anti-emetic medication use was lower in P6 group at baseline and throughout trial
[69]	25 women with morning sickness (23 completed)	Randomized, controlled, crossover trial; duration: 1 day ($n = 7$); 2 days ($n = 18$)	P6 stimulation with TENS unit vs. placebo unit	Nausea and vomiting assessment (worsened, no change, improved)	Average scores for nausea ($P < 0.05$), but not vomiting, were significantly less during TENS phase	Duration of treatment was extended from 1 to 2 days mid-trial
[70]	23 women with morning sickness (15 completed)	Randomized, controlled crossover trial; duration: 16 days (each phase lasted 7 days, with 2-day washout)	P6 acupressure bands vs. placebo point	Nausea and vomiting (visual analog scale)	Nausea, but not vomiting, score significantly lower during P6 phase than during placebo phase	
[71]	70 women (67 completed) with morning sickness	Randomized, double-blind placebo-controlled trial; duration: 4 days (and follow-up 7 days later)	Ginger (1 g per day) vs. placebo	Severity of nausea (assessed by VAS); number of vomiting episodes; and symptom severity (5-item Likert scale)	Compared to placebo, the ginger group had significantly ↓ nausea severity ($P = 0.014$) and significantly fewer vomiting episodes ($P < 0.001$). Nausea improved in 28/32 in the ginger group, compared with 10/35 in the placebo group ($P < 0.001$)	
[72]	30 women (27 completed) hospitalized with hyperemesis gravidarum	Randomized, double-blind, placebo controlled, crossover trial; duration 10 days (each phase lasted 4 days, with 2 days washout)	Ginger (250 mg, 2 times daily) vs. placebo	Symptom relief score (nausea, vomiting, weight change, patient's opinion)	Ginger resulted in significantly lower symptom scores than placebo ($P < 0.05$) 70.4% preferred ginger. One woman had a spontaneous abortion, and one had an induced abortion. 25 patients went to term and all infants born were normal in terms of appearance, birthweight, and Apgar scores. Three women were excluded from analysis (2 for non-compliance, 1 developed gallstones)	
[73]	74 women (59 completed) with morning sickness	Randomized, placebo-controlled trial; duration: 3 days	Vitamin B-6 (pyridoxine, 25 mg every 8 h) vs. placebo	Degree of nausea, vomiting	B6 reduced nausea scores significantly more than placebo only for severe N/V ($P < 0.01$); there was no effect of treatment in mild/moderate N/V	
[74]	342 women (336 completed) with morning sickness	Randomized, double-blind, placebo-controlled trial; duration: 5 days	Vitamin B-6 30 mg vs. placebo	Severity of nausea by VAS, number of vomiting episodes	Compared to placebo, treatment significantly reduced nausea scores on each day of the study ($P < 0.05$). There was no effect on mean number of vomiting episodes	
Pain/cramping						
[75]	26 women in 2nd trimester	Randomized controlled trial; duration: 5 weeks	Massage by massage therapist vs. progressive relaxation exercise (each for two 20-min sessions per week)	Pre- and post-treatment on first and last day of study: STAI, POMS-D,VITAS pain scale for back and leg pain, Depression scale	After first treatment, STAI and leg pain scales decreased in both groups ($P < 0.05$); only the massage group improved in POMS and back pain. Post-intervention scores on the last day showed decreased leg pain in both groups, decreased back pain, STAI, and improved POMS only in massage group	
[76]	60 women (48 completed) with pregnancy-related low-back or pelvic pain	Randomized controlled trial; duration: 40 days	Acupuncture (10 treatments in one month) vs. physiotherapy (10 treatments within 6–8 weeks)	Visual analog pain scale and disability-rating index (DRI)	Mean VAS and DRI scores were significantly lower in acupuncture group than physiotherapy group ($P < 0.05$)	All 12 dropouts were in the physiotherapy group
[77]	73 pregnant women with leg cramps (69 completed)	Randomized, double-blind trial duration: 3 weeks	Magnesium (magnesium lactate, magnesium citrate) 5 mmol qam, 10 mmol qpm	Symptom duration, frequency, diurnal variation, next-day persistence of nocturnal cramps (visual analog scale)	Magnesium-treated group, compared to control, had less next-day persistence of nocturnal cramps (25 vs. 50%), less distress on VAS, and better overall ratings (all $P < 0.05$). Symptoms decreased significantly ($P < 0.05$) in both groups	
Leg edema						
[78]	69 symptomatic pregnant women (28 weeks gestation) with varicosities	Randomized, placebo-controlled trial; duration: 8 weeks	Rutosides (plant flavonoids) 300 mg three times daily vs. placebo	Symptom scores (pain, feelings of leg heaviness/tiredness, nocturnal cramps, paresthesias); ankle circumference	Significantly more treated women (2/3) improved compared to 1/3 controls (1/3) (OR 0.30, 95% CI 0.12–0.77). Ankle circumference decreased in treated group and increased in placebo group	

