Alternative therapies and Department of Veterans' Affairs Gold and White Card arrangements

Literature review

Prepared by Biotext
September 2010



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Abbreviations

CAM	complementary and alternative therapies
DVA	Australian Government Department of Veterans' Affairs
NHMRC	National Health and Medical Research Council
PBS	Pharmaceutical Benefits Scheme
RCT	randomised controlled trial
RPBS	Repatriation Pharmaceutical Benefits Scheme

Summary

Efficacy of treatments

Conclusions from the literature review are presented below in boxes, with an estimate of the level of evidence, based on the levels assigned by the National Health and Medical Research Council, and accompanying explanatory text.

High-quality systematic reviews of randomised controlled trials (eg Cochrane reviews) are level I, and well-designed randomised controlled trials are level II (see Section 1.4 for more information).

Acupuncture and acupressure

Acupuncture may be beneficial for treating the symptoms of low back pain (level II), migraines (level I), allergic rhinitis (level II), vomiting after chemotherapy (level I) and back or pelvic pain in pregnancy (level I).

In general, there is not enough evidence to make recommendations about the safety or efficacy of acupuncture (compared with other treatments, no treatment, or placebo) for other conditions. Trials were often underpowered and characterised by poor methods and reporting.

Relatively few trials looked at acupressure.

Aromatherapy

Results from one randomised controlled trial suggest that aromatherapy massage may have a clinically meaningful benefit on anxiety and depression for people with cancer, but only in the short term (less than six weeks) (level II).

Limited information from randomised controlled trials or systematic reviews is available on aromatherapy or aromatherapy massage.

Homeopathy

The literature on homeopathic treatments is characterised by poor methodology and reporting. No recommendations could be made for any indications.

Few adverse effects have been reported for homeopathy, possibly due to the low concentrations of treatments.

Hypnotherapy and hypnosis

Hypnotherapy may help smokers to continue to abstain from smoking in the long term, when used in conjunction with nicotine patches; however, this is based on a single trial (level II). Hypnotherapy may also help to improves symptoms of depression (level I) and psychosomatic disorders (level I).

Many clinical trials and observational studies have looked at the efficacy of hypnotherapy, although their methodological quality is generally low.

Massage or therapeutic touch

Massage or therapeutic touch can help to reduce the likelihood of perineal tears during and following a vaginal birth (level I).

Many randomised controlled trials have looked at the effects of massage or therapeutic touch for other conditions, and these trials have been summarised in systematic (Cochrane) reviews. Although massage or therapeutic touch seems to be beneficial for some conditions, there is not enough evidence to make any other conclusions, because most trials are poor quality (eg too small, high risk of bias, poorly reported), or no research has been done.

Meditation

Meditation may help to reduce blood pressure (level I).

Many systematic reviews have looked at the effects of different types of meditation, most commonly on anxiety, depression and stress. In general, the reviews found that there are not enough data from high quality trials to tell whether meditation is effective for many indications.

Music therapy

Music therapy appears to be beneficial for improving people's experiences of surgery, specifically preoperative fear and anxiety associated with colonoscopy (level I) and reducing procedure time of colonoscopy (level I).

Music therapy also appears to be beneficial for relieving postoperative pain, when combined with usual pain relief medication (level II) and anxiety, especially when combined with anxiolytic medications (level I).

When combined with standard care, there are also benefits on mental state, negative symptoms and social functioning in people with schizophrenia, in the short term (one to three months), although it is not clear how many sessions are needed (level I).

In general, most trials (individual trials, as well as those included in the Cochrane reviews) had poor reporting of adverse effects. Those that did report adverse effects found few (which were not statistically significant) or none associated with music therapy. Furthermore, music therapy has a low drop-out rate.

Reflexology and relaxation therapy

Relaxation therapy can help to improve self-reported depression compared with a wait list or no treatment, and may be useful as a first-line therapy before more complex psychological interventions is used (level I).

Limited conclusions can be drawn from most trials or reviews of relaxation therapy, because of poor quality. There are no published systematic reviews of reflexology.

Reiki

Reiki administered by experienced practitioners may reduce pain intensity in adults, but higher-quality trials are needed (level I).

Limited high-quality research has been published on the effects of reiki.

Tai chi

Tai chi helps to reduce the rate of falls and risk of falling for elderly people who live at home (but not for those in hospitals or nursing homes) (level I). Tai chi may also help to improve sleep quality, and quality of life for people with fibromyalgia (level II). Evidence for the effect of tai chi on different types of arthritis is mixed. A Cochrane review of rheumatoid arthritis found no significant effects, except for an improvement in plantar flexion, but more trials involving larger numbers of people are needed (level I). Several small trials found that tai chi improved symptoms of osteoarthritis (pain, physical function, bone density and fear of falling), but these effects may only last up to six weeks, and more trials (involving greater numbers of people) are needed (level II).

Yoga

It is likely that yoga helps to improve psychological outcomes (including anxiety) in women with breast cancer, although larger trials are still needed (level II).

Many trials have looked at the effects of yoga on other health and psychological outcomes, and although yoga often appears to be beneficial, few trials are of a high enough quality to draw conclusions.

Qualifications and training of therapists

Complementary and alternative medicine is a largely unregulated industry in Australia and there is variation across the states and territories for registration requirements.

Medical practitioners may be unlikely to refer patients to an unlicensed health practitioner, for fear of legal repercussions if harm is caused. However, if the industry is regulated, medical practitioners may feel more secure in making referrals to CAM practitioners. In addition, patients may be more likely to tell their medical practitioner if they are seeing a CAM practitioner.

How Australia compares internationally

Most guidelines from other countries mention the lack of scientific data for many complementary therapies, and recommend and support further research and revision of guidelines as the evidence base grows.

The United Kingdom has national guidelines for the use of complementary therapies in supportive and palliative care. Therapies include aromatherapy, massage, reflexology, reiki, spiritual healing, therapeutic touch, hypnosis and hypnotherapy, acupuncture, and homeopathy. More recently in the United Kingdom, the Complementary and Natural Healthcare Council was established to regulate a range of complementary therapies. The council has a code of conduct, performance and ethics, and registration is voluntary.

In the United States, the White House Commission on Complementary and Alternative Medicine Policy recommends coordination and support for research and programs on complementary and alternative medicine.

A global survey on policy and regulation for traditional medicine by the World Health Organization (WHO) found that 45 of the 141 responding member states reported having a national policy on traditional or complementary medicines, and 51 member states were in the process of developing one. WHO recognises that countries face major challenges in developing and implementing regulation of traditional or complementary medicines. These challenges relate to regulatory status, safety and efficacy, quality control, safety monitoring, and a lack of knowledge about traditional or complementary medicines within national drug regulatory authorities.

Australia's approach to funding alternative therapies is in line with the rest of the world. Veterans in Canada and New Zealand may be eligible to receive funding from veterans' affairs organisations for some specialist treatments such as acupuncture and massage therapy, but those in the United Kingdom and the United States are not. Similarly, while health care and regulatory systems differ widely between countries, private health insurance benefits for alternative therapies are limited in all countries examined in this review.

Part A — Background and methods

1 Introduction

The Australian Government Department of Veterans' Affairs (DVA) recently reviewed whether to fund services provided by alternative therapy providers under its health purchasing arrangements. The review considered the safety and effectiveness of treatment types, and the availability of appropriately regulated and qualified health professionals to deliver treatment.

The review required updating and amendment to include a more comprehensive summary of the highest-quality studies published on alternative therapies, and an analysis of the evidence base for their effectiveness.

Biotext Pty Ltd was engaged to review the literature on alternative therapies and the qualifications of therapists, and this document provides a report of the review. The task set out in the terms of contract was to 'provide a review of the literature on alternative therapies in Australia'. This included:

- evidence for the effectiveness of the therapy
- adverse effects, where reported
- qualifications and training of therapists
- how the Australian situation compares with what is available or recommended internationally, including a brief overview of national and international guidelines on alternative therapies.

Note that we did not review cost effectiveness of therapies, because of the limited time available for the literature review, and the large volume of information on efficacy to analyse.

1.1 Definition of alternative therapy

Alternative therapies offer an alternative to, and are used instead of, conventional diagnosis and therapies. Complementary and alternative therapies (CAM), complement, or are used alongside, conventional diagnosis and therapies. CAM include a diverse range of health care practices and products, which may not be integrated into conventional medicine or the dominant health care system.

In Australia, the current health care framework of DVA and Medicare does not cover CAM explicitly. Pharmaceuticals and dressings are provided to eligible veterans, war widows/widowers, and their dependants at a concession rate through the Repatriation Pharmaceutical Benefits Scheme (RPBS). This scheme provides pharmaceuticals and dressings that are available to the general community under the Pharmaceutical Benefits Scheme (PBS); it also provides items that are only available to veterans and items that are determined on a case-by-case basis.

1.2 Topics covered by the literature review

The literature review covered the following topics:

1. The efficacy of different alternative therapies for various conditions.

2. The availability of appropriately qualified and regulated health professionals to deliver treatment.

3. How Australia compares internationally — that is, what alternative therapies are covered by international guidelines and consensus statements.

In this review, we used the National Health and Medical Research Council's (NHMRC) definitions of 'effectiveness' (the extent to which an intervention produces favourable outcomes under usual or everyday conditions) and 'efficacy' (the extent to which an intervention produces favourable outcomes under ideally controlled conditions, such as a randomised controlled trial).

Details of methods are provided in the following sections.

1.3 What is meant by the term 'evidence'?

Evidence is the term for the results from a scientific test or study, and can also provide information about the value of a test or type of research. Evidence is highly valued in health care as it takes into account clinical judgement and expertise, and external evidence, to assist the health care practitioner and consumer make treatment decisions that are most likely to lead to a positive outcome.

Evidence generated from well-conducted randomised controlled trials (RCTs) can assist good decision making about interventions. When there have been no RCTs, or where RCTs are impossible or inappropriate, evidence from other types of studies (eg case studies, registries, observational data) can be used. However, these need to be carefully appraised so that any resulting recommendations can be graded according to the quality of the information upon which they are based.

The NHMRC provides a 'hierarchy of evidence' in its handbook, *How to Review the Evidence: Systematic Identification and Review of the Scientific Literature*.[1] This hierarchy (shown in Table 1) sets out the value of different types of evidence, based on how the evidence is gathered.

[1] National Health and Medical Research Council (2000). *How to Review the Evidence: Systematic Identification and Review of the Scientific Literature: Handbook Series on Preparing Clinical Practice Guidelines,* National Health and Medical Research Council, Canberra. http://www.health.gov.au/hfs/nhmrc/publications/synopses/cp65syn.htm .

Table 1.1 NHMRC levels of evidence

Level	Description
I	Evidence obtained from a systematic review of all relevant randomised controlled trials
II	Evidence obtained from at least one properly designed randomised controlled trial
III-1	Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method)
III-2	Evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case–control studies, or interrupted time series with a control group
III-3	Evidence obtained from comparative studies with historical control, two or more single-arm studies, or interrupted time series without a parallel control group
IV	Evidence obtained from case series, either post-test, or pre-test and post-test

NHMRC = National Health and Medical Research Council

Large, high-quality RCTs are difficult, time consuming and expensive to run. It is difficult to recruit suitable participants, and to limit the number of participants who drop out over the course of the trial (especially for trials that run for many years). It is also difficult to run RCTs in cases of rare disease, where the trial group is too small or where it is unethical to withhold treatment for a period of time.

Finding high-quality research in the huge volume of published medical trials is challenging — around 3000 medical articles are published each day. Systematic reviews and meta-analyses, when they are done well, can help overcome these challenges by combining evidence from a large number of scientific studies and providing easily accessible systematised outputs. Systematic reviews can be more powerful than a single study, because they combine multiple studies, show unresolved issues, limit bias and answer questions in a short time frame.

A systematic review starts by defining a specific research question and then including and excluding trials according to precise selection criteria. The quality of the research methods in the included trials is assessed, and the results from separate trials are combined using statistics (pooling of the data, or 'meta-analysis') if the trials are similar or 'homogeneous' enough (that is, if they measure and report characteristics and outcomes in the same way). If trials are too different (heterogeneous), the results cannot be combined in a meta-analysis. Results from meta-analyses can be used to make more robust recommendations about the effects of an intervention than recommendations made from single studies on their own. However, meta-analyses are still limited by the quality of the initial research trials and how similar the trials are to each other.

The Cochrane Collaboration is an international organisation that helps people to make well-informed health care decisions. The collaboration produces and disseminates systematic reviews of health care interventions, in forms that are written, published and structured so that they are accessible by health care consumers and health care providers. Cochrane reviews are considered to be the 'gold standard' in evidence-based medicine.

In this review, we have therefore preferentially selected Cochrane reviews over individual trials, and we have discussed the evidence from these reviews carefully. In particular, we have distinguished between:

- evidence of benefit or harm (drawn from large, high-quality trials showing a statistically and clinically significant effect)
- evidence of no effect (drawn from large, high-quality trials showing a no statistically significant effects)

- no evidence, or not enough evidence (eg no trials, only poor-quality trials; in these cases, more research is required before any conclusions can be made).

In this document, we will interpret the evidence using these criteria.

2 Search methods

2.1 Overview

Even though this literature review is not a systematic review — a systematic search of the literature on such a large number of therapies is beyond the scope of this project (and would take far in excess of the four-week timeframe available) — it does follow the overarching principles of systematic review and evidence-based practice:

- a well-defined research question built according to the PICO (population, intervention, comparator, outcome) model
- a comprehensive search strategy using pre-defined key terms and limits, which incorporates the elements of the research question
- clearly documented and transparent search methods
- objective and critical analysis of the results.

However, we have not compiled an exhaustive list of inclusion or exclusion criteria; nor have we used data extraction tables for included studies or quality appraisal criteria. Finally, we have not attempted to grade the body of evidence in the way set out by the NHMRC (although we have been mindful of the NHMRC's six-point rating system for levels of evidence).[1]

Where available, we have used high-quality systematic reviews (eg Cochrane Reviews) or meta-analyses. Where high-quality systematic reviews or meta-analyses were not available, or were more than five years old, we selected randomised controlled trials (RCTs). We excluded papers that were not peer reviewed or that lacked some other marker of quality. The restrictions imposed by these search criteria (ie restricting the search to Cochrane reviews, meta-analyses less than five years old, and RCTs) meant that other studies (small numbers of meta-analyses, well-designed non-RCTs) were excluded. The consequence is many recommendations to seek higher-quality evidence.

2.2 Search strategy

Our search consisted of three components: the effects of treatment, the availability of practitioners or services, and international standards or practice guidelines.

For each of the three topics, we loosely framed the search on the 'PICO' principle (**p**opulation, **i**ntervention, **c**omparator, **o**utcome), as shown in the topic matrix below. However, we did not define the population at the outset, because veterans include all groups and ages. Therefore, we did not limit the search according to population, although we sought (within the constraints identified) studies that name veterans as the population of interest. Similarly, we included papers that used any comparator (including placebo).

[1] See http://www.nhmrc.gov.au/guidelines/consult/consultations/add_levels_grades_dev_guidelines2.htm

2.2.1 Search 1: treatment efficacy

The search for papers on the effects of various therapy types follows the topic grid shown in Table 2.1, below. Searches were limited to papers published in English in the past five years (since 2005). Inclusion criteria were:

- clinical trials
- practice guidelines
- meta-analyses
- randomised controlled trials
- human trials.

If no papers were retrieved, we removed the inclusion criteria. We also ran one broad search (see below) to check for any papers that may have been missed in the more specific searches listed in the topic grid.

