

Review of evidence: complementary therapies in pregnancy

By Antonia Chitty

Complementary therapies are popular with expectant mothers and midwives, with many women viewing them as 'safe and effective'.¹ During pregnancy, women are advised to avoid many conventional drugs because of their possible effects on their unborn child.^{2,3} Some women may therefore consider 'alternative' remedies in the 'sometimes mistaken belief that they are safer than drugs'.⁴ However there is no scientific basis that herbal medicines, for example, are as natural and safe as some women, and even health care providers, believe.⁵

This paper reviews the research literature to appraise the available evidence on the safety and effectiveness of complementary therapies for a range of common pregnancy complaints. It begins with discussion about the range of complementary therapies used in pregnancy, the current context in terms of debates about safety and evidence for effectiveness, the extent to which complementary therapies are regulated and midwives are trained to offer advice or use complementary therapies as part of their practice, and the level of public awareness about these issues. The paper provides information on use of the following therapies during pregnancy, though the extent of the published evidence is very variable:

- acupuncture
- chiropractic
- herbal medicine
- homoeopathy
- osteopathy
- aromatherapy
- hypnotherapy
- reflexology
- massage.

It looks specifically at using complementary therapies to treat morning sickness, pelvic pain and back pain, constipation, anxiety, heartburn and insomnia.

Background

Range and availability of complementary therapies

Complementary therapies are being offered to pregnant women as part of NHS antenatal care and are also used by many pregnant women, consulting private practitioners or buying over-the-counter treatments. A survey of 221 heads of midwifery in all NHS maternity units in England found that massage, aromatherapy, reflexology and acupuncture were the therapies offered most widely. Sixty four percent of the maternity units who responded provided a complementary therapy service in a variety of combinations to mothers, babies and staff.⁶ An Australian survey found 40% of clients at an antenatal clinic reported using alternative therapies,⁷ whilst three American studies have found 7.7%, 13% and 9.1% of pregnant women to be using herbal remedies respectively.^{8,9,10}

Safety and effectiveness

Denise Tiran, midwife, complementary practitioner and researcher, highlights concern over the safety of complementary therapies used in pregnancy and particularly 'the indiscriminate enthusiasm of midwives [which] has resulted in some injudicious practice in which complementary therapies are used, not only unnecessarily, but also inappropriately and often incorrectly.' Around one in three midwives were using some form of complementary therapies in practice ten years ago, and increasing numbers are advising on natural remedies.^{11,12} Tiran mentions the trend for midwives to advise on complementary therapies of which they have but superficial knowledge.¹³ This concern is compounded by the lack of robust evidence for many therapies and the potential for harm, which is greater for some treatments such as herbal remedies.¹⁴

In a 2001 review of the methodological quality of research on herbal medicine, homeopathy and acupuncture, the authors found variable quality with serious shortcomings in a majority of studies. Larger trials, more recent studies, and those published in journals listed on Medline and in the English language scored more highly than other studies.¹⁵

In 2005 Tiran reported, 'There is limited evidence on the effectiveness of complementary therapies in general and in maternity care specifically', a view backed up by other authors.¹ Tiran continues: 'Often the numbers of subjects are small, studies lack control groups or there are other concerns regarding methodology.'¹⁶

There is debate over the appropriateness of research methods used in science and conventional medicine to evaluate complementary therapies. While some researchers use double-blind and randomised controlled trials (RCTs) to assess complementary interventions, others, often from traditional and alternative therapies backgrounds, feel these methods are not appropriate or cause problems with implementation in therapies such as acupuncture. 'Two apparently different and diverse world-views' are cited as the basis of this debate.¹⁷ It is suggested that difficulties may occur when trying to use research methods from one worldview to assess therapies based on another.¹⁷ What is more, while there may be inherent challenges, some methodological issues are misunderstood. For example, it is not essential that trials with a control group need to be double-blinded.¹⁷

Training and regulation

In many training courses for complementary therapies, there is little mention of the evidence base, and scant focus on use of therapies during pregnancy.¹³ Midwives may

advise on therapies of which they have little knowledge.¹³ UK law forbids anyone other than a midwife or doctor from providing maternity care, except in an emergency. Tiran and Price explain that aromatherapists who are not midwives must liaise with the maternity care team and remember that treatment is complementary to normal antenatal and postnatal care, until 28 days after delivery.¹⁸ This applies to any therapist who is not a qualified doctor or midwife.

The regulation of complementary therapists is a work in progress. Osteopaths and chiropractors have been subject to statutory regulation since 1993 and 1994, respectively, including provision for legal sanctions against those who are unfit to practice. Statutory regulation of practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems has been on the agenda for over a decade but timetables have not been adhered to.¹⁹ Some therapists are resistant to what they see as a costly and bureaucratic process, citing the adequacy of voluntary registers and the low number of complaints as justification.^{19,20} A new regulatory body, the Complementary and Natural Healthcare Council, opened its register of practitioners on 19 January 2009, enabling people to check whether practitioners are registered.²¹ The aim is to have 10,000 approved practitioners on the register by the end of 2009 and for the CNHC kite mark to be established as the quality benchmark for NHS referrals and the symbol of a quality service. However, registration is entirely voluntary so there remains an issue of the need for adequate protection of the public.²²

Public awareness

Health professions, NCT workers and parents should be aware of these issues. Those providing information or offering therapies should ensure that what they say is balanced and addresses issues of effectiveness and safety. Pregnant women need reliable information in order to be able to make choices that are as well informed as is possible when the evidence-base is limited. Parents may not be aware of the limited regulation and may be relying on the therapist's training to have covered which interventions are safe and appropriate for pregnancy.