Table 3 (*Continued*)

Reference	Subjects	Study design and duration	Intervention	Outcome measures	Results	Comments
[79]	11 women	Randomized controlled crossover trial; duration: 3 separate days	Waist deep immersion in bathtub vs. shoulder deep immersion (both in water 32C (90d F) vs. bed rest, each × 50 min	Urine output, mean arterial pressure	Urine output after shoulder-deep immersion significantly greater than other treatments ($P < 0.05$). MAP and heart rate decreased significantly from baseline in all groups ($P < 0.003$)	Symptom relief not recorded
[80]	18 pregnant women (17 primiparas) 20–33 weeks	Randomized controlled crossover trial; duration: 3 separate days	Water aerobics vs. shoulder-deep immersion in heated pool vs. standing on land each time 30 min	Urine volume and specific gravity, blood pressure	Urine output significantly higher for static immersion and water aerobics than standing group ($P < 0.05$); no significant difference between immersed groups. No differences between groups in blood pressure. Specific gravity significantly lower in standing group	Subjects did not have edema
Breech version						
[81]	260 primigravidas (all apparently completed) in 33rd week gestation with breech presentation	Randomized, controlled, open trial	Moxibustion (heat stimulation) of single acupuncture point (L67) by partner daily × 7 days (14 days if breech persisted) vs. routine care	Cephalic presentation at birth	98/130 (75.4%) fetuses in treatment group cephalic vs. 62/130 (47.7%) controls	External cephalic version attempted in 24 in control group (19 successful) and 1 in moxibustion group (unsuccessful)
Labor induction						
[82]	45 pregnant low-risk women, not in labor, on expected day of confinement	Randomized controlled trial	Standardized acupuncture treatment at two points (LI4 and SP6) bilaterally every other day for up to 10 days (after which prostagalandin induction was done). Control group received no acupuncture	Change in cervical length, time from positive fibronectin test to delivery, time from EDC to delivery, duration of labor and stages of labor, proportion treated with oxytocin, mode of delivery	Cervical length shortened at a faster rate, and time from EDC to delivery was significantly shorter in the acupuncture group (5.0 days) than the control group (7.9 days) ($P = 0.03$). There were no differences in other outcome measures	Subjects were not post-dates. No-treatment control is not ideal
[83]	31 post-dates pregnant women (20 analyzed)	Randomized, single-blind controlled trial duration: 4 h (2 h TENS, 2 h sham)	TENS stimulation of standardized acupuncture points vs. sham TENS	Uterine contractions and fetal heart rate	Women in the treated group had significantly more frequent contractions than controls ($P < 0.01$). Fetal heart rate was not affected	None of the subjects went into labor before amniotomy the next day
Labor experience and outcomes						
[84]	90 women in labor (80 analyzed)	Randomized controlled trial	Acupuncture as adjunct or alternative to labor anesthesia vs. conventional analgesia	Hourly assessment of pain intensity and degree of relaxation during labor	Acupuncture significantly reduced the need for epidural analgesia compared to controls (22 vs. 12%, %% 0.52, 95% CI 0.3–0.92) and the acupuncture group reported a better degree of relaxation. No differences between groups in pain intensity or labor outcomes	Acupuncture administered by midwives who had taken a 4-day course in acupuncture for labor pain
[85]	18 women with low-risk, singleton pregnancies, in early, spontaneous labor (cervical dilation 3–4 cm)	Randomized controlled trial	Immersion in portable tub (43 cm deep, 140 cm long, 61 cm wide) with water temperature 36–38 °C, for one hour vs. untreated controls	Anxiety and pain by VAS, (at baseline, 15 min, 60 min) hemoglobin/hematocrit, urine catecholamines	At 15 min, significantly more treated women had decreased anxiety ($P = 0.03$); the difference was not significant at 60 min. After 60 min 83% of treated women reported decreased pain, while all controls reported increased pain ($P = 0.01$). Mean pain scores were lower in bathers at 15 and 60 min (however, mean pain scores were significantly higher among bathers at baseline)	
[86]	107 women in preterm labor (documented contractions with cervical changes) with intact membranes and singleton pregnancies. 23 women stopped doing exercises after 1–2 weeks and were analyzed separately	Randomized controlled trial	Verbal, written and taped instructions on relaxation vs. Untreated controls (both groups were telephoned weekly)	Gestational age and birth weight, rate of pregnancy prolongation (days from study start to birth/days from study start to due date × 100)	The adherent experimental group had significantly longer gestations, and a higher rate of pregnancy prolongation than non-adherent subjects or controls. There was no difference in birth weight	The segregation of non-adherent subjects assigned to treatment calls the results into question. The authors even state that the non-adherent group had the highest risk factor scores. An intention to treat analysis should have been done
[87]	93 pregnant, low-risk women in active labor (cervical dilation 4–7 cm)	Randomized controlled trial	Immersion in a hot tub with molded seats for as long as subjects wanted (usually 30–45 min); water temperature was controlled by subject (32–41 °C)	Cervical dilation, contraction pattern, fetal and maternal vital signs (before and after tub use). Also time to delivery, method of delivery, rate of chorioamnionitis or endometritis, Apgar scores, hospital readmissions	Immersion significantly increased maternal heart rate, maternal temperature, and fetal heart rate; maternal blood pressure was not affected. There were no differences between groups in any other parameters	This was primarily a safety study that shows that hot tub immersion during early labor is safe