Table 2.1 Topic grid for Search 1

Intervention	Outcome	Study type
acupuncture or acupressure aromatherapy massage or healing or therapeutic touch reflexology or relaxation homeopathy or homoeopathy hypnotherapy or hypnosis meditation reiki music therapy tai chi yoga	(treatment outcome, or rehabilitation outcome or treatment effectiveness or treatment efficacy or efficacy or prognosis) or (cost effectiveness or cost-effectiveness or cost or cost-benefit or cost benefit) or (pain or anxiety or depression or well-being or well being or wellbeing or quality of life)	clinical or trial* or controlled or randomised or non-randomised or systematic review* or qualitative or study or research or project or audit or evaluation or pilot or patient* survey* or consumer choice
Broad search string		
(alternative therap* or alternative medicine or complementary medicine or complementary therap* or herbal medicine or Chinese medicine or Chinese herbal medicine) or (acupuncture or aromatherapy or massage or reflexology or homeopathy or homoeopathy or acupressure or hypnotherapy or hypnosis or meditation or relaxation or healing or therapeutic touch or reiki or music therapy or tai chi or yoga)		
AND		
(treatment outcome or rehabilitation outcome or treatment effectiveness or treatment efficacy or efficacy or prognosis) or (cost effectiveness or cost-effectiveness or cost or cost-benefit or cost benefit) or (pain or anxiety or depression or well-being or well being or wellbeing or quality of life) or health		
AND		
(clinical or trial* or controlled or randomised or non-randomised or systematic review* or qualitative or study or research or project or audit or evaluation or pilot or patient* survey* or consumer choice)		

2.2.2 Search 2: practitioners and services

We searched for information on training, qualifications and regulation of therapists using the search string shown in Table 2.2, below. The search was limited to papers published in English in the past five years (since 2005) and on human trials.

Table 2.2 Topic grid for Search 2

alternative therap* or alternative medicine or complementary medicine or complementary therap* or herbal medicine or Chinese medicine or Chinese herbal medicine
AND
(teaching or training or practitioner training or practitioner education or medical education quality or provider training) or (standards or professional standards or professional practices or qualification*) or (therapis* or servic*) or (regulation or registration or industry regulation or self-regulation or competency) or (herbal medicine/education or herbal medicine/standards) or (professional autonom* or professional competenc*) or (quality of health care or safety of health care)
AND
Australia
NOT
(trial or clinical trial) or (intervention or cost effectiveness)

2.2.3 Search 3: standards, regulations, guidelines and codes

The final search, of national and international standards, regulations or guidelines, was limited to those published in English, and fell within the following inclusion criteria:

- practice guidelines
- guidelines
- human trials.

Table 2.3 Topic grid for Search 3

(alternative therap* or alternative medicine or complementary medicine or complementary therap* or herbal medicine or Chinese medicine or Chinese herbal medicine) **or** (acupuncture or aromatherapy or massage or reflexology or homeopathy or homoeopathy or acupressure or hypnotherapy or hypnosis or meditation or relaxation or healing or therapeutic touch or reiki or music therapy or tai chi or yoga)
AND
guidelin* or practice guidelin* or standard or code or regulat* or quality or safety or polic* or decision* or fund*

2.3 Sources searched

We searched the following for relevant reviews and primary studies:

- Cochrane Library (including the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews and Effects, and the Cochrane Central Register of Clinical Trials)
- PubMed (MEDLINE)
- clinicaltrials.gov
- a general web search.

We selected the relevant titles from each database and download included papers into an EndNote database.

Part B — Results of Search 1
Efficacy of therapies

3 Acupuncture and acupressure

3.1 What is it?

Acupuncture is the practice of puncturing the skin with long, very fine needles. Particular areas, called acupoints, are targeted. The result is an analgesic effect. It is not known how this effect occurs, but it is thought that acupuncture may produce endorphins, which are the body's natural pain relievers.

Acupressure is based on the same theory as acupuncture, but rather that using needles to produce an effect, pressure is used from a therapist's fingers or hands, similar to a massage.

3.2 What is the evidence?

Summary

Relatively few trials looked at acupressure.

In general, there is not enough evidence to make recommendations about the safety or efficacy of acupuncture (compared with other treatments, no treatment, or placebo) for most conditions. Trials were often underpowered and characterised by poor methods and reporting.

Acupuncture may be beneficial for treating the symptoms of low back pain (level II), migraines (level I), allergic rhinitis (level II), vomiting after chemotherapy (level I) and back or pelvic pain in pregnancy (level I).

Indications for which acupuncture is effective	
• Lower back pain (possibly) • Migraine prophylaxis (when used with routine care, for regular attacks; is also at least as effective as drug prophylaxis but with fewer adverse effects; however, may be no different from sham acupuncture)	• Allergic rhinitis (for up to three months) • Vomiting after chemotherapy (when used with antiemetic drugs that are now superseded) • Back or pelvic pain in pregnancy
Indications for which acupuncture is not effective	
• Long-term smoking cessation • Conception (if used around the time of oocyte retrieval)	• Epilepsy
Indications for which there is not enough evidence	
• Asthma • Stroke • Joint pain (lateral elbow, shoulder, chronic neck pain) • Rheumatoid arthritis • Bell's palsy • Insomnia	• Breathlessness • Vascular dementia • Restless leg syndrome • Addiction (cocaine; smoking cessation up to three months) • Depression (general; postnatal) • Schizophrenia

• Conception (when used on the day of embryo transfer)	• Induction of labour
• Labour pain	• Uterine fibroids
• Glaucoma	• Irritable bowel syndrome
• Postoperative nausea and vomiting	
Systematic reviews in process	
• Fibromyalgia	• Parkinson's disease
• Premenstrual syndrome	

Note: most trials looked at acupuncture, not acupressure

Many Cochrane reviews have been published on acupuncture or acupressure to treat various conditions. We have summarised these reviews below, as well as any additional RCTs or other studies of a reasonable quality, which were not already included in the Cochrane reviews (eg because of recency of publication, or difference in topic).

Overall, there is a lack of evidence upon which recommendations can be made about the safety or efficacy of acupuncture. Many of the RCTs included in the Cochrane reviews were characterised by poor reporting of adverse effects (few reported any information on adverse effects); poor reporting of methods (especially randomisation, allocation concealment, blinding, intention-to-treat analysis); high risk of bias; and small sample sizes. There was substantial heterogeneity among trials, including in the types of acupuncture, control treatments (eg different types of sham acupuncture[3] or other placebo), acupoints used, delivery methods, number of treatments, and training of those administering the interventions.

3.2.1 Cardiovascular

Asthma

The last Cochrane review of acupuncture for asthma (or asthma-like symptoms) was published in 2003, and concluded that there was not enough evidence to make any recommendations (McCarney et al 2003). The review was updated in 2008, with no changes to the conclusions. The twelve RCTs (*N*=350) that were included were heterogeneous (different types of acupuncture interventions, including some given as a combination therapy; different types of placebo and sham controls; outcomes measured in different ways and at different time points). In addition, the trials' quality and reporting methods were poor; none of the trials reported on adverse effects. Data pooling was only possible for two outcomes (needle acupuncture compared with sham for lung function measures and overall wellbeing), but neither had a statistically or clinically significant difference between treatment and control.

Breathlessness

A Cochrane review of nonpharmacological interventions for breathlessness in advanced stages of diseases (advanced stages of cancer, chronic obstructive pulmonary disease, interstitial lung disease, chronic heart failure or motor neurone disease) included 47 RCTs, three of which used acupuncture (109 participants), and two of which used acupressure (75 participants) (Bausewein et al 2008). Trials were too heterogeneous (different interventions, different length of interventions — from seven days to six weeks,

[3] Note that there are standardised methods for administering sham acupuncture, which is used as a placebo in many trials. Sham acupuncture involves needling an area that is not a recognised acupoint, or an area that is believed to be ineffective for an indication. It can also include placing needles on the skin without penetration.

data collection and timing of measurements) to pool data. The authors concluded that there was not enough evidence to make a decision about the use of acupuncture or acupressure for treating breathlessness.

Stroke

Three Cochrane reviews have looked at acupuncture for stroke:

- Wu et al (2006) reviewed five trials (*N*=368) of acupuncture for rehabilitation after stroke (any outcome), none of which met standards for methodological quality. Trials were too heterogeneous to pool data. The trials did not report death, dependency, institutional care, change of neurological deficit score, quality of life or adverse events.
- Zhang et al (2005) reviewed 14 RCTs (*N*=1208) using acupuncture for acute stroke (eg death, dependency, institutional care, adverse effects). Where trials were adequately homogeneous, data were pooled — although the meta-analyses were based on low numbers of participants, and may therefore be too underpowered to produce robust results. Acupuncture was better than sham acupuncture or open control for death or dependency (OR 0.66, 95%CI 0.43 to 0.99), and for death or institutional care (OR 0.58, 95%CI 0.35 to 0.96). Global neurological deficit scores were significantly better in the acupuncture group during treatment (SMD 1.17, 95%CI 0.30 to 2.04). Acupuncture was significantly better than sham acupuncture for death or requiring institutional care (OR 0.49, 95%CI 0.25 to 0.96), but not for death or dependency (OR 0.67, 95%CI 0.40 to 1.12), or change of global neurological deficit score (SMD 0.01, 95%CI –0.55 to 0.57). Severe adverse events with acupuncture (dizziness, intolerable pain and infection of acupoints) were rare (6/386, 1.55%). The review authors concluded that acupuncture appeared to be safe, but no other conclusions could be drawn based on the data available.
- Xie et al (2008) reviewed acupuncture for dysphagia after acute stroke. They only found one trial (*N*=66), in which 34 people received acupuncture plus standard Western medical treatment (compared with 34 controls who received standard Western medical treatment only). There was no statistical difference between groups for returning to normal feeding.

Vascular dementia

Weina et al (2007) searched for RCTs of acupuncture to treat vascular dementia (with outcomes of cognitive function, activities of daily living, behaviour, quality of life, institutional care and mood, and adverse effects). However, no trials met the inclusion criteria, due to inadequate randomisation, acupuncture used as a combined treatment, and control participants receiving other medications of unknown efficacy.

No other RCTs of acupuncture for vascular dementia have been published in English since 2007.

3.2.2 Musculoskeletal conditions

Back or joint pain

Furlan et al (2005) reviewed the evidence for acupuncture to treat lower back pain. Only three small RCTs were found, and no conclusions could be made because of a lack of data (although the data suggested that acupuncture may be better than no treatment or sham treatment for chronic low-back pain). A small nonrandomised, uncontrolled trial of 72 Japanese factory workers with lower back pain (70 men) investigated the effect of acupuncture on perceived pain, mood disturbances and medical expenses related to back pain (Sawazaki et al 2008). After eight weeks (one session of acupuncture a week), participants reported less pain ($P<0.01$) and decreased total mood disturbance score ($P<0.001$). Number of hospital visits were also decreased (12.1 ± 8.0 vs. 0.8 ± 0.8 per month; $P<0.05$), as were standardised medical expenses (100.1 ± 89.6 vs. 7.3 ± 6.9 per month; $P<0.05$).

Green et al (2002) searched for RCTs of acupuncture for lateral elbow pain. Any trials that compared acupuncture with placebo or other interventions, and measured outcomes of pain decrease, improvement in function, grip strength and adverse effects were deemed eligible for inclusion. Only four small RCTs were found (sizes ranging from 48–93 participants), and meta-analysis was impossible due to clinical differences among the trials, and poor methodological quality. Although there appeared to be some short-term benefit of needle acupuncture (compared with placebo) (weighted mean difference=18.8 hours, 95%CI 10.1 to 27.5), this was based on 48 participants only, and there was a moderate risk of bias. Therefore, the review authors concluded that there is not enough evidence to make any conclusions. None of the trials reported on adverse effects.

Green et al (2005) looked at the safety and efficacy of acupuncture for different types of shoulder disorders (eg adhesive capsulitis, rotator cuff disorder, osteoarthritis). Once again, there was limited research — only nine were included, all with small sample sizes and poor methodological quality, including inadequate reporting of interventions. There was also a great deal of variation among the types of acupuncture and controls used. Despite this, the review authors pooled trial data where possible. Acupuncture was no different from placebo for short-term effects, although this was based on a very small sample, and may have been caused by type II error (where a hypothesis is rejected incorrectly). Conversely, acupuncture appeared to be better then placebo for shoulder function at four weeks (weighted mean difference 17.3 [7.79, 26.81]), but at four months, the difference was not clinically significant, despite being statistically significant (weighted mean difference 3.53 [0.74, 6.32]). Overall, the review authors concluded that there was not enough evidence to determine the effects of acupuncture on shoulder disorders.

In another Cochrane review, Trinh et al (2006) reviewed 10 trials of acupuncture for chronic neck pain (N=661). The trials were too heterogeneous to pool data for most outcomes, and most were low quality (average score of 2.3/5 on the Jadad Scale), due to inappropriate allocation concealment, or inadequate reporting of blinding, withdrawals and drop-outs, and intention-to-treat analysis. Two of the trials (N=114) independently reported that acupuncture was better than some types of sham treatments for pain relief (SMD –0.37, 95%CI –0.61 to –0.12). The Cochrane review reported these findings in an ambiguous manner, describing the evidence as ‘moderate’. However, more (and larger) trials with longer follow-up and standardised interventions are needed before any real recommendations can be made.

A small, sham-controlled randomised trial (Sahin et al 2010) used electroacupuncture to treat 31 people with chronic neck pain (this RCT was not included in the Cochrane review discussed above). After 10 sessions of either conventional acupuncture (13 participants) or sham (16 participants), there was no difference between the groups' visual analogue scale (VAS) scores (although scores were reduced in both groups compared with baseline). However, the acupuncture group had a significant improvement in bodily pain after therapy ($P<0.01$). The authors concluded that 'stimulation of conventional acupuncture points was not generally superior to needling of nonspecific points on the neck, and both treatments were associated with improvement of symptoms'. However, this trial was likely too underpowered for robust conclusions.

Fibromyalgia

Historically, fibromyalgia has been classified as a musculoskeletal condition, although it is of unknown cause. Fibromyalgia is often comorbid with psychiatric conditions, including depression and anxiety and stress-related disorders, such as posttraumatic stress disorder. A protocol for a Cochrane review has been registered, but no results are available yet (Deare et al 2008). This review will compare different types of acupuncture with no treatment, placebo or usual care.

Osteoarthritis

A review of acupuncture for peripheral joint osteoarthritis included 16 RCTs (N=3498) (Manheimer et al 2010). The trials included people with OA in a variety of joints (knee, hip, or both). There were statistically significant short-term improvements in pain compared with a sham control (standardized mean difference –0.28, 95%CI –0.45 to –0.11); however, this was not clinically meaningful (ie it did not meet predefined improvements on a pain scale).

Restless leg syndrome

A Cochrane review of interventions for restless leg syndrome (Cui et al 2008) found only two trials (N=170) that met inclusion criteria, although both trials had serious methodological and reporting flaws. They were also too heterogeneous to pool; therefore, there are not enough data to draw any conclusions on the effects (or adverse effects) of acupuncture on restless leg syndrome.