Search strategy and review structure

This review is based on searches carried out on the following databases: Ovid, PubMed, NCT Reference Manager, Cochrane, MIDIRS, Google Scholar, Pubmed.

The searches used the following terms: 'complementary therapy' and safety; 'complementary therapy' and effectiveness; pregnancy and aromatherapy; pregnancy and physical therapies; pregnancy and massage; pregnancy and osteopathy; pregnancy and chiropractic; pregnancy and reflexology; pregnancy and herbal medicine; pregnancy and homoeopathy; 'complementary therapy' and pregnancy; 'complementary therapy' morning sickness; 'complementary therapy' constipation; 'complementary therapy' back pain; 'complementary therapy' SPD; 'complementary therapy' anxiety; 'complementary therapy' heartburn; 'complementary therapy' insomnia.

Extent of the evidence for different therapies

Before going on to the main body of the paper which addresses specific pregnancy-related conditions, a short summary is provided on the evidence available for specific therapies and their use in pregnancy.

Acupuncture

A number of studies have been carried out including some using rigorous methods. However, safety and effectiveness still needs to be demonstrated for most of the conditions examined in this briefing.

Aromatherapy

Price and Tiran conclude that, 'There is currently very little direct evidence for the safety of essential oils in pregnancy',¹⁸ and that 'there are many oils which should be avoided in pregnancy, either because they cause miscarriage or affect the developing foetus'.¹⁴

Herbal medicine

This is an area of particular concern as women may consider herbs to be safer than pharmaceutical drugs.²³ Tiran says, 'natural' does not necessarily mean 'free of side effects'...there are reports of misuse through lack of knowledge...There are

many plants which are thought to be unsafe to use in pregnancy...'¹⁴

Homeopathy

No research was found during this review on homeopathy and maternity care bar three studies on caulophyllum in labour.²⁴ While treatment itself is unlikely to be harmful, there is the potential for harm if a homeopathic treatment is used rather than conventional medicine for conditions such as postpartum haemorrhage or urinary burning.²⁵

Reflexology

Much of what is written is anecdotal or case study based. Information is sparser than for other complementary therapies.⁴ Caution is advised when using reflexology during the first trimester, although it is unclear whether this is evidence-based or purely to avoid the association of reflexology with a miscarriage.

Evidence on use of complementary therapies for common pregnancy complaints

Each of the following sections begins with the range of complementary therapies used for the condition. This is followed by a summary of the findings from the relevant Cochrane review where one is available. Based on a systematic search for and assessment of research studies, Cochrane reviews provide the best available evidence 'for and against the effectiveness and appropriateness of treatments (medications, surgery, education, etc.) in specific circumstances'. (www.cochrane.org/reviews/revstruc.htm) The reviews are usually based solely on evidence from randomised controlled trials, but other types of evidence may also be taken into account, if considered appropriate. In this review, findings from some additional studies may be added, for example research published since the Cochrane review was last updated and further information about dose and regimen.

Morning sickness

Nausea affects an estimated 70-85% of women during pregnancy with half experiencing vomiting.²⁶ Complementary therapies which are used for treating nausea and vomiting during pregnancy include: acupuncture, acupressure;²⁶ aromatherapy;²⁷ herbal medicine (ginger, chamomile,

peppermint and raspberry leaf);²⁸ homeopathy (pulsatilla, nux vomica, sepia, ipecacuanha, actea recemosa, tabacum);²⁹ reflexology; shiatsu;³⁰ vitamin B6.²⁶

Cochrane review

A Cochrane review by Jewell and Young of Interventions for nausea and vomiting in early pregnancy, last updated in 2003, included both conventional and complementary therapies.²⁶ Twenty eight studies met the inclusion criteria for the study, 'acceptably controlled trials', of which there were two trials on vitamin B6 (416 women); six trials on acupuncture or acupressure (1,309 women) and one trial on extract of ginger (70 women) for nausea and vomiting. There was one further trial of ginger for hyperemesis (30 women). The quality of the studies was variable. For example, three of the acupressure trials did not state the method of randomisation. Severity of symptoms also varied, as did the stage during pregnancy when women were recruited.

The two trials on pyridoxine (vitamin B6) on its own showed no evidence of an effect on vomiting (OR 0.64, 95% CI 0.18 to 2.26) but there was evidence of effectiveness in reducing the severity of nausea.^{31,32} Jewell and Young highlight that 'The two trials used very different doses of medication': 75 mg daily,³¹ and 30 mg daily.³² The two trials report similar effects on nausea score, but only the study with the higher dosage showed an effect on vomiting. The reviewers conclude that, 'It is possible there is a dose response effect here, with the higher dose showing greater effect in those with worse symptoms. Unfortunately, there are not enough data to draw such conclusions with any confidence.'