[88]	60 nulliparous women, at the end of the second trimester	Randomized, rater-blinded trial	Hypnotic induction (one session with therapist, then tape-recorded instruction) vs. progressive relaxation exercises using a tape-recording. Both interventions were performed daily, and both groups underwent childbirth education classes	Pain threshold for ischemic pain task (IPT; 6 sessions in third trimester), pain ratings during labor and delivery (McGill Pain Questionnaire. MPQ), duration of Stage I and Stage II labor, use of medication during labor and delivery, and Apgar scores	Hypnosis group had higher pain threshold than relaxation group on IPT at sessions 3 + 4, and sessions 5 + 6. Hypnosis group had lower scores on MPQ ($P < 0.01$), shorter Stage I labor ($P < 0.001$), more spontaneous deliveries ($P < 0.05$) and their infants had higher Apgar scores at 1 and 5 min ($P < 0.001$)	
[89]	60 postpartum, primaparous women	Duration: 4 weeks	Relaxation and guided imagery, using a tape-recording, 15 min daily vs. control (listening to taped music for 15 min)	State-Trait Anxiety Inventory, Center for Epidemiologic Studies Depression scale, Rosenberg Self-Esteem scale	Compared to controls, the relaxation group had significantly improved scores on the STAI, CES-D, and Rosenberg Self-Esteem scale	
[90]	28 women (mean 37 weeks gestation)	Randomized controlled trial; duration: labor	After 10 min massage lesson, partner massaged woman × 20 min at 3–5 cm dilation) vs. attention control (partner present)	Pre/post-massage: POMS-D VAS for well-being; stress level and labor pains (5-point Likert) Post-labor: Depression scale, Touch sensitivity	Compared with controls, treated group had significantly better mood, less stress and decreased pain. Postpartum depression, touch sensitivity, hours in labor and days in hospital were significantly reduced in the treated group than controls	Comparisons were post-hoc
Perineal outcome						
[91]	861 nulliparous women with singleton pregnancy (664 analyzed)	Randomized, controlled, single-blind trial	Perineal massage by subject (3–4 times per week for 4 min, starting 6 weeks before estimated due date) vs. no massage	Perineal status (intact/tears); Delivery type	For women >30 years old: Treatment reduced tears 12% and reduced instrument deliveries 12.9%. For women <30 years old, no differences between groups.	
[92]	1527 women (1034 without previous vaginal birth); 1522 completed	Randomized, single-blind, controlled trial	Perineal massage(self-administered), 10 min daily from 34–35th weeks till delivery) vs. usual obstetric care	Intact perineum; Episiotomy	Treated women without previous vaginal birth were more likely to have intact perineum (24.3% than controls (15.1%); there was no difference in perineal outcome among women with a previous vaginal birth)	
[93]	949 women (572 women without previous vaginal birth); all apparently completed	Randomized, single-blind, controlled trial	Perineal massage (self-administered, 10 min daily from 34–35th weeks till delivery) vs. no massage	Perineal pain; Dyspareunia; Sexual satisfaction; Incontinence of urine, gas or stool	Among primiparas, no differences in any outcomes. More treated women with previous vaginal birth free of perineal pain (93.6%) than controls (85.8%) ($P = .01$); no differences in dyspareunia, incontinence, or sexual satisfaction.	
[94]	1340 women carrying singleton pregnancies (all apparently completed)	Randomized controlled trial	Perineal massage (by a midwife) during second stage of labor	Intact perineum; Episiotomy	There were no differences in rates of intact perineum or number of episiotomies, or 1st or 2nd degree tears. Third degree tears were significantly less common in the treated group (RR 0.47, 95% CI 0.23–0.93)	
Postpartum discomfort						
[95]	635 postpartum women	Randomized, single-blind, controlled trial; duration: 10 days	Lavender oil (6 drops in bath water daily) vs. synthetic lavender oil vs. aromatic placebo (2-methyl 3-isobutyl pyrazine)	Perineal discomfort (visual analogue scale)	No significant differences among groups	Investigators were blinded; however, compounds had different odors
[96]	161 Women with episiotomy or perineal tearing requiring suturing	Randomized, placebo-controlled trial	Homeopathic *Arnica montana* in two potencies (D6 and D30) vs. placebo (3 tablets sublingually every 4 hours for two days, then 3 times daily for 3 days)	Perineal pain, breast pain, perineal appearance, mood	No difference between groups in perineal pain, breast pain, or perineal appearance. Women treated with Arnica D30 were significantly more likely to describe their mood as "unhappy" and to feel that the treatment was ineffective	
Lactation						
[97]	71 mothers of premature infants (55 completed)	Randomized controlled trial; duration: 7 days	Daily listening to 20 min audiotape consisting of progressive relaxation exercise and imagery vs. routine supportive care	Breast milk volume and fat proportion of milk ("creamatocrit")	Average volume significantly higher in relaxation group (90.1 ml) than in control group (55.4 ml) ($P < 0.05$). No difference in creamatocrit	