Rheumatoid arthritis

A Cochrane review investigated acupuncture or electroacupuncture for rheumatoid arthritis (only RCTs published in French or English; therefore at risk of bias) (Casimiro et al 2005). Only two studies (N=84) were included. The first, which used acupuncture, found no significant difference between the intervention and control (placebo) groups for several outcomes (erythrocyte sedimentation rate, creactive protein, visual analogue pain scale, number of swollen or tender joints, general health questionnaire, modified disease activity scale, decrease in analgesic intake). In the second study, which used electroacupuncture, there was a significant decrease in knee pain in the intervention group compared with placebo after 24 hours (weighted mean difference: –2.0, 95%CI –3.6 to –4.0) and after four months (weighted mean difference: –0.2, 95%CI –0.36 to –0.04). However, the trials were poor quality and small; therefore, no conclusions could be made.

3.2.3 Neurological or mood disorders

Addiction

Auricular acupuncture (insertion into the auricle of the ear) is sometimes used to treat cocaine addiction. A Cochrane review (Gates et al 2006) included seven trials (*N*=1433) of auricular acupuncture for cocaine addiction. All trials had low methodological and reporting quality; trials were also small and generally underpowered. Where possible, data were pooled — although numbers of participants were still low. There was no difference between acupuncture and sham acupuncture for rates of treatment drop-out (RR 1.05, 95%CI 0.89 to 1.23) or acupuncture and no acupuncture (RR 1.06, 95%CI 0.90 to 1.26). No other meaningful analyses could be done. In summary, there is not enough evidence to determine the effects of auricular acupuncture on cocaine dependency.

Another Cochrane review investigated acupuncture, acupressure, laser therapy and electrostimulation for smoking cessation (White et al 2006). Twenty-four RCTs were included, but data could only be pooled for those comparing acupuncture with sham acupuncture. This meta-analysis was broken down into duration of effects. Analysis of short-term effects (12 RCTs, *N*=893) showed a significant benefit from acupuncture (fixed-effect odds ratio 1.36, 95%CI 1.07 to 1.72); however, there was no significant difference when re-analysed using the random-effects model to account for the heterogeneity. There was no significant difference between acupuncture and sham acupuncture when the long-term effects were analysed (six RCTs; *N*=549). Therefore, the authors concluded that 'acupuncture for smoking cessation may, in the short term, be more effective than either no treatment or sham acupuncture. However, both these results rely heavily on single positive studies and the choice of model for pooling, and the evidence that acupuncture has an effect is not consistent. Results from meta-analysis of studies with long-term outcomes did not detect a significant benefit of acupuncture over sham acupuncture'.

Bells palsy

No recommendations could be made about acupuncture for Bells palsy, because of poor quality of trials. A Cochrane review (Chen et al 2010) included six RCTs of acupuncture (one used acupuncture in combination with medication) (*N*=537). The quality of the trials was too poor for analysis; none of the trials reported adverse effects.

Depression

A Cochrane review of acupuncture for depression, originally published in 2005, was updated to included 23 new trials — taking the total to 30 trials (*N*=2812) (Smith et al 2010). Most trials had a high risk of bias (mainly due to inadequate blinding, randomisation or concealment). Data were pooled, where possible, but the review authors concluded that there were insufficient data to make any recommendations on the efficacy or safety of acupuncture compared with nonspecific or sham controls or wait list controls, or to see whether there is an additive effect of acupuncture used in conjunction with standard medication for depression.

A second Cochrane review of nonpharmacological interventions for antenatal depression (Dennis and Allen 2008) found only one small trial (*N*=61) of maternal massage and acupuncture for antenatal women diagnosed with depression (according to the DSM-IV). There was no significant difference between depression-specific acupuncture and nonspecific acupuncture in terms of number of women diagnosed with clinical depression

immediately after treatment (RR 0.48, 95%CI 0.11 to 2.13) or at final assessment at 10 weeks' postpartum (RR 0.64, 95%CI 0.06 to 6.39). However, this is based on a small sample size and poorly reported methods of randomisation. More data from larger and higher quality trials are needed before any conclusions can be drawn. Furthermore, the results are unlikely to be generalisable, because participants were Caucasian females from a high socioeconomic background.

Epilepsy

A Cochrane review of acupuncture for epilepsy (frequency and severity of seizures, quality of life) included 11 RCTs, most of which were small (total *N*=914), had short-term follow-up, and were of poor quality (Cheuk and Wong 2008). Data from some of the trials were pooled: pooled results of four RCTs showed no significant difference between the treatment and the control groups in any reduction of seizure frequency (pooled RR 1.05, 95%CI 0.97 to 1.17). The authors concluded that 'the current evidence does not support acupuncture for epilepsy'.

Insomnia

Cheuk et al (2007) reviewed the efficacy and safety of acupuncture for insomnia. Seven trials (*N*=590) enrolled people of any age, with any type of insomnia and a range of coexisting medical conditions. Similar to reviews of acupuncture for other indications, the trials were characterised by poor methods (and therefore a high probability of bias) and poor reporting (eg incomplete or unreported randomisation, no reported intention to treat analysis, variation in type and frequency of acupuncture, inadequate training of acupuncturists, inadequate reporting of adverse effects, inadequate length of follow-up). Furthermore, insomnia was measured in many different ways. Meta-analysis was therefore difficult, although data were pooled from three trials that reported subjective insomnia improvement to show that there was no significant difference between acupuncture (or variants) and control (RR = 1.66, 95%CI 0.68 to –4.03). Because of the lack of high-quality trials, no recommendations could be made about efficacy or safety.

Parkinsons disease

Protocol only (Wang et al 2006).

Schizophrenia

A 2005 Cochrane review (Rathbone and Xia 2005) included five RCTs (two compared acupuncture to antipsychotics; and four also compared acupuncture and antipsychotics to antipsychotics alone). Some statistically significant effects favoured acupuncture (lower extrapyramidal adverse events [RR 0.05, 95%CI 0.0 to 0.8, number needed to treat 2, 95%CI 2 to 8]) or acupuncture plus antipsychotics (short-term psychiatric scale score [weighted mean difference –4.31, 95%CI –7.0 to –1.6; depression scale score [weighted mean difference –10.41, 95%CI –12.8 to –8.0]). There were also fewer adverse effects in the acupuncture plus antipsychotic group (weighted mean difference –0.50, 95%CI –0.9 to –0.1). However, it must be remembered that these results were from only two small trials. The authors concluded that there were not enough data to draw conclusions on the use of acupuncture for people with schizophrenia: 'the numbers of participants and the blinding of acupuncture were both inadequate, and more comprehensive and better designed studies are needed to determine the effects of acupuncture for schizophrenia'.

3.2.4 Reproductive health

Conception

Cheong et al (2008) reviewed RCTs of acupuncture for assisted conception. Interventions included acupuncture alone, or acupuncture with assisted reproductive technology (ART), and were compared with no treatment, placebo or sham acupuncture (the latter two relate to needling an area that is not a recognised acupuncture point, or an area that is believed to be ineffective for the indication). A total of 13 RCTs (average size of approximately 250 participants) were included, most of which were of reasonable quality apart from inadequate blinding (which was often not possible, due to the nature of the intervention). The lack of blinding throws doubt on the results, due to the high risk of placebo effect. Data from three trials (*N*=542) were pooled, and acupuncture on the day of embryo transfer was associated with an increase in live birth rate (OR 1.86, 95%CI 1.29 to 2.77), but not when it was done two to three days after (OR 1.79, 95%CI 0.93 to 3.44). However, there is a high likelihood that this result was due to the placebo effect, or the relatively small sample size. There was no evidence of benefit on pregnancy outcomes when acupuncture was performed around the time of oocyte retrieval.

Induction of labour

Smith and Crowther (2004) found only three trials (*N*=212) of acupuncture to induce labour. Data from two of the trials were combined to show that fewer women in the acupuncture group needed other induction methods compared with standard care (147 women, relative risk 1.45, 95%CI 1.08 to 1.95). However, this meta-analysis was based on very small numbers.

Modlock et al (2010) looked at acupuncture for inducing labour in post-term pregnancies (*N*=125). The women were randomised into two groups: one that received acupuncture and one that received sham acupuncture. There was no statistical difference (*P*=0.79) between the two treatment groups.

Another group (Selmer-Olsen et al 2007) performed an RCT to look at inducing labour in nulliparous women (*N*=106). The women were allocated to an acupuncture group or a control group. There was no statistical difference (*P*=0.34) in the two groups, although the acupuncture group reported their treatment to be more positive (*P*=0.003).

There is not enough evidence to make any recommendations about the safety or efficacy of acupuncture to induce labour.

Management of pain during labour, pregnancy or breastfeeding

Smith et al (2006) reviewed RCTs of complementary and alternative therapies for managing labour pain (a Cochrane review). Three small trials of acupuncture enrolled 496 women. Two of these trials (*N*=288) showed that women receiving acupuncture needed less pain relief than those who did not (RR 0.70, 95%CI 0.49 to 1.00); however, this conclusion was based on underpowered studies. More research is needed before a recommendation can be made.

A Cochrane review by Pennick and Young (2007) reviewed the evidence for management of back and pelvic pain during pregnancy. One trial (*N*=386) compared acupuncture or stabilising exercises to usual care; the usual care group reported more pain than the acupuncture group after one week (difference of medians: 12; 95%CI 5.9 to 17.3; *P*<0.001). The women who received acupuncture also had significantly less intense

evening pain than those who received physiotherapy (difference of medians: –14; 95%CI –18 to –3.3; *P*=0.013).

Mangesi and Dowswell (2010) reviewed the evidence of acupuncture for relieving breast engorgement during lactation. Eight trials (*N*=212) investigated a number of interventions, but only two trials (with a total of 293 participants) looked at acupuncture (compared with usual care). More research is needed before any conclusions can be drawn.

Other reproductive conditions

A 2010 Cochrane review of evidence for using acupuncture for the management of uterine fibroids retrieved no RCTs (Zhang et al 2010).

A Cochrane review protocol has been registered for the efficacy and safety of acupuncture to treat premenstrual syndrome; no results have been published yet (Yu et al 2005).

In a non-Cochrane review, Smith and Carmady (2010) reviewed RCTs and systematic reviews for the efficacy of acupuncture in common women-specific health complaints. Five systematic reviews and six RCTs were included. The evidence for treating dysmenorrhoea and menopause is unclear due to small sample sizes and introduced bias. Acupuncture used to treat premenstrual syndrome, polycystic ovarian syndrome and other menstrual-related condition is under-studied; many reports were based on single studies only, which is not sufficient to base a recommendation on.

Similarly, in another non-Cochrane systematic review, Cho and Kim (2010) searched for RCTs done on acupuncture and premenstrual syndrome. They reviewed nine trials; but a recommendation cannot be drawn from these due to flaws in methodology of the studies.

3.2.5 Miscellaneous conditions

Allergies

A large RCT of acupuncture for allergic rhinitis (Brinkhaus et al 2008) randomly assigned 5237 adults to receive 15 acupuncture sessions (*N*=487) or routine care (*N*=494), while 4256 were included in the nonrandomized acupuncture group. After three months, the acupuncture group had improved quality of life scores (mean [SE] of 1.48 [0.06]; control group 0.50 [0.06]; difference in improvement, 0.98 [0.08]; *P*<0.001). These improvements were not as great at six months.

A pilot study (a placebo-controlled, partially blinded study of 27 people) found a similar benefit of acupuncture over sham acupuncture for treating vasomotor rhinitis (measured as ‘nasal sickness score’) (Fleckenstein et al 2009). The acupuncture group had a significantly reduced score (from 9.3 ± 3.89 to 4.1 ± 3.20 points; *P*<0.001), compared with the sham acupuncture group (5.6 ± 2.74 to 3.7 ± 2.61 points; *P*<0.05). However, this trial’s methods were not robust; it was intended as a pilot study only.

Glaucoma

A Cochrane review from 2007 (Law and Li 2007) found no RCTs (evidence was limited to some small case series); therefore, no conclusions can be drawn about acupuncture for glaucoma.

Headaches

Linde et al (2009b) updated a 2001 Cochrane review of acupuncture for migraine prophylaxis. This earlier review concluded that the evidence supporting the use of acupuncture was 'considered promising but insufficient'. In the 2009 update, 12 new trials were reviewed, taking the total to 22 trials (*N*=4419). Acupuncture was compared with no treatment or routine care, placebo (sham acupuncture), or other interventions. Six of the trials (including two large trials that enrolled 401 and 1715 participants) compared acupuncture with no treatment or routine care. The acupuncture group had fewer headaches after three to four months; however, these effects were not evident in the only study that had a longer (nine-month) follow-up time. Acupuncture was compared with sham acupuncture in 14 trials, but there was no statistically significant difference between the two when data were pooled. The authors concluded that acupuncture 'provides additional benefit to treatment of acute migraine attacks only or to routine care'. However, there is evidence that it is no better than sham acupuncture. Finally, acupuncture appears to be at least as effective as prophylactic drug treatment, but has fewer adverse effects.

An RCT of electroacupuncture (EA) at a particular acupoint to treat migraine was not included in the Cochrane review by Linde et al (2009b) — either as an included or excluded study (Jia et al 2009). This trial randomised 275 people with migraine (in three different treatment centres) to receive EA at acupoint GB40, or acupoint ST25 (the control group). The results showed statistically significant differences in visual analogue scores between the acupuncture and control groups, in favour of the acupuncture group ($P<0.01$), although it is not clear whether these differences were also clinically important. Measurements at the three-month follow-up were mixed, with outcomes favouring the acupuncture groups at two centres, but no significant difference at the third. After six months, treatment appeared to favour the acupuncture groups at all three centres.

Linde et al (Linde et al 2009a) updated another Cochrane review of acupuncture for prophylaxis of tension headache (first published in 2001). The earlier review concluded that there was not enough evidence to determine the efficacy of acupuncture (compared with no treatment, usual care, a sham acupuncture placebo, or other interventions). The updated review added six new trials (for a total of 11 trials; *N*=2317), including two large trials that found clinically and statistically significant benefits of acupuncture (compared with routine care) for headache frequency, number of headache days and pain intensity, over the short term (three months). Pooled data from five trials showed small but statistically significant benefits of acupuncture (compared with placebo) for frequency. Overall, the authors concluded that 'acupuncture could be a valuable nonpharmacological tool in patients with frequent episodic or chronic tension-type headaches', although this applies only to the short term (three months or less).

An RCT that assessed acupuncture for chronic daily headaches (Coeytaux et al 2005) enrolled 74 people, randomised to receive medical management, or medical management plus 10 sessions of acupuncture. There were no differences in daily pain scores between the groups, but the acupuncture group had a greater improvement on headache impact tests (95%CI, 1.0 to 4.9). The acupuncture group were also 3.7 times more likely (95%CI, 1.7 to 8.1) to report less suffering from headaches at six weeks (ARR 46%; number needed to treat 2), leading the authors to conclude that acupuncture, in conjunction with medical management, improves health-related quality of life and patients' perception of suffering from headaches. Note that this RCT was not included in the Cochrane review by Linde et al (2009a).

Irritable bowel syndrome

A 2006 Cochrane review of acupuncture for irritable bowel syndrome (IBS) looked for RCTs that compared acupuncture with no treatment, placebo (sham acupuncture) or other interventions (Lim et al 2006). Six RCTs were included, but the authors reported that trial quality was too low, and interventions, controls and outcomes were too heterogeneous for any conclusions to be made on how acupuncture compares with no treatment, or with sham acupuncture, for symptoms of IBS.

A preliminary RCT (Reynolds et al 2008) was done to investigate whether or not acupuncture treatment for IBS was worth studying further. Two groups (*N*=30) were randomised to acupuncture or treatment-as-usual. The authors found that acupuncture did improve IBS symptoms (*P*=0.001); however, this sample size is too small to form a recommendation. The authors concluded that this result justifies further studies.