Dichotomised data (morning sickness yes or no) for the six acupuncture or P6 acupressure trials give odds ratios of 0.25 (95% CI 0.14 to 0.43) when compared with no treatment, and 0.35 (95% CI 0.12 to 1.06) compared with sham or dummy acupuncture or acupressure. These positive results were 'comparable to those obtained with drugs'.²⁶ However, further analysis was carried out using a scale to reflect the extent of troublesome symptoms using results from only two trials^{33,34} comparing acupuncture or acupressure with sham acupuncture or acupressure and produces a summary statistic where the 95% CI

includes no effect in both cases. The data from two of these studies, one by O'Brien et al.³⁵ and one by Knight et al.,³⁶ were 'not in a form that could be included in a meta-analysis', the review authors said. 'However, both trials achieved high rates of completion and were generally 'conducted to a high standard'. The reviewers went on to state that the first of these studies 'showed no benefit of acupressure compared with either sham acupressure or no treatment' and that the second 'showed real acupuncture to have no greater effect than sham acupuncture.'

'One trial compared ginger with placebo, each in capsule form, for nausea and vomiting in pregnancy, with 96% of women completing the trial. It reports benefit both for vomiting (OR 0.31, 95% CI 0.12 to 0.85) and for nausea (OR 0.06, 95% CI 0.02 to 0.21), with no adverse effects.'³²

Jewell and Young concluded that:

- Pyroxidine (vitamin B6) appears to be more effective in reducing severity of nausea and less likely to cause side-effects compared to drug treatments. Advice should be taken about dosage as overdose can cause numbness and difficulty walking.
- Results from trials of P6 (an acupuncture point on the wrist) acupuncture are mixed. It has not been shown to be clearly more effective than dummy acupuncture.
- No trials of treatments for hyperemesis gravidarum (a rare, and severe, form of morning sickness) show any benefits.
- No evidence is found that the therapies assessed cause birth defects.
- Acupressure and ginger may work with no side effects: caution is needed as the composition of ginger supplements may vary according to where it is grown and how it is treated after harvest.^{26,32}

Other research

Acupuncture and acupressure

A review of three studies, published more recently than the Cochrane review, did not find significant evidence of benefit.³⁷

Herbal remedies

In a review of popular literature, ginger, chamomile, peppermint and raspberry leaf were listed as the most popular herbs used for morning sickness, but there was no con-

sensus about whether these herbs were safe for use in pregnancy. A small number said that chamomile and peppermint were unsafe, and slightly more suggested ginger and raspberry leaf were unsafe during pregnancy. Information was found to be contradictory, and the author concludes that the 'dearth of original research related to their safety indicates that these compounds should be used with caution'.²⁸

There is a significant amount of research on using ginger to prevent pregnancy nausea and vomiting. A review published three years after the Cochrane review, specifically addressing the safety of herbal medicines during pregnancy, highlights four studies which found ginger effective for nausea and vomiting in pregnancy.³⁸ Two of the four studies had been included in the Cochrane review.^{39,32} They found no adverse effects from ginger when used during pregnancy. The other two studies also concluded that ginger appears to be safe; however, the sample sizes were small:

- A prospective comparative matched study of 187 women was conducted with women taking ginger in the first trimester and a control group of women exposed to non-teratogenic drugs (i.e. those which do not cause deformity or other abnormal development in the foetus) that were not antiemetic. There were no statistically significant differences in outcome between the two groups, and the authors conclude that ginger does not appear to increase the rate of major malformations and has a mild positive effect on reducing nausea and vomiting.⁴⁰
- In a double-blind RCT on 120 women, nausea and retching was significantly reduced in the treatment group, although there appeared to be no significant effect on vomiting. Infants in the study were within normal birth weight and frequency of congenital deformities compared to the general population of infants at that hospital in the same time period.⁴¹
- In another trial that was in progress when the Cochrane review was taking place, ginger root was found to be as effective as vitamin B6 for treatment of morning sickness.⁴² In studies where a dose was specified, doses were given three or four times a day with 250mg being the most commonly cited dose.

Marcus and Snodgrass express concerns about tests on laboratory rats which showed an increase in loss of embryos when exposed to ginger, but the authors acknowledge that this may not predict a human response. The same paper highlights ginger's effect on cell disintegration processes, including the remodelling of the human brain and other organs, and on testosterone binding processes.⁵ Tiran advises caution with respect to the use of ginger during pregnancy. In personal communication she said, 'There is growing concern about the safety and appropriateness of ginger for morning sickness. It has strong anti-coagulant properties so should not be used in large doses or for prolonged periods of time in pregnancy. Further, it ...can cause heartburn or exacerbate nausea and vomiting' (by email 15 February 2009).

Homeopathy

While women may turn to homeopathic remedies for morning sickness, there appears to be no evidence on their safety or effectiveness for nausea or vomiting in pregnancy. Concern has been raised about women self-administering 'wrong' remedies which may have no effect or worsen symptoms, although this clearly depends on whether one believes homeopathic remedies have an effect.⁴³

Reflexology or shiatsu

No trials were found for reflexology or shiatsu in pregnancy-induced nausea and vomiting.

Conclusion

More research has been carried out on complementary therapy interventions to prevent nausea and vomiting than for any other pregnancy related complaint. Pyroxidine (vitamin B6) used under medical supervision appears to be effective in reducing severity of nausea. There are mixed results with acupuncture and more research is needed. The Cochrane review suggests that acupressure and ginger may work with no side-effects. Trials seem consistent about the suggested dose of ginger, but the composition of ginger supplements may vary, so caution is required. Other therapies do not have evidence to support their use for nausea and vomiting.