Table 3 (*Continued*)

Reference	Subjects	Study design and duration	Intervention	Outcome measures	Results	Comments
[98]	39 breastfeeding women with engorgement	Randomized, placebo- controlled trial	Cabbage extract topical cream vs. placebo cream, each applied to the breast and left there for 2 h	Level of breast engorgement (by probe protraction) and symptoms (modified Hill and Humenick Breast Engorgement scale, Bourbonais pain scale) pre-treatment, pre-feed, and post-feed	No difference between groups	
[99]	28 breastfeeding women with engorgement	Randomized controlled trial	Chilled cabbage leaves applied to one breast vs. room temperature cabbage leaves applied to the other breast; leaves were applied between feeds	Pre-treatment and post-treatment pain scores (Bourbonais pain scale)	No difference between groups	No blinding, no negative control
[100]	34 breastfeeding women with engorgement	Randomized controlled trial	Chilled cabbage leaves applied to one breast vs. chilled gel pack applied to the other; each treatment renewed as needed (usually every 2–4 h) for 8 h	Pre-treatment and post-treatment pain scores (Bourbonais pain scale)	No difference between groups	No blinding, no negative control
[101]	120 breastfeeding women (72 h postpartum) (96 completed)	Randomized, controlled, open trial; duration: 6 weeks	Application of cold cabbage leaves vs. routine care including hot compresses	Breast engorgement (questionnaire before each feeding and at 6 weeks)	No significant change in engorgement	

4. Fibroids, endometriosis, and pelvic pain

No controlled trials of CAM treatments were identified for the treatment of fibroids, endometriosis, or pelvic pain.

5. Pregnancy

Many women are concerned about taking drugs during pregnancy, and may explore CAM therapies to treat symptoms. A surprisingly large number of CAM trials were identified for relieving pregnancy-related conditions. These 42 studies are summarized in Table 3 [57–97].

5.1. Nausea and vomiting

Several treatments for pregnancy-related conditions appear promising. Acupuncture point stimulation for nausea and vomiting of pregnancy should be considered a proven treatment; 10 of 14 studies found significant benefit on at least one measure. Only three studies utilized needles; nine utilized acupressure bracelets, one used self-applied finger pressure, and one used TENS unit stimulation. All but one study tested stimulation of the P-6 acupuncture point, which is easily located on the volar aspect of the wrist. Two studies (including one that also tested P6) tested individualized acupuncture. It is difficult to conduct such studies in a truly double-blind manner. Nonetheless, non-invasive, self-administered therapy for morning sickness is benign and should be encouraged; health care practitioners should familiarize themselves with the P6 point (Fig. 1) to be able to instruct patients in this procedure.