A 2009 study (Lembo et al) looked at the effect of acupuncture in three groups: an acupuncture group, sham acupuncture group (*N*=230) and a waitlist control group. Although there was not statistical difference in IBS symptoms between the acupuncture and sham acupuncture groups (*P*=0.25), there was a statistical improvement between these two groups and the waitlist group (*P*=0.001). This study did not find evidence to support a recommendation.

Nausea and vomiting

A 2006 Cochrane review of acupuncture plus antiemetics for chemotherapy-induced nausea and vomiting included 11 RCTs (*N*=1247) (Ezzo et al 2006). Electroacupuncture appeared to be helpful for reducing acute vomiting after chemotherapy, although more trials are needed using current antiemetics: pooled data showed a significant reduction in the proportion of patients experiencing acute vomiting (RR=0.82; 95%CI 0.69 to 0.99; *P*=0.04), but not acute or delayed nausea severity compared to control. Subgroup analyses for different modes of administration found that needles reduced proportion of acute vomiting (RR=0.74; 95%CI 0.58 to 0.94; *P*=0.01), but not the severity of acute nausea. Electroacupuncture reduced vomiting in the acute phase (RR=0.76; 95%CI 0.60 to 0.97; *P*=0.02), but manual acupuncture did not. Acupressure reduced mean acute nausea severity (SMD= –0.19; 95%CI –0.37 to –0.01; *P*=0.04) but not acute vomiting or delayed symptoms. Noninvasive electrostimulation showed no benefit for any outcome. All trials used concomitant pharmacologic antiemetics; however, those used in the electroacupuncture trials are now considered suboptimal — more trials are needed using current antiemetics.

Lee and Fan (2009) reviewed RCTs that investigated the effect of stimulating wrist acupuncture point P6 on postoperative nausea and vomiting. Of the 40 trials included (*N*=4858), 10 different types of interventions were used, including acupuncture, electroacupuncture, transcutaneous nerve stimulation, laser stimulation, capsicum plaster, an acu-stimulation device and acupressure. Therefore, it is difficult to assess the effects of acupuncture alone. Methodological shortcomings were common (eg unclear allocation concealment, incomplete reporting of outcomes). Pooling all data (ie for all types of point stimulation) showed that, compared with sham treatment, P6 acupoint stimulation significantly reduced nausea (RR 0.71, 95%CI 0.61 to 0.83), vomiting (RR 0.70, 95%CI 0.59 to 0.83), and the need for rescue antiemetics (RR 0.69, 95%CI 0.57 to 0.83). There was no evidence of difference between P6 acupoint stimulation and antiemetic drugs in the risk of nausea (RR 0.82, 95% CI 0.60 to 1.13), vomiting (RR 1.01, 95% CI 0.77 to 1.31), or the need for rescue antiemetics (RR 0.82, 95% CI 0.59 to 1.13). The side effects associated with P6 acupoint stimulation were minor.

Finally, another Cochrane review looked at different interventions for nausea and vomiting during early pregnancy, including acupuncture, acupressure and acustimulation (Matthews et al 2010). Twenty-seven RCTs (*N*=4041) were included. Those that looked at P6 acupressure, auricular acupressure and acustimulation of the P6 point provided limited data. There were no significant effects of acupuncture (P6 or traditional).

3.3 Ongoing clinical trials

A search of clinicaltrials.gov for as-yet unpublished trials retrieved 13 trials (11 in adults). Three were recruiting (acupuncture and myofascial trigger point dry needling and acupressure for chronic low back pain; acupressure to relieve itching for atopic dermatitis; acupuncture for improving fatigue in women with breast cancer). Six trials have been completed, although results may not yet be published:

- acupuncture and acupressure for relieving postoperative nausea and vomiting
- acupuncture for IBS (effectiveness and cost effectiveness)
- acupressure for relieving nausea and vomiting in people with HIV/AIDS
- acupuncture and acupressure for pain relief in advanced pancreatic cancer
- acupuncture for relieving symptoms of advanced colon cancer
- acupuncture, and acupuncture and acupressure for knee osteoarthritis.

One trial (acupressure wrist bands for nausea and vomiting after chemotherapy) was active but not recruiting, and one (acupuncture for stimulation of labour) was terminated due to 'exhausted staff after a long recruitment process'.

3.4 Adverse effects

Few trials reported adverse effects, making it difficult to assess the safety of acupuncture.

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4 Aromatherapy

4.1 What is it?

Aromatherapy uses plant materials, known as essential oils, and other aromatic substances to affect a patient's mood or cognitive functions. Aromatherapy can be administered in different ways, including inhalation (direct and indirect), combined with massage, or by applying essential oils directly to the skin.

4.2 What is the evidence?

Summary

Limited information from randomised controlled trials or systematic reviews is available on aromatherapy or aromatherapy massage.

Results from one randomised controlled trial suggest that aromatherapy massage may have a clinically meaningful benefit on anxiety and depression for people with cancer, but only in the short term (less than six weeks).
Level II

Indications for which aromatherapy is effective	
• Possible short-term clinical benefit for anxiety and depression in people with cancer	
Indications for which there is not enough evidence	
• Dementia	• Labour pain

4.2.1 Cancer

A Cochrane review of aromatherapy and massage for symptom relief in cancer patients, last updated in 2004, was withdrawn in 2008 because it was out of date and could be misleading (Fellowes et al 2008). A new review team is being sought to update this review.

4.2.2 Anxiety and depression

An RCT used aromatherapy massage (compared with usual care) to relieve symptoms of anxiety and depression in 288 people with cancer (Wilkinson et al 2007). After six weeks, those receiving aromatherapy massage greater improvement in clinical anxiety and depression (OR 1.4; 95%CI, 1.1 to 1.9; $P = 0.001$), but there was no difference between the groups at 10 weeks (OR 1.3; 95%CI, 0.9 to 1.7; $P=0.1$). Self-reported anxiety was better for those receiving aromatherapy massage at both six and 10 weeks (OR 3.4; 95%CI, 0.2 to 6.7; $P=0.04$; and OR 3.4; 95%CI, 0.2 to 6.6; $P=0.04$, respectively). The authors concluded that aromatherapy massage 'does not appear to confer benefit on cancer patients' anxiety and/or depression in the long-term, but is associated with clinically important benefit up to 2 weeks after the intervention'.

4.2.3 Dementia

There is substantial interest in using aromatherapy for people with dementia, because of the low risk of adverse effects, and the benefits for people with impaired verbal communication. However, aromatherapy can be expensive; therefore, a critical review of its efficacy is useful. A Cochrane review of aromatherapy to relieve the symptoms of dementia (eg cognitive function, anxiety, quality of life) found that, although many nonrandomised studies have been published, only four RCTs (*N*=163) met quality criteria for their review (Holt et al 2003). Furthermore, only one of these trials (*N*=72) was used in a meta-analysis (combined with additional data provided by the paper's author). Aromatherapy (essential oil applied topically to face and arms) relieved agitation and neuropsychiatric symptoms compared with control (sunflower oil applied in the same way) (total change in score on an agitation scale from baseline to four weeks: effect [SE] -11.08 [3.62]; 95%CI -19.95 to -2.21; *P*=0.022; total change in neuropsychiatriac score from baseline to four weeks: -15.80 [3.50], 95%CI -24.37 to -7.22; *P*=0.004). However, the trial was underpowered. Therefore, there is not enough evidence to determine the effects of aromatherapy on dementia.

A cross-over randomised trial (Lin et al 2007) randomised 70 adults with dementia to receive lavender oil (intervention) or sunflower oil (control); groups switched oils after three weeks. Agitation and neuropsychiatric signs were measured using defined inventories. Lavender oil appeared to have a statistically significant benefit: mean total scores for agitation decreased from 24.68 to 17.77 (t=10.79, df=69, *P*<0.001); mean total neuropsychiatric scores changed from 63.17 (SD=17.81) to 58.77 (SD=16.74) (t=14.59, df=69, *P*<0.001).

An RCT of aromatherapy to relieve stress, anxiety and depression found that lemon oil improved mood, compared with water (adjusted *P* <0.004) and lavender (adjusted *P*=0.001) (Kiecolt-Glaser et al 2008). However, the trial was not properly randomised (participants were recruited using advertisements). There were also inherent biases due to the self-reporting nature of the data collection, as well as other methodological flaws.

A blinded randomised clinical trial has been registered on the Australian Clinical Trials Registry for lavender oil to treat the behavioural symptoms of dementia (ACTRN 12609000569202, 2010) (van der Ploeg et al 2010). The trial will compare lavender oil with placebo (jojoba oil) in a cross-over design, with the oils applied by trained nursing staff over three consecutive days for two weeks (with a two-day washout period between conditions). This trial's design appears robust, but results will depend on the number of participants recruited (77 participants will be needed for adequate power; the authors will aim for 85 participants to overcome the predicted 10% attrition rate).

4.2.4 Pain management during labour

A Cochrane review reviewed a range of complementary and alternative therapies for reducing pain during labour (Smith et al 2006). Only one small RCT (*N*=22) assessed aromatherapy — essential ginger oil versus lemongrass oil (the control) for maternal satisfaction, use of pharmacological pain relief, and maternal and neonatal outcomes. No difference was seen between the two groups, although the trial was underpowered (power calculations showed that 116 participants were needed for adequate power). The risk of bias in this trial was low, but no conclusions can be made based on these data.

4.3 Clinical trials

Four clinical trials were listed on clinicaltrials.gov, three of which involved adults. One (active, not yet recruiting) will look at the effects of aromatherapy on lowering anxiety and pain during childbirth. A second is completed but not yet published (aromatherapy to reduce conscious sedation during colon cancer screening).

4.4 Adverse effects

There are very few reported adverse effects for aromatherapy.

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6 Homeopathy

6.1 What is it?

Homeopathy is based on the concept of treating 'like with like', in which substances that elicit symptoms in healthy individuals are used to treat patients presenting with those symptoms. Substances are serially diluted with violent shaking, and often the final treatment does not contain any molecules of the starting substance. Treatments are individualised according to the symptoms and feelings of each patient, and there is no uniform treatment for any given condition.

6.2 What is the evidence?

Summary

The literature on homeopathic treatments is characterised by poor methodology and reporting. No recommendations could be made for any indications.

Few adverse effects have been reported for homeopathy, possibly due to the low concentrations of treatments.

Indications for which homeopathy is effective	
• Not enough evidence to determine.	
Indications for which homeopathy is not effective	
• Dementia	
• Osteoarthritis	
Indications for which there is not enough evidence	
• Symptoms associated with cancer treatment	• Hot flushes in women with breast cancer
• General symptoms of cancer	• Asthma
• Labour induction	• Prevention or treatment of influenza
• Knee surgery (pain, swelling and other outcomes)	

6.2.1 Symptoms associated with cancer or its treatment

A Cochrane review of homeopathy to prevent or treat the symptoms associated with cancer treatments included eight trials (*N*=664) (Kassab et al 2009). Three trials studied the adverse effects of radiotherapy, three studied the effects of chemotherapy, and two studied menopausal symptoms after breast cancer treatment. One trial with a low risk of bias (*N*=254) showed that topical calendula was superior to trolamine (a noncorticosteroid topical treatment) for preventing radiotherapy-induced dermatitis. Of the two other radiotherapy trials, one (*N*=82) did not contain sufficient data for analysis, and one (*N*=66) showed no significant difference between homeopathy and placebo. One trial (*N*=32) showed that Traumeel S (a proprietary complex homeopathic mouthwash) was superior to placebo for preventing chemotherapy-induced stomatitis in children. Of the two other chemotherapy trials, one (*N*=65) showed no significant difference between

homeopathy and conventional treatment, and one (*N*=29) showed no significant difference between homeopathy and placebo. The two trials on menopausal symptoms reported no significant differences between homeopathic and placebo groups. The review authors concluded that more trials are needed before any conclusions can be made.

A Cochrane review of nonhormonal interventions for hot flushes in women with a history of breast cancer included two RCTs on homeopathy (Rada et al 2010). Results could not be pooled due to inconsistent presentation of data, but the homeopathy trials did not show significant differences in frequency or severity of hot flushes between groups. The authors noted that adverse effects were poorly and inconsistently reported.

A non-Cochrane meta-analysis of patients with cancer or past experience of cancer who received single or combined homeopathic interventions included five RCTs and one nonrandomised trial (Milazzo et al 2006). The quality of the studies varied, but overall there was insufficient evidence to determine the efficacy of homeopathic treatments in cancer care.

6.2.2 Asthma

Six RCTs (*N*=556) of varying quality were included in a Cochrane review of homeopathy for asthma. Heterogeneity in homeopathic treatments prevented data pooling, but no trial reported significant differences between groups receiving homeopathy or placebo (McCarney et al 2004).

6.2.3 Dementia

A Cochrane review of homeopathy for dementia found no RCTs to include in the review (McCarney et al 2003).

6.2.4 Osteoarthritis

A Cochrane review protocol for homeopathy for arthritis has been published (Munar et al 2007). No results are available yet.

6.2.5 Labour induction

Smith (2003) conducted a Cochrane review on homeopathy for inducing labour, including two poor-quality trials (*N*=133). Neither trial reported significant differences between groups; there is insufficient evidence for homeopathy to induce labour.

6.2.6 Influenza syndromes

A Cochrane review comparing a patented homeopathic treatment (Oscillococcinum) to placebo for preventing or treating influenza was withdrawn after it was unable to be updated (Vickers and Smith 2009). The most recent update in 2006 showed that Oscillococcinum did not prevent influenza-like syndrome (relative risk (RR) 0.64, 95%CI, 0.28 to 1.43), but did reduce the length of illness by 0.28 days (95%CI, 0.50 to 0.06). Participants taking Oscillococcinum were more likely to consider the treatment to be effective (RR 1.08; 95%CI, 1.17 to 1.00).

6.2.7 Knee surgery

Brinkhaus et al (2006) conducted three RCTs on the efficacy of arnica homeopathic remedy compared with placebo on postoperative pain and swelling after arthroscopy (n=227), artificial knee joint implantation (n=35), and cruciate ligament reconstruction (n=57). Patients were given one dose of five globules of arnica prior to surgery, and five globules three times daily for one or two days after surgery. Primary outcome was percentage change in knee circumference after surgery. There were no significant differences between the treatment and placebo groups for arthroscopy (group difference delta=–0.25%, 95%CI, –0.85 to 0.41, *P*=0.204) and artificial knee joint implantation (delta=–1.68%, 95%CI, –4.24 to 0.77, *P*=0.184). Homeopathic arnica had a beneficial effect after cruciate ligament reconstruction (delta=–1.80%, 95%CI, –3.30 to –0.30, *P*=0.019). It is not clear whether these effects are clinically meaningful.

Another RCT investigated the efficacy of a complex homeopathic treatment including arnica on reducing morphine intake over 24 hours after cruciate ligament reconstruction (Paris et al 2008). Patients were given homeopathic remedy (n=67), placebo (n=66), or no intervention (n=25). There were no significant differences between the three groups. Additional trials enrolling larger numbers are needed.