Pelvic pain and back pain

Estimates of the incidence of back pain in pregnancy vary from a third to more than two-thirds of women. Pain interferes with normal activities affecting social activities, disturbing women's sleep and may prevent them from working.⁴⁴ Almost one-fifth experience pelvic pain, which can be symphysis pubis dysfunction or pelvic girdle dysfunction.⁴⁵ Therapies used for treating backache related to pregnancy include: acupuncture;^{46,47} aromatherapy;^{48,27} chiropractic;^{46,47,49} homeopathy (arnica, rhus tox, bryonia, sepia, pulsatilla, nex vomica, kali carb);²⁹ massage;⁴⁷ physiotherapy;⁴⁶ relaxation;⁴⁷ shiatsu;³⁰ yoga.^{46,47} There is most evidence available regarding the use of acupuncture.

Cochrane review

The Cochrane review looking at the effectiveness of Interventions preventing and treating back and pelvic pain in pregnancy was last updated in 2006.⁴⁴ Eight studies were included (1,305 women) looking at a range of interventions alongside usual antenatal care including:

- pregnancy-specific exercises
- physiotherapy
- acupuncture
- use of pillows.

Low back pain

Sitting pelvic tilt exercises (standardised mean difference (SMD) -5.34; 95% confidence interval (CI) -6.40 to -4.27), and water gymnastics were found to reduce pain intensity and back pain-related sick leave (relative risk (RR) 0.40; 95% CI 0.17 to 0.92) better than usual prenatal care alone.^{50,51}

A specially designed pillow was more effective than a regular one in relieving back pain (RR 1.84; 95% CI 1.32 to 2.55), but is no longer available to buy.

Pelvic pain

Pelvic pain was relieved more by both acupuncture and stabilising exercises when compared to usual prenatal care. Acupuncture gave more relief from evening pain than exercises.⁵²

Both pelvic and back pain

In one study on women with both types of pain:

- acupuncture was more effective than

physiotherapy in reducing pain intensity;⁵³

- stretching exercises resulted in more total pain relief (60%) than usual care (11%);
- 60% of those who received acupuncture reported less intense pain, compared to 14% of those receiving usual prenatal care.

Women who received usual prenatal care reported more use of analgesics, 'physical modalities' and sacroiliac belts.

The review authors noted that all but one study had moderate to high potential for bias, and indicated that as any effects demonstrated were small, results should be viewed with caution.

Massage therapy

One trial has been found on massage therapy. It was neither included by the Cochrane review nor specified as an excluded study. Twenty-six pregnant women were assigned to a massage therapy or a relaxation therapy group for five weeks. Only the massage therapy group, reported less back pain by the last day of the study. This is a small study and can only indicate the need for more research on this topic.⁵⁴

Conclusion

Acupuncture is one of the therapies with a greater research evidence base, and showed better results than physiotherapy. In the area of treatment for back and pelvic pain in pregnancy there are several randomised controlled trials. The Cochrane reviewers concluded that, 'Adding pregnancy-specific exercises, physiotherapy or acupuncture to usual prenatal care appears to relieve back or pelvic pain more than usual prenatal care alone, although the effects are small'. They also highlighted a moderate to high potential for bias in all but one study, so positive results should be viewed cautiously. More research is needed.

Constipation

There are a number of therapies where claims are made for effectiveness in treating constipation, including: aromatherapy;²⁷ homeopathy (nux vomica, alumina, opium);²⁹ massage (clockwise abdominal massage); reflexology.⁵⁵

Cochrane review

A Cochrane review on Interventions for treating constipation in pregnancy, last updated in 2001, included only two trials, one of which tested the use of dietary fibre supplements. It did not specifically look at complementary therapies for constipation. Fibre supplements increased the frequency of defecation (odds ratio 0.18, 95% confidence interval 0.05 to 0.67), and led to softer stools. Stimulant laxatives are likely to be effective if the problem doesn't resolve with fibre supplements.⁵⁶

Reflexology

One review was found on the effectiveness of a complementary therapy in treating constipation in pregnancy. It indicated that reflexology may be as effective as laxatives, but the studies were carried out on people with a diverse range of medical conditions, not including pregnancy, so there needs to be further evaluation of its effectiveness in pregnant women.⁵⁵

Conclusion

There is a paucity of research on complementary therapies to relieve constipation during pregnancy, perhaps because the conventional treatment of dietary fibre supplements is likely to help. Conventional medical advice to drink plenty of fluid and eat foods containing bran or fibre is unlikely to be objectionable to women as a first line treatment for constipation.

Anxiety

A number of therapies are said to alleviate maternal stress including: aromatherapy; Bach flower remedies; homeopathic remedies (such as chamomilla, gelesemium, lycopodium, nux vomica, pulsatilla, seria, aconite, aurum met);²⁹ massage; Qi Gong; reflexology; shiatsu;³⁰ yoga.

Cochrane review

No Cochrane review on this aspect of pregnancy has yet been conducted though a title has been registered for a future review on Mind-body interventions during pregnancy for preventing or treating women's anxiety and other perinatal outcomes.