Two relatively small studies of ginger for morning sickness have found a significant benefit [71,72]. Ginger is safe in the dose used (1 g per day), which does not exceed what would be expected in some meals. Ginger is used medicinally by many traditional cultures.

Vitamin B6 lessened nausea in two trials [72,73]. Vitamin B6 was one component of Bendectin, the only treatment for morning sickness ever approved by the Food and Drug Administration.

The duration of studies on CAM therapies for nausea and vomiting of pregnancy ranged from 1 day to 4 weeks; most lasted less than 2 weeks. Duration and consideration of gestational age are both important in evaluating outcomes, because nausea and vomiting of pregnancy is generally self-limited and improves over time. Most studies of CAM therapies for nausea and vomiting of pregnancy have found a benefit. Given the prevalence of the problem, larger trials are warranted.

5.2. Other pregnancy symptoms

Back pain, leg cramps, and leg edema are common symptoms during pregnancy. One study supports acupuncture over physiotherapy for pregnancy-related back or pelvic pain; massage improved both back pain and mood in one study. Plant-derived rutosides reduced leg edema and cramps in one trial [78]; magnesium also decreased leg cramps compared to placebo [77]. Immersion in water (whether passive [79] or active [80]) increased urine output, but no studies have examined the effect of immersion specifically on pregnancy-related leg edema. These treatments are benign.

5.3. Labor induction and outcomes

Two studies have tested acupuncture point stimulation for inducing labor; no dramatic effects were seen in either trial. One trial indicated a promising role for moxibustion (heat stimulation of acupuncture points) as a non-invasive treatment for turning breech babies [81]. There may be a place for mind-body therapies or massage in decreasing anxiety and pain during labor, but more research needs to be done to delineate benefits. Perineal massage may increase the likelihood of an intact perineum; however, although four studies found a benefit in at least one subgroup [91–94], there was no consistency among trials in which subgroups benefited. In single trials, neither aromatherapy [95] nor homeopathy [96] reduced perineal discomfort . Listening to a relaxation/imagery tape increased breast milk volume in mothers of premature infants [97]. Application of cabbage leaves or cabbage extract failed to help breast engorgement in four controlled trials [98–101].

6. Discussion

Most controlled trials of alternative approaches for the conditions we have reviewed have been small. Definitive efficacy studies are lacking, and mechanisms of action are largely unexplored. But encouraging and intriguing studies do exist.

Substantial evidence supports the use of acupuncture point stimulation (primarily by acupressure) for nausea of pregnancy. Calcium, magnesium, Vitamin B6, and *Vitex* may be helpful for PMS, and there is intriguing preliminary information on ginger or Vitamin B6 for morning sickness, and on mind–body therapies to reduce pain and anxiety during labor or postpartum.

CAM therapies are quite popular among pregnant women, and safety issues must be more clearly delineated. Larger clinical trials and determination of subpopulations of women for whom particular treatments may be most appropriate are needed.

Herbs and dietary supplements are not all risk-free. Many herbs are being promoted for new, non-traditional uses. Newly formulated combination herbal products (often containing novel mixtures and/or subtherapeutic doses) should be avoided until research data are available; currently no safety or efficacy data on such combinations have been published. The subtherapeutic doses often found in such

preparations may render them harmless, but harmlessness cannot be assumed. There are, of course, numerous herbs with a long history of use in many cultures. Only a small number of these herbs have been studied to date. The guidance of knowledgeable herbalists can be sought (easier said than done) while research data slowly accumulate.

While plant foods are presumed safe, the isolated, often concentrated components that are now flooding the market have not been tested for safety of long-term use. Further, the lack of adequate product quality control in the United States makes it difficult to know which supplement brands are reliable. The number of herbal products in the American market is increasing rapidly, and recommended dosages are increasing, without research supporting the need for or safety of these larger doses.

Health care providers and consumers should be aware that despite the potential usefulness of many CAM therapies, scientific research to date is limited. Product advertising hype far exceeds scientific knowledge, and scientific evaluation is essential to enable an informed choice among treatments. Many studies on CAM therapies are not well-reported. Future studies would benefit from enrolling an adequate number of subjects, appropriate blinding, and placebo controls, use of standard outcome measures, and presentation of all data and statistical analyses. However, because herbs, vitamins, and other natural products have limited patentability, and because there is no requirement for testing before marketing, industry-sponsored research will remain limited. Federal, private, and other alternative funding sources must bridge this gap; scientific evaluation of both safety and efficacy of these therapies is important to public health.

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