6.2.8 Other indications

Other RCTs have studied the efficacy of homeopathic remedies on:

- minor, recurrent apthous ulcers (Mousavi et al 2009a) (homeopathy was beneficial)
- oral lichen planus (Mousavi et al 2009b) (homeopathy was beneficial)
- chronic primary insomnia (Naude et al 2010) (homeopathy was beneficial)
- analgesia consumption and pain following tonsillectomy (Robertson et al 2007) (homeopathy was beneficial)
- disease severity and quality of life for a variety of illnesses (Witt et al 2005, Witt et al 2008) (homeopathy was beneficial)
- dysmenorrhoea (Witt et al 2009b) (homeopathy was beneficial)
- acute maxillary sinusitis (Zabolotnyi et al 2007) (homeopathy was beneficial)
- recurrent vulvovaginal candidiasis (Witt et al 2009a) (homeopathy had a negative effect).

6.3 Clinical trials

The search term ‘homeopathy’ returned 42 trials for numerous indications on the United States National Institutes of Health clinical trials register. One trial has published results (Witt et al 2009a) and 14 trials have been completed but results have not yet been published. Four are active but not recruiting, 11 are currently recruiting patients, 10 are not yet recruiting patients and 2 trials were terminated.

6.4 Adverse effects

One Cochrane review reported that there were no serious adverse effects or interactions reported for the homeopathic medicines used (Kassab et al 2009).

In their RCT, Zabolotnyi et al (2007) reported eight adverse effects 'that were assessed as being mild or moderate in intensity'. No information on potential conflicts of interest was given.

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7 Hypnotherapy and hypnosis

7.1 What is it?

Hypnotherapy or hypnosis is a sleep-like state of deep, focused relaxation that is associated with feelings of well being, muscle relaxation and improved ability to recall memories. It is used for a range of psychological and physiological problems, from stress and anxiety, to disruptive behaviours and substance dependency.

7.2 What is the evidence?

Summary

Many clinical trials and observational studies have looked at the efficacy of hypnotherapy, although their methodological quality is generally low.

Hypnotherapy may help smokers to continue to abstain from smoking in the long term, when used in conjunction with nicotine patches; however, this is based on a single trial (level II).

Hypnotherapy may also help to improves symptoms of depression (level I) and psychosomatic disorders (level I).

Indications for which hypnotherapy is effective	
• Smoking (possible benefit in conjunction with nicotine patches)	• Hot flashes in women who have had breast cancer
• Depression	• Psychosomatic disorders
• Preoperative anxiety	
Indications for which there is not enough evidence	
• Overweight and obesity	• Irritable bowel syndrome
• Posttraumatic stress disorder and acute stress disorder	• Pain management (nonspecific chest pain, labour pain, chronic pain, operative pain and anxiety, jaw and tooth pain)
• Non-epileptic attack disorder and conversion disorder	• Non-ulcer dyspepsia
• Depression	• HPV in women
• Fibromyalgia	• Schizophrenia

We found many Cochrane reviews and additional trials examining the effects of hypnotherapy or hypnosis on a range of indications, as summarised below.

7.2.1 Schizophrenia

A Cochrane review found that there was not enough information to see the effect of hypnosis on people with schizophrenia, even as an adjunctive treatment (Izquierdo de Santiago and Khan 2007). Only three trials were included in the review, with a total of 149 participants. Two of the trials compared hypnosis with standard treatment, while the third trial compared hypnosis with relaxation and music. The trials were published in 1979, 1980 and 1983 respectively, and one contained only 10 participants. Reporting within the trials was described as poor.

7.2.2 Smoking cessation

A Cochrane review evaluated nine RCTs comparing 14 different control interventions with hypnosis, as a strategy for smoking cessation (Abbot et al 1998). There was considerable heterogeneity in the length of the programs (from a single session through to nine weeks), type of induction (only three trials specified the type of induction), duration of the sessions (30 minutes through to seven hours), leaving the reviewers unable to perform a meta-analysis. The comparators to hypnosis included waiting list/no treatment, attention placebo/advice group, psychological treatments, rapid/focused smoking and in conjunction with group therapy versus group therapy alone. There was not enough evidence to determine the effect of hypnotherapy on smoking cessation. The review was updated in 2008, with no changes to conclusions made.

A randomised trial published 10 years after the initial publication of the Cochrane review in 1998 reported significantly higher point prevalence quit rates at six and 12 months, when hypnotherapy was compared with standard treatment (Carmody et al 2008). The participants (*N*=286) were recruited from a Veterans Affairs Medical Centre in San Francisco, and were randomly assigned to either receive standard behavioural counselling plus nicotine patches, or hypnotherapy plus nicotine patches. All participants attended two 60-minute sessions (counselling or hypnotherapy) and received three follow-up phone calls at weeks three, four and six. Two months' worth of nicotine patches were provided to all participants. Hypnosis was scripted and administered by trained public health educators, and participants were provided with an audio-recording of each session to use daily at home. The behavioural counselling sessions discussed the dangers of smoking and benefits of, and potential barriers to, quitting.

Point-prevalence of six-day abstinence at six months was higher in the hypnosis group than the standard treatment group (29% versus 23%; RR=1.27; 95%CI 0.84 to 1.92). At 12 months, 24% of the hypnosis group and 16% of the standard treatment group reported seven-day point prevalence (RR=1.47, 95%CI, 0.90 to 2.40). A subgroup of participants with depression appeared to particularly benefit from the hypnosis, as significantly higher validated point-prevalence rates were found at both 6 and 12 months, compared to participants who received standard treatment. The authors concluded that hypnosis (in conjunction with nicotine patches) helped former smokers to continue to abstain from smoking.

7.2.3 Overweight or obesity

A Cochrane review (Shaw et al 2005) investigated psychological interventions for overweight and obesity. The review included 30 trials, one of which included hypnotherapy using audiotape. The trial compared hypnotherapy with a placebo, for 54 participants. Of these, the hypnotherapy group lost 7.9 kg while the placebo group lost 0.2 kg by six months follow-up. Despite this difference reaching significance, the reviewers concluded that there was insufficient evidence for the reviewers to recommend whether hypnotherapy would be effective in improving weight loss.

7.2.4 Irritable bowel syndrome

A Cochrane review evaluating the use of hypnotherapy in the treatment of irritable bowel syndrome (IBS) included four RCTs, with a total of 1487 people (Webb et al 2007). Hypnotherapy was compared to psychotherapy and placebo pill in one trial, while two trials compared hypnotherapy with waiting-list controls. Hypnotherapy was compared to usual medical management in the fourth trial. Serious side effects were not reported in any trial. While hypnotherapy was found to offer superior treatment effects to that of being on a waiting list or usual medical management, the reviewers could not draw conclusions regarding the efficacy of hypnotherapy in IBS treatment, because the trials were methodologically poor.

7.2.5 Posttraumatic stress disorder

Psychological interventions are widely used in the treatment of post-traumatic stress disorder (PTSD). This Cochrane review (Bisson and Andrew 2007) was a systematic review of randomised controlled trials of a range of psychological treatments with adults who had been experiencing traumatic stress symptoms for three months or longer. Among the interventions reviewed, hypnotherapy was regarded as one of a range of 'other therapies', and compared with trauma-focused cognitive behaviour therapy/exposure therapy (TFCBT), stress management, and eye movement desensitisation and reprocessing (EMDR).

For reduction in clinician-assessed PTSD symptoms measured immediately after treatment:

- TFCBT did significantly better than 'other therapies' (SMD = –0.81; 95%CI –1.19 to –0.42)
- stress management did significantly better than 'other therapies' (SMD = –1.22; 95%CI –2.09 to –0.35)
- there was no significant difference between the waitlist/usual care control and 'other therapies' (SMD –0.43; 95%CI –0.90 to 0.04).

For reducing self-reported traumatic stress symptoms, depressive symptoms, anxiety symptoms, adverse effects and dropouts, EMDR did significantly better than 'other therapies' (SMD –0.84; 95%CI –1.21 to –0.47).

Thus, other non trauma focused psychological treatments (including hypnotherapy) did not reduce symptoms of PTSD as significantly as TFCBT, stress management and EMDR. There is insufficient evidence to show whether or not psychological treatment is

harmful. Psychological treatments can reduce symptoms of PTSD and trauma focused treatments are more effective than non trauma focused treatments.

Combat veterans may experience posttraumatic stress disorder (PTSD) with olfactory-induced flashbacks, where smelling certain stimuli evokes painful memories associated with the particular smell. The usefulness of a new hypnotic technique called hypnotherapeutic olfactory conditioning (HOC) was investigated in a prospective observational study with 36 outpatients (from a group receiving treatment at an Israeli PTSD unit) (Abramowitz and Lichtenberg 2010). The technique is intended to assist the development of new olfactory associations. Participants attended six weekly 1.5-hour sessions. Three standardised depression and psychological function scales were administered at baseline, six weeks (i.e. completion of the HOC), six months and one year. One participant discontinued the study after the first session and was not included in analyses. Remaining participants were male (average age 41.2 years) and had been receiving treatment for an average 2.44 years. Age at time of trauma and period from trauma to HOC sessions were not associated with outcomes. The authors reported significant reductions in PTSD symptoms on all three scales at the six-week, six-month and one-year follow up. However, as this was a small observational study with no control group, these results should be interpreted with caution.

Another RCT evaluated the benefits of add-on hypnotherapy in 32 participants with chronic PTSD, who were being treated with SSRI antidepressants and supportive psychotherapy (Abramowitz et al 2008). Participants were assigned randomly to a group of 15 who received Zolpidem (10 mg nightly for 14 nights) and a group of 17 treated by symptom-oriented hypnotherapy (in four 1.5-hour sessions over 2 weeks). There was a significant main effect of the hypnotherapy treatment on PTSD symptoms as measured by the Posttraumatic Disorder Scale, which remained at follow-up 1 month later. The hypnotherapy group also has decreased intrusion and avoidance reactions, and improvement in all sleep variables assessed.

7.2.6 Acute stress disorder

The efficacy of hypnotherapy combined with cognitive behavioural therapy (CBT) in treating acute stress disorder was investigated with civilian trauma survivors in an RCT (Bryant et al 2006). Participants (*N*=87) were randomised to six sessions of CBT, CBT combined with hypnosis or supportive counselling. Intention-to-treat analyses conducted at two year follow-up indicated that patients who received CBT alone or in conjunction with hypnosis in the initial month following their trauma had fewer PTSD symptoms than those receiving supportive counselling only.

7.2.7 Non-epileptic attack disorder and conversion disorder

Two trials assessing the role of hypnotherapy in treating non-epileptic attack disorder were included in a Cochrane review (Martlew et al 2007). There was not enough information to recommend hypnotherapy for treatment of non-epileptic attack disorder. The same two trials were included in a Cochrane review investigating treatments for conversion disorder (Ruddy and House 2005). Again, the reviewers were unable to use the trials to make recommendations for treatment.

7.2.8 Pain management

Labour pain

A Cochrane review (Smith et al 2006) investigating alternative therapies for pain management in labour included five trials of hypnosis (*N*=729). Self-hypnosis decreased participants' need for pain relief medication (RR 0.53; 95%CI 0.36 to 0.79). Participants were also more satisfied with pain management compared with controls (RR 2.33; 95%CI 1.15 to 4.71). The reviewers concluded that hypnotherapy may help relieve labour pain, but they also cautioned against any firm recommendations due to the small numbers of participants.

Operative pain and anxiety

An RCT investigated whether hypnotic analgesia reduces pain and anxiety during electromyography (EMG) (Slack et al 2009). Twenty-six people were randomised to receive education about EMG (*N*=8); hypnotic induction without analgesic suggestion (*N*=10) or hypnotic induction with analgesic suggestion (*N*=8). The interventions were delivered by 20-minute audio recordings. After the EMG, participants completed a visual analogue scale by rating the worst pain, average pain and anxiety levels that they had experienced during the procedure. The mean values for all three conditions were not significantly different. The hypnosis groups were combined and compared against the group that received EMG education only, and average and worst pain and anxiety were less in the hypnosis group, but that was only statistically significant for ratings of worst pain. This trial was likely to be too small for reliable results.

A Cochrane review (Kisely et al 2010) investigating the efficacy of psychological interventions for treating nonspecific chest pain in patients with normal coronary anatomy included one trial investigating the role of hypnotherapy. Short-term efficacy was reported; however, the small sample size of 28 participants (of whom only 15 received hypnotherapy) did not allow any firm recommendations to be made. The authors simply concluded that hypnotherapy could be a 'possible alternative'. More research is needed.

Chronic pain

The efficacy of self-hypnosis training and EMG biofeedback in reducing chronic pain associated with spinal cord injury was compared in 37 adults (mean age 49.5 years) in a small RCT (Jensen et al 2009). Assignment to the two groups was random (computer-generated), with more participants were deliberately assigned to the hypnosis group; 23 (63%) compared with 14 (37%) in the biofeedback group. Participants in both groups reported similar decreases in pain at pre and post-session follow-up. When intention-to-treat (ITT) analyses were calculated, only the hypnosis group had significant pre to post-treatment decreases in pain intensity that was maintained at three months. This group also reported significant pre- to post-treatment increases in perceived control over pain; however, this was not sustained at three months. Based on this single trial, it is still unclear what effect hypnosis has on chronic pain.

The efficacy of hypnosis in the treatment of chronic widespread pain was investigated in another small RCT (Grondahl and Rosvold 2008). Sixteen people received standardised hypnosis treatment with 10 consecutive sessions once a week, for 30 minutes, in addition to usual treatment, or usual treatment only. The hypnosis group was given an audio-tape of the session to listen to at home. Seven out of the eight patients allocated to the hypnosis group completed the intervention, and showed an average improvement in

scores of –7.1, from 62.5 to 55.4. The control group had a deterioration of 7.9, from 37.2 to 45.1. Five people from the control group chose to also receive hypnosis (after they had first completed the 10-week control period) and showed an improvement in scores of –1243, from 35.97 to 23.54. The 12 participants who received hypnosis completed a questionnaire one year later that showed a mean improvement of 41.3, which indicated the improvement was sustained (initial improvement was from 51.5 to 41.6). Limitations of the trial include the very small sample size and differences in level of suffering at baseline level; the treatment group entered the trial with mean symptom score of 62.5 whereas the mean symptom score in the control group was 37.2. In addition, the questionnaire to measure symptoms was not piloted nor validated. The shortcomings of the trial make it difficult to make any recommendations.

Jaw and tooth pain

In an RCT, 43 women suffering with temporomandibular disorders (TMD) were randomised to receive either hypnosis (*N*=21) or simple relaxation (*N*=22) (Abrahamsen et al 2009). Group allocation to one of four individual one-hour treatment sessions was blinded to participants, who were all told that they would receive hypnotic intervention. The hypnosis sessions were delivered by a dentist with specialist training in hypnosis for pain control. Patients completed a pain diary throughout the intervention period, and the McGill Pain Questionnaire and Coping Strategies Questionnaire at baseline and after the final treatment. Psychological symptoms were assessed by the 60-item Symptom Checklist and sleep quality by the Pittsburgh Sleep Quality Index. A statistically significant difference in daily pain scores was achieved, with pain scores reducing by 50.4% in the hypnosis group, compared to 0.7% in the control group. No adverse effects were noted in the hypnosis group, leading the authors to conclude hypnosis is an effective and safe treatment for TMD. This was a small trial, and larger numbers of participants are needed.

To investigate the use of hypnosis as an adjunct to intravenous sedation, people having a third molar removed were randomly assigned to either the treatment (*N*=46) or control (*N*=54) group (Mackey 2010). The treatment group received hypnotic suggestions via headphones throughout their dental procedure, as well as the standard sedation dose. The control group listened to music through headphones, and also received the standard sedation dose. Scores on all outcome measures, intraoperative Propofol administration, postoperative self-reports of pain ratings and postoperative prescription of pain relief consumption were all lower in the treatment group. However, further investigation is needed before conclusions can be made.