Other research

A number of studies were found:

Aromatherapy

Twenty-six pregnant women were assigned

to a massage therapy or a relaxation therapy group for five weeks. Both groups reported feeling less anxious after the first session but only the massage therapy group reported reduced anxiety.⁵⁷ Another study, described as a systematic review⁵⁸ and including six small studies described as 'trials or 'clinical trials'. The methodological quality of the studies varied considerably, including methods of randomisation and blinding. The studies did not include pregnant women and no outcome statistics were reported. Although it appeared that aromatherapy might have a mild temporary effect in reducing anxiety, the authors concluded that the studies were 'all sufficiently flawed to prevent firm conclusions from being drawn'.⁵⁸

Hypnosis

In a study of 25 pregnant women who defined themselves as anxious, relaxation induced by hypnosis was found to be associated with increased foetal movements. Self-hypnosis (n = 16) and physician-induced hypnosis (n = 9) were both found to be associated with increased fetal movements, $p < 0.005$ and $p < 0.01$, respectively. The women reported that these techniques for inducing relaxation helped them to feel less tense. The authors concluded that hypnotherapy may have reduced maternal anxiety and catecholamine release, and as a consequence there was an improvement in placental blood perfusion and fetuses moved into a more active state.⁵⁹

Massage

One small-scale trial on 26 women reported decreased anxiety after five weeks of massage therapy with a reduction in level of norinephrine in the urine in the massage group.⁵⁴ A larger study (n=84) by the same author group on the effects of massage therapy on pregnant women with depression found lower levels of anxiety and depressed mood, reduced cortisol and norinephrine, higher dopamine and serotonin.⁵⁷

Conclusion

A review of aromatherapy and massage for antenatal anxiety found a reduction in anxiety, but recommended that further research is needed to establish the efficacy of such treatments.⁶⁰ The limited available evidence suggests that massage may be helpful in

treating anxiety during pregnancy, but more research is needed. Further research is also needed on inducing relaxation using hypnosis, which appears to be very promising.

Heartburn

The following complementary therapies are used for treating heartburn: aromatherapy;²⁷ homeopathic remedies (calc carb;²⁹ calc fluor;²⁹ carbo vegetalis;⁶¹ graphites;²⁹ lycopodium;²⁹ sandalwood or Asilone).⁴⁸ However there appear to be no RCTs of high quality as the Cochrane review on Interventions for heartburn in pregnancy, published in October 2008, includes no complementary therapies.⁶²

No other relevant studies were found.

Insomnia

A number of therapies are used for treating insomnia including: acupuncture;⁵⁴ aromatherapy;¹⁸ chiropractic;⁴⁹ herbal remedies (passionflower, valerian, Jamaican dogwood, hops, California poppy, chamomile, lemon balm, St. John's wort, kava kava, wild lettuce, scullcap, Patrinia root);⁶³ homeopathic remedy (coffea cruda);²⁹ massage.⁵⁴

Cochrane review

There is a Cochrane review on *Acupuncture for Insomnia*, published in 2007, but this is not limited to treatment of pregnant women. Seven studies were eligible for inclusion in the review (590 participants). The authors concluded that 'The studies were of low methodological quality and were diverse in the types of participant, acupuncture treatments and sleep outcome measures used, which limited the ability to pool the findings and draw conclusions.'⁶⁴

Other research

The search for this briefing found four relevant studies on different therapies.

Acupuncture

A study of 30 women indicated that acupuncture alleviates insomnia, but the study suffered from a high drop-out and small numbers, so further research is needed to confirm this finding.⁶⁵ A review study of the effect of acupuncture in the general population found that, despite methodological limitations, all consistently indicated improvements in insomnia.⁶⁶

Herbal remedies

No randomised controlled trials or reviews of such trials on herbal remedies in pregnant women were found, possibly due to the risks of running such a trial. A large-scale review of non-prescription sleep treatment research found a lack of rigorous scientific data for the majority of herbal supplements. The authors found that, 'Studies are limited by small numbers of participants and, in some instances, inadequate design, lack of statistical analysis, and sparse use of objective measurements.' There was sparse or no data on the efficacy of most products including chamomile and St. John's wort, and preliminary but conflicting evidence suggesting Valerian officinalis L. is efficacious in the short term. The paper highlighted significant potential risks associated with the use of Jamaican dogwood and kava kava, and did not address safety for pregnant women.⁶³

Massage

A small study (n=26) looked at massage therapy compared to relaxation therapy over a five week period. The massage therapy group reported better sleep by the last day of the study.⁵⁴

Conclusion

There is a lack of research evidence on the treatment of pregnant women with insomnia. Further research is needed. Some remedies, such as herbal remedies, may not be safe, particularly during pregnancy.

Implications for women

Many women experience uncomfortable and sometimes seriously distressing conditions associated with pregnancy. Not surprisingly, they want to find treatments that alleviate their symptoms and will not harm their baby or themselves. As many complementary therapies are unregulated and training for therapists may not be focused around the use of rigorous evidence or the need for particular caution during pregnancy, women need to be vigilant and aware of the potential for harm. On the other hand, therapies that are non-invasive and are based on a mind-body integrated or holistic approach to healthcare, such as massage, meditation, forms of gentle exercise and relaxation, may be beneficial and are unlikely to do harm. There is an urgent need for further research in order to answer ques-

tions of importance to women and families.