7.2.9 Non-ulcer dyspepsia

A Cochrane review (Soo et al 2005) investigating psychological interventions for non-ulcer dyspepsia included one trial that used hypnotherapy. Participants were randomised to receive either hypnotherapy (*N*=32), supportive therapy (*N*=48) or ranitidine (*N*=46). The dose of hypnotherapy sessions was generous, with patients receiving twelve 30-minutes sessions over 16 weeks. Symptoms were assessed (using an adaptation of an IBS questionnaire incorporating VAS) at 56 weeks, and total dyspepsia scores were lowest in the hypnotherapy group (median score 0.6, inter-quartile range 0.1 to 0.5). More trials are needed before any recommendations can be made.

7.2.10 Depression

The effects of meditation with yoga (with psycho-education), versus group therapy with hypnosis (and psycho-education) versus psycho-education alone on the treatment of depression were compared in 46 adults (mean age 50.4 years) with long-term depressive disorders, in an RCT (Butler et al 2008). Participants were randomised to receive meditation and yoga (*N*=17, 32.7%), group therapy with hypnosis (*N*=17, 32.7%) or a control of psycho-education (*N*=18, 34.6%). Statistically more participants in the meditation group than controls experienced remission in symptoms at nine-month follow-up. Remission was observed in eight hypnosis group participants but this was not statistically significant from controls. Limitations acknowledged by the authors were small sample size and the fact the hypnosis intervention was still being refined.

Cognitive hypnotherapy is hypnosis combined with cognitive behavioural therapy (CBT). An RCT randomised 84 participants with depression to 16 weeks of either cognitive hypnotherapy or CBT alone (Alladin and Alibhai 2007). At the end of treatment, both groups had improved significantly compared with baseline scores, but the cognitive hypnotherapy group had larger changes in the Beck Depression Inventory, the Beck Anxiety Inventory and the Beck Hopelessness Scale. Effect size calculations showed that the cognitive hypnotherapy group had greater reduction in depression (6%), anxiety (5%) and hopelessness (8%), over and above the CBT group. This was maintained at 6 and 12-month follow up.

A separate meta-analysis examined the efficacy of hypnosis in the treatment of depressive symptoms (Shih et al 2009). Six studies were identified and analysed using the Comprehensive Meta-analysis software package and the combined effect size was 0.57; thus, hypnosis appeared to significantly improve symptoms of depression ($P<0.001$).

7.2.11 HPV in women

Current medical treatments for human papillomavirus concentrate on tissue assaults, such as the application of acids, freezing and surgery, but medical wart clearance rates are only 30–70% and recurrence is common. An RCT compared hypnosis-only with medical-only therapies in participants from urban hospital and rural communities (Barabasz et al 2010). Both therapies resulted in statistically significant reduction in areas and numbers of lesions ($P<0.04$). At the 12-week follow-up, clearance rates were 5 to 1 in favour of hypnosis. More research, in addition to this single trial, is needed before any conclusions can be made.

7.2.12 Hot flashes amongst breast cancer survivors

An RCT looked at the efficacy of hypnosis for treating hot flashes experienced by breast cancer survivors (Elkins et al 2008). Sixty female participants were randomly assigned to receive hypnosis (five weekly sessions) or no treatment, with 51 women completing the trial. Hot flash scores decreased by 68% from baseline in women who received hypnosis ($P<0.001$), and improvements in self-reported anxiety, depression, sleep and impact of hot flashes on daily life were reported ($P<0.005$). This trial indicates that hypnosis may benefit women who have had breast cancer. Further investigation via larger trials would be useful.

7.2.13 Psychosomatic disorders

A (non-Cochrane) meta-analysis of 21 RCTs assessed whether hypnotherapy is effective in treatment of psychosomatic disorders (Flammer and Alladin 2007). Trials compared patients treated with hypnotherapy only to untreated controls (both groups may also have been receiving adjunctive standard medical care). Hypnotherapy was categorised as classic (n = 9), mixed form (n = 5) and modern (n = 3). Results showed the weighted mean effect size for 21 studies was d(+) = 0.61 (P = 0.0000). There were significant differences between the categories of hypnosis. There was no relationship between dose and outcome of treatment. Numerical values for correlation between hypnotic suggestibility and outcome were only reported in three studies (mean r = 0.31). Hypnotherapy is effective in treatment of psychosomatic disorders.

7.2.14 Preoperative anxiety

An RCT randomised participants into three groups: a hypnosis group (n = 26) who received suggestions of wellbeing; an attention-control group (n = 26) who received attentive listening and support without specific hypnotic suggestion; and a standard of care control group (n = 24) (Saadat et al 2006). Anxiety was measured pre and post-intervention and on entrance to the operating room, to score levels of preoperative anxiety. Patients in the hypnosis group were significantly less anxious post-intervention compared with the attention-control group and the control group (31 ± 8 compared with 37 ± 9 and 41 ± 11, respectively, ANOVA, P = 0.008). On entrance to the operating rooms, the hypnosis group had a significant decrease in their anxiety level (56%), whereas the attention-control group had an increase of 10% and the control group an increase of 47% (P = 0.001). The authors concluded that hypnosis significantly alleviates preoperative anxiety. Further research would be useful.

7.3 Clinical trials

A search of the United States National Institutes of Health clinical trials registry retrieved more than 50 clinical trials of hypnosis or hypnotherapy for many different indications. These have not been summarised here, due to the large volume of published information already summarised.

7.4 Adverse effects

Few or no adverse effects have been reported for hypnotherapy. However, it is not clear whether this is because there are no associated adverse effects, or because of poor reporting. One Cochrane review stated that there was not enough evidence to determine whether psychological treatment was harmful (Bisson and Andrew 2007).

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8 Massage or therapeutic touch

8.1 What is it?

Massage involves manipulating the body with pressure, tension, motion or vibration. Therapists use manual or mechanical methods to target the tissues (including muscles, connective tissues or lymphatic vessels), joints and organs.

Therapeutic touch is a therapy in which practitioners enter a meditative state and pass their hands above the patient's body to correct any imbalances in the patient's 'life energy'.

8.2 What is the evidence?

Summary

Massage or therapeutic touch can help to reduce the likelihood of perineal tears during and following a vaginal birth.
Level I

Many randomised controlled trials have looked at the effects of massage or therapeutic touch for other conditions, and these trials have been summarised in systematic (Cochrane) reviews. Although massage or therapeutic touch seems to be beneficial for some conditions, there is not enough evidence to make any other conclusions, because most trials are poor quality (eg too small, high risk of bias, poorly reported), or no research has been done.

Indications for which massage or therapeutic touch is effective	
• Antenetal perineal massage to reduce likelihood of perineal tears during vaginal birth	
Indications for which massage or therapeutic touch is not effective	
• No reviews or trials with conclusive findings	
Indications for which there is not enough evidence	
• Antenatal depression (compared with nonspecific acupuncture)	• Pain management in labour
• Uterine massage to prevent postpartum haemorrhage	• Low back pain
• Agitation in dementia	• Mechanical neck disorder
• Quality of life for people with HIV/AIDS	• General pain relief, or pain relief for cancer
• Wound healing	• Lymphoedema
• Bell's palsy	• Anxiety disorder
• Asthma	

Our search found 14 Cochrane reviews on massage, summarised below.

8.2.1 Pregnancy and birth

Beckmann and Garrett (2006) conducted a Cochrane review of the evidence for antenatal perineal massage for reducing perineal trauma during and following vaginal birth. Four good-quality RCTs trials were included that compared perineal massage with control for at least the last four weeks of pregnancy. Antenatal perineal massage reduced the incidence of trauma that needed suturing (four trials, 2480 women, risk ratio [RR] 0.91; 95%CI 0.86 to 0.96; number needed to treat [NNT] 15; 95%CI 10 to 36). Women practising perineal massage were less likely to have an episiotomy (four trials, 2480 women; RR 0.84; 95%CI 0.74 to 0.95; NNT 21, 95%CI 12 to 75). These results were significant for women who had not previously given birth vaginally. Women who had previously given birth vaginally reported a significant reduction in pain incidence at three months postpartum (one trial, 376 women; RR 0.45; 95%CI 0.24 to 0.87; NNT 13; 95%CI 7 to 60). There were no differences in incidence of perineal tears or trauma, instrumental deliveries, sexual satisfaction or incontinence. The authors concluded that antenatal perineal massage reduces the likelihood of perineal trauma.

A Cochrane review on interventions for antenatal depression included one RCT of women with major depression (Dennis and Allen 2008). Maternal massage compared to nonspecific acupuncture (control group) did not significantly decrease the number of women diagnosed with clinical depression immediately posttreatment (*N*=38; RR 0.80; 95%CI 0.25 to 2.53) or at final assessment at 10 weeks' postpartum (*N*=32; RR 1.93; 95%CI 0.37 to 10.01). This single trial provides insufficient evidence to evaluate the efficacy of massage for antenatal depression compared with acupuncture.

In a Cochrane review of complementary and alternative therapies for pain management during labour, one small RCT investigated the effects of massage (*N*=60) (Smith et al 2006). Women in the massage group had a significant reduction in pain perception in all three phases of labour, and reduced anxiety in the first phase of labour. There was no difference in duration of labour or satisfaction with the birth experience. This single RCT does not provide enough data to determine the efficacy of massage during labour.

One RCT (200 participants) was included in a Cochrane review of uterine massage to prevent postpartum haemorrhage (Hofmeyr et al 2008). There were no significant differences between the massage group and the control (no massage) group in incidence of blood loss more than 500 mL. The mean blood loss was less in the uterine massage group at 30 minutes (mean difference [MD] -41.60; 95%CI -75.16 to -8.04) and 60 minutes after enrolment (MD -77.40; 95%CI -118.71 to -36.09). The need for uterotonics to reduce postpartum haemorrhage was less in the uterine massage group (RR 0.20; 95%CI 0.08 to 0.50), and two blood transfusions were administered in the control group. Further trials are needed with sufficient numbers to more precisely assess the effect of uterine massage on postpartum haemorrhage.

8.2.2 Pain management

Thirteen RCTs were included in a Cochrane review of massage for low back pain (Furlan et al 2008). Eight of the trials had a high risk of bias; five had a low risk of bias. Two trials that compared massage to sham treatment showed that massage improved pain and function in short and long-term follow-ups. In the eight trials where massage was compared to active treatment, massage was similar to exercises, and better than joint mobilisation, physical therapy, relaxation therapy, acupuncture and self-care education. Acupuncture massage had better results than Swedish massage, and Thai and Swedish

massage styles produced similar results. The beneficial effects of massage for patients with chronic low back pain lasted for at least one year after treatment. More trials are needed to confirm these conclusions due to the high risk of bias.

A Cochrane review of massage for mechanical neck disorders included 19 RCTs, 12 of which were of low quality (Haraldsson et al 2006). Heterogeneity in treatment and control groups prevented statistical pooling. Six trials on massage alone showed inconsistent results. Fourteen trials used massage as part of a multimodal treatment, but none were designed to assess the relative contribution of massage to the outcome. The efficacy of massage to treat neck pain remains unclear due to the poor quality of the trials.

Massage and touch therapies for dementia were evaluated by Hansen et al (2006) in a Cochrane review. Two RCTs were included: one on hand massage to reduce agitation, and one on touch with verbal encouragement to eat for nutritional intake. These limited trials provide insufficient data to make general conclusions about efficacy or possible adverse effects (although no severe adverse effects were noted).

A Cochrane review by Hillier et al (2010) evaluated the safety and efficacy of massage therapy on quality of life, pain and immune system parameters in people living with HIV or AIDS. The four RCTs that were included were small, highly heterogeneous, and had a moderate risk of bias. Adverse effects were not well reported. Massage therapy in combination with other therapies, such as meditation and stress reduction, is more effective for improving quality of life measures than massage therapy alone, or the other therapies alone. One trial reported positive changes in immune function; another trial found no difference between the massage group and the controls in immune function. This review is inconclusive, and more studies are needed.

A Cochrane review by So et al (2008) evaluated trials on touch therapies for pain relief in adults. There were 24 included RCTs — 16 on therapeutic touch, 5 on healing touch and 3 on reiki. Outcomes were pain intensity and analgesic requirements. Overall, participants in touch intervention groups had 0.83 units (on a 0 to 10 scale) lower pain intensity than non-touch participants (95%CI -1.16 to -0.50), although the review authors cautioned against making conclusions due to the limited number of studies. There were no adverse effects.

8.2.3 Wound healing

A Cochrane review of therapeutic touch for healing acute wounds included four trials, all with a high risk of bias (O'Mathúna and Ashford 2003). Two trials (*N*=44 and 24) showed significantly better healing with therapeutic touch, one trial showed significantly worse healing after therapeutic touch, and one trial reported no significant difference. No conclusions can be drawn from these data.

8.2.4 Circulation

Various physical therapies for reducing and controlling lymphoedema of the limbs were reviewed in a Cochrane review by Preston et al (2004). Only one of the three RCTs that were included used massage. This crossover trial of manual lymph drainage manual lymphatic drainage followed by self-administered massage versus no treatment concluded that improvements in both groups were attributable to compression sleeves and that manual lymphatic drainage provided no extra benefit at any point during the trial. The

relative contribution of massage was not assessed. No conclusions can be drawn from these data.

8.2.5 Other indications

Teixeira et al (2008) published a Cochrane review of physical therapies for treatment of Bell's palsy (idiopathic facial paralysis). Electrotherapy, exercises, biofeedback, manual therapy (including massage) and laser were evaluated in some of the 45 potential trials, but only six trials involving electrostimulation and exercise were of sufficient methodological quality for inclusion in the systematic review. There are no data to evaluate the efficacy of massage for Bell's palsy.

A Cochrane review of therapeutic touch for anxiety disorders found no randomised or quasi-randomised trials (Robinson et al 2007).

A Cochrane review of aromatherapy and massage for symptom relief in cancer patients, last updated in 2004, was withdrawn in 2008 because it was out of date and could be misleading (Fellowes et al 2008). A new review team is being sought to update this review.

A Cochrane review of manual therapies for asthma included three RCTs (*N*=156) — two used chiropractic manipulation and one used massage (Hondras et al 2005). Data could not be pooled due to study heterogeneity, and there was insufficient evidence to support or refute the use of manual therapy for patients with asthma.

8.3 Clinical trials

There are seven clinical trials registered on the United States National Clinical Trials Register:

- one completed: hypnosis, massage therapy and healing touch for chemotherapy (no results published yet)
- two active but not recruiting: multimedia program about massage therapy for cancer patients and their care partners, and polarity or massage therapy to reduce fatigue in breast cancer patients during radiation therapy
- four active but not recruiting: massage therapy given by caregiver in treating quality of life of young patients undergoing treatment for cancer; the impact of giving a massage; depression in older adults (comparison of drug and physical interventions); and osteopathic manipulative medicine in pregnancy: physiological and clinical effects.

8.4 Adverse effects

Very few or no adverse effects were reported for massage or therapeutic touch.

8.5 References

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9 Meditation

9.1 What is it?

Meditation is a holistic process that can take many different forms. It involves focusing on a feeling, process or object to achieve psychological or physical benefits (eg mindfulness, tranquillity, reduced anxiety).

9.2 What is the evidence?

Summary

Many systematic reviews have looked at the effects of different types of meditation, most commonly on anxiety, depression and stress. In general, the reviews found that there are not enough data from high quality trials to tell whether meditation is effective for many indications.

Meditation may help to reduce blood pressure (level I).

Indications for which meditation is effective	
• Reducing blood pressure	
Indications for which meditation is not effective	
• Insufficient data	
Indications for which there is not enough evidence	
• Attention-deficit/hyperactivity disorder	• Anxiety and depression
• Stress	• Sleep disturbances
• Asthma	• Relapse to substance abuse

Our search found two Cochrane reviews and 10 other systematic reviews on meditation.

9.2.1 Attention-deficit/hyperactivity disorder

A Cochrane review of meditation therapies for attention-deficit/hyperactivity disorder (ADHD) in children or adults (Krisanaprakornkit et al 2010) included four RCTs (n=83). Two studies used mantra meditation and two used yoga compared with drugs, relaxation training, non-specific exercises and standard treatment control. All studies had a high risk of bias, none reported any adverse effects, and only one provided data appropriate for analysis. In this study, there was no significant difference on the teacher rating ADHD scale between the meditation group and the drug therapy group (MD -2.72, 95%CI -8.49 to 3.05, 15 patients), or the standard therapy group (MD -0.52, 95%CI -5.88 to 4.84, 17 patients). There was also no statistically significant difference between the meditation therapy group and the standard therapy group in the distraction test (MD -8.34, 95%CI -107.05 to 90.37, 17 patients). Overall, there is insufficient data to evaluate the efficacy of meditation for this indication.

9.2.2 Stress and blood pressure

A meta-analysis and objective quality assessment of the impact of transcendental meditation on blood pressure (Anderson et al 2008) included a search of PubMed and Cochrane databases. A rating system assessed the quality of studies and nine randomised controlled trials were selected. In these trials systolic and diastolic blood pressure were measured after transcendental meditation or control procedures and compared to a control group. A meta-analysis found that the systolic blood pressure had the following reductions after transcendental meditation -4.7 mm Hg (95%CI -7.4 to -1.9 mm Hg) and diastolic blood pressure had reduced -3.2 mm Hg (95%CI, -5.4 to -1.3 mm Hg). A hypertensive subgroup found the same kind of changes. The authors conclude that transcendental meditation has clinically significant results in reducing blood pressure.

Other systematic reviews included the effect of transcendental meditation on blood pressure (Canter and Ernst 2004). Six RCTs (n=491) were included, but all had methodological weaknesses (such as inadequate baseline blood pressure assessment or no followup) and a high risk of bias. The authors concluded there was insufficient evidence to evaluate this intervention.

A meta-analysis (non-Cochrane) on the efficacy of mindfulness-based stress reduction (MBSR) meditation was conducted (Chiesa and Serretti 2009) to see if this intervention reduced stress in healthy subjects. A literature search in PubMed, ISI Web of Knowledge, Cochrane database and subsequent article references found 10 low-quality research trials. When pooled, these trials showed that subjects exhibited a non-specific stress reduction and spiritual enhancing effects after MBSR. It was also found that MBSR and standard meditation had similar effects in reducing stress. Further research is required to see if there is any difference between MBSR and other meditation techniques.

A (non-Cochrane) systematic review of the literature revealed 107 studies that looked at stress and blood pressure reduction interventions (Rainforth et al 2007). From these, 17 trials were well-designed randomized controlled trials replicating treatments. A meta-analysis found blood pressure changes for biofeedback, -0.8/-2.0 mm Hg (P = NS); relaxation-assisted biofeedback, +4.3/+2.4 mm Hg (P = NS); progressive muscle relaxation, -1.9/-1.4 mm Hg (P = NS); stress management training, -2.3/-1.3 mm (P = NS); and the transcendental meditation program, -5.0/-2.8 mm Hg (P = 0.002/0.02). This evidence suggests that transcendental meditation has the largest impact on blood pressure reduction and, from related data, potential for minimising risk factors and improving clinical outcomes of cardiovascular disease.

Smith et al (2005) reviewed the use of mindfulness-based stress reduction (MBSR) as supportive care for cancer patients, including three RCTs and seven uncontrolled studies. Most of the studies had methodological limitations (such as small sample size, lack of control group, poor reporting of various parameters). One RCT showed no statistically significant difference between MBSR and control in mood or stress, but did show a significant relationship between class attendance and beneficial outcome. Another RCT showed no difference in sleep efficacy, but did show a beneficial effect over time (for an unspecified outcome). The third RCT's results were yet to be published. Most of the uncontrolled studies showed improvements in outcomes such as function, fatigue, relaxation, pain and mood. The limitations in the quality of the evidence prevent statements of efficacy, and more research is required.

9.2.3 Anxiety and depression

A meta-analysis of relaxation training for anxiety (Manzoni et al 2008) included several relaxation methods (autogenic training; Jacobson progressive relaxation; meditation; Benson's technique; applied relaxation; and combinations of techniques). The review included 27 studies, of which 19 were RCTs and the remainder were uncontrolled. Statistically significant heterogeneity was detected between studies, and pooled effect sizes were large, especially for meditation (0.86). The review concluded that relaxation training showed consistent and significant efficacy in reducing anxiety; however, the synthesis was poorly reported and there was no attempt to assess the validity of the included studies. Given these limitations, it was difficult to determine the reliability of the authors' conclusions.

A comparison of mindful and nonmindful exercises on people with depression included 12 RCTs (Tsang et al 2008), with interventions including physical exercise treatment with mindful elements (qigong, yoga and tai chi; six RCTs) and physical exercise treatment without mindful elements (aerobic exercise, walking, pram walking, jogging and other forms of physical exercise; six RCTs). Most studies had less than 50 participants (n=591 in total) and there was heterogeneity between studies. Reductions of at least 50% of baseline score were reported for mindful (four studies) and non-mindful (two studies) interventions. The authors concluded that physical exercise was efficacious for a variety of populations, but the limitations of the review process and of the included studies require further research on efficacy.

A Cochrane review of meditation for anxiety disorders (Krisanaprakornkit et al 2006) included two RCTs of moderate quality. In one study, transcendental meditation showed a reduction in anxiety symptoms and electromyography score comparable with electromyography-biofeedback and relaxation therapy. The other study compared Kundalini yoga with relaxation/mindfulness meditation. The Yale-Brown Obsessive Compulsive Scale showed no statistically significant difference between groups. The overall dropout rate in both studies was high (33–44%). Neither study reported on adverse effects of meditation.

A meta-analysis (Ledesma and Kumano 2009) investigated the mental and physical impacts of MBSR on cancer patients. A comparison and statistical analysis of ten research trials found that MBSR may improve the mental and physical states of cancer patients (Cohen's effect size d=0.48). The study also found that more research is needed to strengthen findings of these trials (Cohen's effect size d=0.18).

A Japanese study (Ando et al 2009) looked at the changes that mindfulness-based meditation therapy had on the anxiety, depression and spiritual well-being of patients receiving cancer treatment. The 28 patients had two sessions of meditation therapy that they then continued at home with a CD. The therapy included breathing, yoga and meditation. Patient interviews two weeks later showed significant reduced levels on the Hospital Anxiety and Depression Scale of 12 +/- 5.3 to 8.6 +/- 6.3 ($p = 0.004$) and a non-significant slight increase on the Spiritual well-being scale 32 +/- 6.5 to 33 +/- 6.9 ($p = 0.69$). There was a significant relationship between these two scales. This suggests that meditation may be effective in relieving anxiety and depression but more studies on the effect of this therapy are needed.

9.2.4 Sleep disturbances

MBSR has also been used to treat sleep disturbance (Winbush et al 2007). This systematic review included three controlled studies (n=325) and four uncontrolled studies (n=158). All uncontrolled studies reported that MBSR was associated with a statistically significant improvement in measures of sleep quality or duration. The three controlled studies reported no differences between treatment and control groups. Further research is needed to determine the efficacy of MBSR for this indication.

9.2.5 Miscellaneous conditions

A systematic review of relaxation therapies for asthma (Huntley et al 2002) included therapies that involved regular self practice of a psychophysiological technique that promotes primarily physical or mental relaxation without suggestion or repetition of phrases aimed at a specific effect on asthma. This included progressive muscle relaxation, mental and muscular relaxation, hypnotherapy, autogenic training, biofeedback training and transcendental meditation. The included studies were generally of a poor quality and were often underpowered, and the authors concluded that there was insufficient evidence.

A literature review of the effect of mindfulness meditation-based interventions on relapse in substance use disorders (Zgierska et al 2009) found 22 relevant manuscripts (22 published, 3 unpublished: 8 randomized controlled trials, 7 controlled nonrandomized, 6 noncontrolled prospective, and 2 qualitative studies, and 1 case report). An assessment of methodology, risk reduction, trial and effect size showed that although mindfulness meditation interventions may be effective, more high-quality research is needed to ascertain the specific efficacy for substance use disorders and relapse.

9.3 Clinical trials

A search of the United States National Institutes of Health clinical trials database using the search term ‘meditation’ retrieves more than 140 trials, for a range of indications. Due to the large number of systematic reviews discussed above, these have not been analysed further here.

9.4 Adverse effects

Adverse effects reported for meditation have included anxiety or panic induced by relaxation, decreased motivation, disorientation and boredom.

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10 Music therapy

10.1 What is it?

Music therapy involves using music to affect a patient in a physical, emotional or spiritual way. It is often used to improve cognitive functioning, behavioural traits and quality of life. Music therapy can be delivered by a trained music therapist (eg listening to music, performing or improvising music, combining music with imagery or movement), or by a health care professional (eg listening to pre-recorded music).

10.2 What is the evidence?

Summary

Music therapy appears to be beneficial for improving people's experiences of surgery, specifically preoperative fear and anxiety associated with colonoscopy (level I) and reducing procedure time of colonoscopy (level I).

Music therapy also appears to be beneficial for relieving postoperative pain, when combined with usual pain relief medication (level II) and anxiety, especially when combined with anxiolytic medications (level I).

When combined with standard care, there are also benefits on mental state, negative symptoms and social functioning in people with schizophrenia, in the short term (one to three months), although it is not clear how many sessions are needed (level I).

It is not clear whether music therapy has clinical meaningful effects on other indications.

In general, most trials (individual trials, as well as those included in the Cochrane reviews) had poor reporting of adverse effects. Those that did report adverse effects found few (which were not statistically significant) or none associated with music therapy. Furthermore, music therapy has a low drop-out rate.

Indications for which music therapy is effective	
• Postoperative pain management and anxiety, particularly when combined with standard care • Operative procedures — stress and anxiety before and after (particularly colonoscopies)	
Indications for which there is not enough evidence	
• Stress and anxiety in coronary heart disease patients • End-of-life care • Sleep disorders • Depression and psychosis	• Autism spectrum disorders • Acquired brain injury • Dementia • Chronic pain management (either as a first-line treatment for all-cause major pain, or for labour pain)

10.2.1 Stress, pain, anxiety and depression

A Cochrane review of music for stress and anxiety reduction in coronary heart disease patients included 23 RCTs (1461 participants) (Bradt and Dileo 2009). Music listening was the main intervention used. Most of the trials had a high risk of bias, and quality of reporting was poor. Twenty-one of the trials did not include a trained music therapist. Pooled data from 12 trials indicated that music listening has a moderate effect on anxiety in patients with coronary heart disease (SMD = –0.49, 95%CI –0.83 to –0.15, *P*=0.004), but the results were inconsistent across the trials (Chi^2=46.91, *P*<0.00001, I^2=77%). Pooled data from four of the trials that measured depression found no difference between listening to music and receiving standard care (SMD = –0.12, 95%CI –0.42 to 0.18, *P*=0.44). It is not clear whether these results are clinically meaningful.

Variation in five trials of music therapy for depression prevented meta-analysis in another Cochrane review (Maratos et al 2008). Four of the five studies individually reported greater reduction in symptoms of depression among those randomised to music therapy than to those in standard care conditions; the fifth study reported no significant change in general mental health (measured using standard inventories) for music therapy compared with standard care. No conclusions can be made from these data.

A small RCT done in Hong Kong looked at music therapy and its effect on depression in elderly people (>65 years old) (Chan et al 2009). They used 47 participants (23 were given to music therapy and 24 were not) and looked at blood pressure (BP), heart rate (HR), respiratory rate (RR) and depression levels. In the group that had music therapy for one month, statistically significant decreases were seen in all four parameters — depression scores (*P*<0.001), BP (*P*=0.001), HR (*P*<0.001) and RR (*P*<0.001). Although the results are promising, the sample size was very small.

10.2.2 Major mental disorders

Gold et al (2009) looked at the impact of music therapy on major mental disorders, including psychosis and depression (this was a non-Cochrane systematic review and meta-analysis). Results show that music therapy can have a positive impact on their mental state (measured using a range of scales), symptoms and functions when given in combination with standard care. The authors saw a dose-effective relationship, and concluded that longer and more frequent sessions would be beneficial for people with severe mental disorders, in out-patient or private practice settings. However, more research is needed, because the reliability of these conclusions is unclear due to the different study designs and the small sample sizes for some outcomes.

A Cochrane review showed that, for patients with schizophrenia or schizophrenia-like illnesses, music therapy in addition to standard care improves global state compared to standard care alone (Gold et al 2005). Music therapy can have some beneficial effects on mental state (one RCT, *N*=69, SMD average endpoint PANSS –0.36, 95%CI –0.85 to 0.12; one RCT, *N*=70, SMD average endpoint BPRS –1.25, 95%CI –1.77 to –0.73),on negative symptoms (three RCTs, *N*=180, SMD average endpoint SANS –0.86, 95%CI –1.17 to –0.55) and social functioning (one RCT, *N*=70, SMD average endpoint SDSI score –0.78, 95%CI –1.27 to –0.28) over one to three months' follow-up. There were inconsistencies among the four studies included in the review, and results depended on the number of music therapy sessions (there was not enough evidence to determine the minimum number of sessions required).

Another Cochrane review of autism spectrum disorders evaluated auditory integration therapy (AIT) (Sinha et al 2004). Six RCTs of AIT, including one cross-over trial, were identified with a total of 171 people aged 3 to 39 years. Four trials had fewer than 20 participants. The studies measured different outcomes and reported mixed results, and meta-analysis was not possible. There is insufficient evidence to assess AIT in this setting.

A 2010 Cochrane review on music therapy for acquired brain injury (Bradt et al 2010) included seven trials (184 participants). Based on two studies with a low risk of bias, rhythmic auditory stimulation may be beneficial for improving gait parameters in stroke patients, including gait velocity, cadence, stride length and gait symmetry; however, there were not enough data to draw firm conclusions. Similarly, no conclusions could be made about the effect of music therapy on other outcomes.

10.2.3 Dementia

Vink et al (2003) reviewed music therapy for dementia. Five trials were included, but the methodology was poor and results could not be validated or pooled for further analysis. No conclusions could be drawn: the review authors concluded that none of the trials 'presented any quantitative results in sufficient detail to justify the authors' conclusions'.

A small RCT that was not included in the Cochrane review by Vink et al examined the effects of music therapy on cognitive change in elderly people with dementia or dementia-like symptoms (N=28) (Bruer et al 2007). The eight-week trial used a cross-over design in which participants were randomly assigned music therapy once a week, or a control intervention (an age-appropriate film). The final analysis only included 17 participants (those who were formally diagnosed with dementia). Next-day scores on the Mini-Mental State Examination test were better for the music therapy group, but there was no significant difference after a week. The trial was too small to determine whether music therapy is of benefit in this context.