Currently, women should be made aware that there is a lack of high quality evidence for either the safety or effectiveness of most therapies for most pregnancy related complaints, including constipation, heartburn and insomnia. The interventions with most evidence are:

- **Pyroxidine (vitamin B6) for morning sickness** - women need information about the correct dose level from a competent practitioner.
- **Acupressure and ginger for morning sickness** - these therapies may work. There are no reported side effects for acupressure. The safety of ginger is less clear cut. The Cochrane review found no adverse side-effects, however Tiran cautions that it should not be used in large doses or for prolonged periods because of its anti-coagulant properties. It is difficult to control the composition of ginger supplements due to lack of regulation.
- **Acupuncture for back and pelvic pain in pregnancy** - may be effective but effects demonstrated were small, so more research is needed.
- **Massage and aromatherapy for anxiety** - may have a beneficial effect but more research is needed.

Implications for maternity services

Women like complementary therapies and will use them in pregnancy, so it is important that further research is carried out. In the meantime, all maternity services should ensure that there are some midwives and other health professionals who have been trained in the use of complementary therapies so that they can provide reliable and relevant information to women and their colleagues, using the best available knowledge.

Midwifery training should include the opportunity to learn about complementary therapies. In particular, as there is currently limited evidence in terms of both effectiveness and safety, midwives should be clear about the extent of their knowledge and the dangers of advising on, or offering, therapies of which they have limited knowledge.

Questions to ask when choosing a complementary therapist or considering a complementary treatment

As training in complementary therapies and regulation of complementary therapists is variable, it is important for women to ask questions and get satisfactory answers. Key issues are:

- The midwife's or therapist's length of training, whether it was full or part time etc.
- How pregnancy-related issues were covered in the training.
- The therapist's experience of treating pregnant women with a relevant condition.
- How the therapist stays up-to-date with new research in the area.
- Which professional body the therapist belongs to.
- How the therapy is regulated, if at all.
- Whether the therapist has insurance.

Summary and recommendations

- More research is needed into popular complementary therapies for common pregnancy conditions, particularly those where conventional medicine offers limited or no solutions or solutions with unacceptable side-effects.
- Women need access to clear information outlining the current lack of evidence and those very limited areas where there is evidence of effectiveness and safety.
- Midwives, GPs, obstetricians and health visitors need to understand the popularity of complementary therapies, and the large number of women who believe they are safe and natural. Their training and continuing education should enable them to assess the safety and effectiveness of therapies that they are asked about.
- NCT specialist workers should be aware of the limited evidence base and, in line

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with NCT policy, provide evidence-informed information within their competence and not give advice.

- Funding is needed for research on complementary therapies for use during pregnancy. Greater efforts need to be made to speed up the process for developing a regulatory process for all who claim to be therapists of any sort.
- There is a particular need for standardisation of herbal supplements, including their labelling, and regulation of those who prescribe their use.
- A future review will consider complementary therapies used by women when preparing for birth, including raspberry leaf, perineal massage, and therapies used when babies are presenting in a breech position.

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References

- Gaffney L, Smith C. The views of pregnant women towards the use of complementary therapies and medicines. *Birth Issues* 2004; 13 (2): 43-50.
- Drug use during pregnancy*. Available from: <http://www.merck.com/mmhe/sec22/ch259/ch259a.html#>
- Royal Pharmaceutical Society of Great Britain, British Medical Association. *British National Formulary*. 56th edition London: Pharmaceutical Press; 2008.
- Tiran D. The use of complementary therapies in midwifery practice: a focus on reflexology. *Complement Ther.Nurs.Midwifery* 1996; 2 (2): 32-7.
- Marcus DM, Snodgrass WR. Do no harm: avoidance of herbal medicines during pregnancy. *Obstet Gynecol* 2005; 105 (5): 1119-22.
- Mitchell M, Williams J, Hobbs E, et al. The use of complementary therapies in maternity services: a survey. *British Journal of Midwifery* 2006; 14 (10): 576-82.
- Gibson PS, Powrie R, Star J. Herbal and alternative medicine use during pregnancy: a cross sectional survey. *Obstet Gynecol* 2001; 97: S44-S45.
- Hepner DL, Harnett M, Segal S, et al. Herbal medicine use in parturients. *Anesthesia and Analgesia* 2002; 94 (3): 690-3.
- Ernst E, Pastore L. Home remedies used in pregnancy. *The Cochrane Library* 2000;3:529 In: Herbal medicinal products during pregnancy: are they safe? *Br J Obstet Gynaecol* 2002; 109 (3): 227-35.
- Pinn G, Pallett L. Herbal medicine in pregnancy. *Complement Ther.Nurs.Midwifery* 2002; 8 (2): 77-80.
- NHS Confederation. *Complementary medicine in the NHS: managing the issues*. NHS Confederation; 1997.
- The midwives rules and code of practice*. London: United Kingdom Central Council for Nursing, Midwifery and Health Visiting; 1998.
- Tiran D. *Is midwives' use of complementary therapies always justified? A risk assessment tool to guide practice*. Available from: [http://www.midirs.org/midirs/midszone.nsf/48BF3504CB45772B8025741E00515BA11OpenDocument](http://www.midirs.org/midirs/midszone.nsf/www.midirs.org/midirs/midszone.nsf/48BF3504CB45772B8025741E00515BA11OpenDocument)
- Tiran D. Complementary medicine and childbearing. *Diplomate* 1997; 4 (1): 7-11.
- Linde K, Jonas WB, Melchart D, et al. The methodological quality of randomized controlled trials of homeopathy, herbal medicines and acupuncture. *International Journal of Epidemiology* 2001; 30 (3): 526-31.
- Tiran D. The midwife's perspective: accountability versus advocacy. *MIDIRS Midwifery Digest* 2005; 15 (Suppl 1): S8-S11.
- Richardson J. The use of randomized control trials in complementary therapies: exploring the issues. *Journal of Advanced Nursing* 2000; 32 (2): 398-406.
- Tiran D, Price S. Pregnancy and childbirth. In: Price S, Price L, editors. *Aromatherapy for health professionals*. Churchill Livingstone: Edinburgh; 2006. pp. 269-84
- Report to Ministers from the Department of Health Steering Group on the statutory regulation of practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems practised in the UK. London: Department of Health; 2008. Available from: http://www.dh.gov.uk/en/Publicationsandstatistics/Publication/PublicationsPolicyAndGuidance/DH_086359
- Pittilo RM. An overview of the regulation of complementary medicine. *MIDIRS Midwifery Digest* 2005;15(Supplement 1):S5-S8.
- Complementary & Natural Healthcare Council. Available from: <http://www.cnhc.org.uk/pages/index.cfm>
- Bowen-Simkins P. A perspective from the Royal College of Obstetricians and Gynecologists. *MIDIRS Midwifery Digest* 2005; 15 (Supplement 1): 8.
- Westfall RE. Herbal healing in pregnancy: women's experiences. *J Herb Pharmacother* 2003; 3 (4): 17-39.
- Beal MW. Women's use of complementary and alternative therapies in reproductive health care. *J.Nurse Midwifery* 1998; 43 (3): 224-34.
- Johnston J. Homeopathy in midwifery. *MIDIRS Midwifery Digest* 2008; 18 (2): 185-7.
- Jewell D, Young G. Interventions for nausea and vomiting in early pregnancy. *Cochrane Database of Systematic Reviews* 2003, Issue 4. Art. No.: CD000145. DOI: 10.1002/14651858.CD000145. Available from: <http://www.library.nhs.uk/Default.aspx>
- Aromatherapy and midwifery. *Aromatherapy Quarterly* 1996; (49): 19-23.
- Wilkinson JM. What do we know about herbal morning sickness treatments? A literature survey. *Midwifery* 2000;16 (3): 224-8.
- Ford JM. Homeopathy in pregnancy. 2. *Midwives Chronicle* 1988; 101 (1205): 185-7.
- Yates S. Supporting women with shiatsu - another tool for keeping birth normal. *MIDIRS Midwifery Digest* 1998; 8 (4): 422-4.
- Sahakian V, Rouse D, Sipes S, et al. Vitamin B6 is effective therapy for nausea and vomiting of pregnancy: a randomized, double-blind placebo-controlled study. *Obstetrics and Gynecology* 1991; 78 (1): 33-6.
- Vutyavanich T, Kraissarin T, Ruangsri R. Ginger for nausea and vomiting in pregnancy: randomized, double-masked, placebo-controlled trial. *Obstet Gynecol* 2001; 97 (4): 577-82.
- Belluomini J, Litt RC, Lee KA, et al. Acupressure for nausea and vomiting of pregnancy: a randomized, blinded study. *Obstetrics and Gynecology* 1994; 84 (2): 245-8.
- Smith C, Crowther C, Beilby J. Acupuncture to treat nausea and vomiting in early pregnancy: a randomized controlled trial. *Birth* 2002; 29 (1): 1-9.
- O'Brien B, Relyea MJ, Taerum T. Efficacy of P6 acupressure in the treatment of nausea and vomiting during pregnancy. *American Journal of Obstetrics and Gynecology* 1996; 174 (2): 708-15.
- Knight B, Mudge C, Openshaw S, et al. Effect of acupuncture on nausea of pregnancy: a randomized, controlled trial. *Obstet Gynecol* 2001; 97 (2): 184-8.
- Anderson FW, Johnson CT. Complementary and alternative medicine in obstetrics. *Int J Gynaecol Obstet* 2005; 91 (2): 116-24.
- Fugh-Berman A, Lione A, Scialli AR. Do no harm: avoidance of herbal medicines during pregnancy. *Obstet Gynecol* 2005; 106 (2): 409-11.
- Fischer-Rasmussen W, Kjaer SK, Dahl C, et al. Ginger treatment of hyperemesis gravidarum. *Eur J Obstet Gynecol Reprod Biol* 1991; 38 (1): 19-24.
- Portnoi G, Chng LA, Karimi-Tabesh L, et al. Prospective comparative study of the safety and effectiveness of ginger for the treatment of nausea and vomiting in pregnancy. *American Journal of Obstetrics and Gynecology* 2003; 189 (5): 1374-7.
- Willetts KE, Ekangaki A, Eden JA. Effect of a ginger extract on pregnancy-induced nausea: a randomised controlled trial. *Aust.N.Z.J Obstet Gynaecol* 2003; 43 (2): 139-44.
- Smith C, Crowther C, Willson K, et al. A randomized controlled trial of ginger to treat nausea and vomiting in pregnancy. *Obstet Gynecol* 2004; 103 (4): 639-45.
- Tiran D. Nausea and vomiting in pregnancy: safety and efficacy of self-administered complementary therapies. *Complement Ther.Nurs.Midwifery* 2002; 8 (4): 191-6.
- Pennick VE, Young G. *Interventions for preventing and treating pelvic and back pain in pregnancy*. Cochrane Database of Systematic Reviews 2007, Issue 2. Art. No.: CD001139. DOI: 10.1002/14651858.CD001139.pub2. Available from: <http://www.library.nhs.uk/Default.aspx>
- Stapleton DB, MacLennan AH, Kristiansson P. The prevalence of recalled low back pain during and after pregnancy: a South Australian population survey. *Aust.N.Z.J Obstet Gynaecol* 2002; 42 (5): 482-5.
- Wang SM. Backaches related to pregnancy: the risk factors, etiologies, treatments and controversial issues. *Curr.Opin.Anaesthesiol.* 2003;16 (3): 269-73.
- Wang SM, DeZinno P, Fermo L, et al. Complementary and alternative medicine for low-back pain in pregnancy: a cross-sectional survey. *J Altern.Complement Med* 2005; 11 (3): 459-64.
- Price S. Aromatherapy and the pregnant woman. *Association of Radical Midwives Magazine* 1986; (31): 18-9.
- Fuscaldo M. The chiropractor in maternal care. *Ovarian Connection* 2004; 2 (3): 23-4.
- Suputtitada A, Wacharapreechanont T, Chaisayan P. Effect of the "sitting pelvic tilt exercise" during the third trimester in primigravidas on back pain. *Journal of the Medical Association of Thailand* 2002; 85 Suppl 1:S170-S179.
- Kihlstrand M, Stenman B, Nilsson S, et al. Water-gymnastics reduced the intensity of back/low back pain in pregnant women. *Acta Obstetrica et Gynecologica Scandinavica* 1999; 78 (3): 180-5.
- Elden H, Ladfors L, Olsen MF, et al. Effects of acupuncture and stabilising exercises as adjunct to standard treatment in pregnant women with pelvic girdle pain: randomised single blind controlled trial. *BMJ* 2005; 330 (7494): 761-4.
- Wedenberg K, Moen B, Norling A. A prospective randomized study comparing acupuncture with physiotherapy for low-back and pelvic pain in pregnancy. *Acta Obstet Gynecol Scand.* 2000; 79 (5): 331-5.
- Field T, Hernandez-Reif M, Hart S, et al. Pregnant women benefit from massage therapy. *J Psychosom.Obstet Gynaecol* 1999; 20 (1): 31-8.
- Tiran D. Self help for constipation and haemorrhoids in pregnancy. *British Journal of Midwifery* 2003; 11 (9): 579-81.
- Jewell D, Young G. *Interventions for treating constipation in pregnancy*. Cochrane Database of Systematic Reviews 2001, Issue 2. Art. No.: CD001142. DOI: 10.1002/14651858.CD001142. Available from: www.library.nhs.uk/Default.aspx
- Field T, Diego MA, Hernandez-Reif M, et al. Massage therapy effects on depressed pregnant women. *J Psychosom.Obstet Gynaecol* 2004; 25 (2): 115-22.
- Cooke B, Ernst E. Aromatherapy: a systematic review. *Br J Gen Pract* 2000; 50 (455): 493-6.
- Zimmer EZ, Peretz BA, Eyal E, et al. The influence of maternal hypnosis on fetal movements in anxious pregnant women. *Eur J Obstet Gynecol Reprod Biol* 1988; 27 (2): 133-7.
- Bastard J, Tiran D. Aromatherapy and massage for antenatal anxiety: its effect on the fetus. *Complement Ther Clin Pract* 2006; 12 (1): 48-54.
- Geraghty B. *Homeopathy for midwives*. New York: Churchill Livingstone; 1997.
- Dowswell T, Neilson JP. *Interventions for heartburn in pregnancy*. Cochrane Database of Systematic Reviews 2008, Issue 4. Art. No.: CD007065. DOI: 10.1002/14651858.CD007065.pub2. Available from: www.library.nhs.uk/Default.aspx
- Meolie AL, Rosen C, Kristo D, et al. Oral nonprescription treatment for insomnia: an evaluation of products with limited evidence. *J.Clin.Sleep Med.* 2005; 1 (2): 173-87.
- Cheuk DK, Yeung J, Chung KF, and Wong V. *Acupuncture for insomnia*. Cochrane Database of Systematic Reviews 2007, Issue 3. Art. No.: CD005472. DOI: 10.1002/14651858.CD005472.pub2. Available from: www.library.nhs.uk/Default.aspx
- da Silva JB, Nakamura MU, Cordeiro JA, et al. Acupuncture for insomnia in pregnancy - a prospective, quasi-randomised, controlled study. *Acupunct.Med.* 2005; 23 (2): 47-51.
- Kalavapalli R, Singareddy R. Role of acupuncture in the treatment of insomnia: a comprehensive review. *Complement Ther.Clin.Pract.* 2007;13(3):184-93.