A similar experimental trial looked at the effects of music therapy for institutionalised elderly people with dementia (mean age of 81.7 years) (Chang et al 2010). Forty-one participants were played background music during their lunchtime meal for eight weeks. The authors found a statistically significant decrease in physical and verbally aggressive behaviours following the music therapy. However, it does not mention a control group, and the sample size was very small.

10.2.4 End-of-life care

Five trials (175 participants) were included in a Cochrane review of music therapy for end-of-life care (Bradt and Dileo 2010). Due to the limited number of studies and small sample sizes, there was insufficient evidence for music therapy on quality of life in these patients.

10.2.5 Improving experiences of surgery

A (non-Cochrane) meta-analysis of music therapy for people undergoing colonoscopy pooled data from eight RCTs (N=712) (Bechtold et al 2009). Patients' experiences of colonoscopy were significantly improved with music therapy compared with no music therapy (P<0.01). There were no significant differences between music and no music for

total procedure time (*P*=0.06), dose of sedative medications (midazolam and mepiridine; *P*=0.10 and *P*=0.23, respectively), pain scores (*P*=0.09), or willingness to repeat the same procedure in the future (*P*=0.10).

Rudin et al (2007) performed a meta-analysis of the effects of music therapy on patient anxiety and pain during gastrointestinal endoscopy procedures (this meta-analysis was not part of a Cochrane review). Four separate meta-analyses were done, involving 641 people. Two groups were considered: those who did not use drugs in conjunction with the music therapy, and those who did (compared with standard care). In the first group, people who received music therapy had lowered anxiety levels (8.6% reduction, *P*=0.004). In the second group, people who received music therapy had lower analgesic doses (29.7% reduction, *P*=0.001) and lower procedure times (21% reduction, *P*=0.002), and a reduction in sedative dosing (15% reduction, *P*=0.055). The authors concluded that music therapy is effective in this scenario.

Another non-Cochrane meta-analysis was done in 2008 (Tam et al 2008). The authors reviewed eight studies (*N*=722) and measured the mean time for the procedure in a music therapy group and a control group. The music therapy group had a shorter procedure time (–2.84 with 95%CI –5.61 to –0.08). The authors also considered use of sedatives in the same two groups, and again, the music therapy group had a lower sedative use (–0.46 with 95%CI –0.91 to –0.01). The authors concluded that music therapy is beneficial for people undergoing colonoscopy, and should be recommended.

Music to relieve pain and anxiety one day after surgery was also examined in a small RCT (56 participants) (Allred et al 2010). Secondary outcomes of interest were mean arterial pressure, heart rate, respiratory rate or oxygen saturation. A musical intervention was compared with a quiet rest period. There was no statistically significant difference in pain scores or anxiety between the music group and control group, although there was a statistically significant difference for pain (F=6.699; *P*=0.001) and anxiety (F=4.08; *P*=0.013) over time. It is not clear whether these effects were clinically meaningful. The lack of adverse effects makes music therapy an attractive choice for pain or anxiety management, especially when compared with potential adverse effects of opiates.

Another RCT compared relaxing music as pre-medication before surgery (to relieve fear and anxiety) with midazolam (an anxiolytic drug) (Bringman et al 2009). A standardised inventory was used to measure general anxiety in 372 people scheduled for elective surgery (177 randomised to receive music; 150 received midazolam). There was a greater decrease in anxiety scores for the music therapy group (*P*<0.001, 95%CI –3.8 to –1.8). The trial did not report whether these results wear meaningful for the participants, although there were no adverse effects.

An RCT investigated the effect of music therapy on anxiety, pain, relaxation and general comfort, before and after coronary angiography and percutanenous coronary intervention, according to sex (Nilsson et al 2009). Two hundred and forty patients were allocated to relaxing music or standard care therapies (groups were further subdivided according to sex). The authors concluded there was no differences in the studied outcome measures (puncture and angina pain and discomfort, anxiety, experience to the surrounding noises, discomfort of lying still, and doses of anxiolytics and analgesics) between the groups, although the music was well received by patients and hospital staff.

10.2.6 Pain management

Cepeda et al (2006) evaluated the effect of music on acute, chronic or cancer pain intensity, pain relief and analgesic requirements in a Cochrane review. They included 51 RCTs involving 1867 participants exposed to music, and 1796 controls. Pain intensity was evaluated in 31 RCTs, with considerable statistical heterogeneity (I^2=85.3%). Music therapy lowered pain intensity by 0.5 units on a zero-to-ten scale in people with postoperative pain (95%CI –0.9 to –0.2), compared with control. Four RCTs measured pain relief: participants exposed to music had a 70% higher likelihood of pain relief than the control group (95%CI 1.21 to 2.37). Two hours after surgery, the music therapy group required 1.0 mg (18.4%) less morphine (95%CI –2.0 to –0.2) than controls. After 24 hours, the music group required 5.7 mg (15.4%) less morphine than controls (95%CI –8.8 to –2.6). Although these results are statistically significant, they are small — it is not clear whether they are clinically meaningful. The authors do not recommend using music therapy as a first-line treatment for pain relief due to the small magnitude of effects, despite the relative ease, cost advantages and low risk of adverse effects.

A Cochrane review of complementary therapies for pain management in labour included 14 trials, with data reporting on 1537 women using different modalities of pain management, including one trial of women using audio-analgesia (*N*=24) (Smith et al 2006). There were no differences between women receiving audio-analgesia and the controls (RR 2.00, 95%CI 0.82 to 4.89), although the sample size was possibly too small to see real effects.

Music therapy has been considered as an adjuvant therapy in postoperative pain management. In a 2010 paper, the authors randomised 517 patients into four groups: patient teaching (PT), relaxation and music therapy (RM), combination (PTRM) and control (Good et al 2010). Positive RM effects on pain management were seen in the first two days after abdominal surgery (day 1 am: $P<0.001$; day 1 pm: $P=0.04$; day 2 am: $P=0.04$). This suggests that RM can be useful in pain management when used with normal pain relievers.

10.2.7 Sleep quality

A non-Cochrane meta-analysis reviewed five RCTs to determine the influence of music therapy on sleep behaviour (de Niet et al 2009). A total of 170 participants and 138 controls were considered; the music had a moderate effect on sleep quality (SMD –0.74; 95%CI –0.96 to –0.46). Although this effect is modest, the authors concluded that music therapy is cheap, easy to do and does not require training.

10.3 Clinical trials

A search of clinicaltrials.gov for ‘music therapy’ returned 68 trials. A wide variety of indications are being investigated, mainly falling under the broad categories discussed in this review; they will therefore not be discussed further.

10.4 Adverse effects

In general, most trials (individual trials, as well as those included in the Cochrane reviews) had poor reporting of adverse effects. Those that did report adverse effects found few (which were not statistically significant) or none associated with music therapy. Furthermore, music therapy has a low drop-out rate.

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11 Reflexology and relaxation therapy

11.1 What is it?

Reflexology is a type of touch therapy that manipulates pressure points in the feet and hands to treat corresponding areas and organs of the body. It is thought to relieve tension, improve circulation and promote healthy body function. This search also included relaxation therapies, which teach people to relax their muscles to promote physiological and psychological wellbeing.

11.2 What is the evidence?

Summary

There are no published systematic reviews of reflexology.

Relaxation therapy can help to improve self-reported depression compared with a wait list or no treatment, and may be useful as a first-line therapy before more complex psychological interventions is used.
Level I

Limited conclusions can be drawn from most trials or reviews of relaxation therapy, because of poor quality.

Indications for which relaxation therapy is effective	
• Self-reported depression (relaxation), as a first-line treatment	
Indications for which relaxation therapy is not effective	
• No reviews or trials with conclusive findings.	
Indications for which there is not enough evidence	
• Breathlessness in advanced stages of disease	• Asthma
• Occupational stress in health workers	• Hypertension
• Chronic low back pain	• Labour pain
• Dysmenorrhoea	• Menopausal hot flushes in women with breast cancer
• Epilepsy	• Overweight or obesity
• Non-ulcer dyspepsia	• Irritable bowel syndrome

For reflexology, we found a Cochrane review protocol to assess the efficacy and safety of reflexology for the treatment of chronic idiopathic constipation (Woodward et al 2009). No results have been reported yet.

The following summaries are of Cochrane reviews on relaxation therapy.

11.2.1 Airways

A Cochrane review by Bausewein et al (2008) reviewed the evidence for nonpharmacological interventions for breathlessness in advanced stages of malignant and nonmalignant diseases. This included four RCTs (*N*=238 participants) using relaxation and two RCTs (153 participants) using counselling and support with breathing-relaxation training. The authors concluded that there were insufficient data to evaluate the efficacy of relaxation or counselling and support with breathing-relaxation training for these indications.

A Cochrane review of psychological interventions in adults with asthma found that the use of 'as needed' medications was reduced in two trials (47 patients) by relaxation therapy (OR 4.47, 95%CI 1.22 to 16.44) (Yorke et al 2006). There was no significant difference in FEV1 (lung function test) for relaxation therapy in four trials of 150 patients, (SMD –0.01, 95%CI –0.41 to 0.40). There was no statistically significant improvement in depression levels following relaxation therapy (SMD 0.17, 95%CI –0.25 to 0.59). Overall, the quality of the trials was poor and the sample sizes often small.

11.2.2 Psychological indications

A Cochrane review of interventions for occupational stress in healthcare workers analysed 14 RCTs, 3 cluster-randomised trials and 2 crossover trials, with a total of 1564 participants in intervention groups and 1248 controls (Marine et al 2006). Interventions were grouped into person-directed (relaxation, music making, therapeutic massage and multicomponent) and work-directed (attitude change and communication, support from colleagues and participatory problem solving and decision making, and changes in work organisation). Person-directed interventions had limited effects on reducing stress (standardised mean difference [SMD] –0.85; 95%CI –1.21 to –0.49); burnout or emotional exhaustion (weighted mean difference [WMD] –5.82; 95%CI –11.02 to –0.63) and lack of personal accomplishment (WMD –3.61; 95%CI –4.65 to –2.58); and anxiety (state anxiety [WMD –9.42; 95%CI –16.92 to –1.93] and trait anxiety [WMD –6.91; 95%CI –12.80 to –1.01]). Work-directed interventions may also reduce stress symptoms (mean difference [MD] –0.34; 95%CI –0.62 to –0.06); depersonalisation (MD –1.14; 95%CI –2.18 to –0.10), and general symptoms (MD –2.90; 95%CI –5.16 to –0.64). Most of the trials were small and of poor quality, and their clinical relevance is not clear.

Jorm et al (2008) investigated relaxation techniques to reduce symptoms of depression and improve response or remission in a Cochrane review. Interventions included progressive muscle relaxation, relaxation imagery or autogenic training, and 11 trials were included. In five trials, relaxation reduced self-reported depression compared to wait list, no treatment, or minimal treatment post intervention (standardised mean difference [SMD] –0.59; 95%CI –0.94 to –0.24). Two additional trials showed the same trend without statistical significance for clinician-rated depression (SMD –1.35; 95%CI –3.06 to 0.37). Nine trials showed relaxation was not as effective as psychological treatment on self-reported depression (SMD=0.38; 95%CI 0.14 to 0.62). Three trials showed no significant difference between relaxation and psychological treatment on clinician-rated depression (SMD 0.29; 95%CI –0.18 to 0.75). The authors concluded that relaxation may be useful as a first-line psychological treatment for depression, with other, more complex interventions being used if there is no response.

11.2.3 Hypertension

A Cochrane review on relaxation therapies to manage primary hypertension in adults evaluated 25 trials (*N*=1198 participants) (Dickinson et al 2008). The trials were mostly of poor quality (for example, inadequate randomisation, no concealment of allocation) and the substantial heterogeneity between trials was not explained by duration of follow-up, type of control, type of relaxation therapy or baseline blood pressure. Small, non-significant reductions in blood pressure were found in the nine trials that reported blinding of outcome assessors (systolic blood pressure [SBP] mean difference: –3.2 mmHg; 95%CI –7.7 to 1.4; I^2=69%) and the 15 trials that compared relaxation to sham therapy (SBP mean difference: –3.5 mmHg; 95%CI –7.1 to 0.2; I^2=63%).

11.2.4 Pain management

Henschke et al (2010) published a Cochrane review on behavioural interventions for chronic low back pain, including one RCT on reflexology. They found poor-quality trials showing that progressive relaxation is more effective than a waiting list control for improving pain and functional status in the short term. Very low-quality trials indicate that there is little or no difference between progressive relaxation and waiting list controls for depression in the short term. The included trials had a high risk of bias, making it difficult to draw any conclusions.

Proctor et al (2007) produced a Cochrane review of behavioural interventions for dysmenorrhoea (menstrual cramps).The three trials of relaxation techniques compared to controls had varied results: two trials showed no difference in pain severity compared to controls; one trial reduced symptoms. No conclusions could be made, based on these data.

One of 14 trials in a Cochrane review of complementary therapies for pain during labour assessed relaxation therapy, but there was insufficient evidence to reach a conclusion (Smith et al 2006).

11.2.5 Menopausal symptoms

Relaxation therapy showed a mild to moderate effect (based on two RCTs) on reducing the frequency and severity of hot flushes in women with a history of breast cancer in a Cochrane review by Rada et al (2010). These effects were transient and not significant three months after therapy. More trials enrolling larger numbers are needed.

11.2.6 Epilepsy

In a Cochrane review of psychological treatments for epilepsy, three small trials (50 participants) of relaxation therapy were evaluated (Ramaratnam et al 2008). They were of poor methodological quality and a meta-analysis was not undertaken. No trial found a significant effect of relaxation therapy on seizure frequency.

11.2.7 Overweight and obesity

Of 36 trials evaluated in a Cochrane review of psychological interventions for overweight or obesity, 4 included a relaxation intervention (Shaw et al 2005). There was insufficient evidence to reach a conclusion on relaxation therapy.

11.2.8 Gastrointestinal conditions

There was insufficient evidence to assess relaxation in the treatment of non-ulcer dyspepsia in a Cochrane review (Soo et al 2005).

A Cochrane review of psychological treatments for irritable bowel syndrome evaluated 25 trials (Zijdenbos et al 2009). For relaxation or stress management, the standardised mean difference (SMD) in symptom score improvement at two months was 0.50 (95%CI 0.02 to 0.98) compared with usual care. The SMD in improvement of abdominal pain at three months was 0.02 (95%CI –0.56 to 0.61) compared with usual care. The effect size was small, and it is not clear whether these results are clinically meaningful.

11.3 Clinical trials

The search term 'reflexology' retrieved three clinical trials:

- reflexology for radiation-related fatigue in breast cancer patients (completed; not yet published)
- a pilot study of reflexology for polycystic ovary syndrome (PCOS) (not yet recruiting)
- a clinical trial of reflexology for PCOS (not yet recruiting).

11.4 Adverse effects

Adverse effects were scantily reported, reflecting the general poor reporting quality of the trials. Rates of drop out were generally low.

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12 Reiki

12.1 What is it?

Reiki is a type of touch therapy originating in Japan. It uses a technique known as palm healing, where practitioners believe they transfer healing energy through their palms to the patient.

12.2 What is the evidence?

Summary

Limited high-quality research has been published on the effects of reiki. A Cochrane review found that reiki administered by experienced practitioners may reduce pain intensity in adults, but higher-quality trials are needed.

Indications for which reiki is effective
• Pain relief
Indications for which reiki is not effective
• No published data
Indications for which there is not enough evidence
• No published data

A Cochrane review on touch therapies (healing touch, therapeutic touch and reiki) for pain relief in adults included 24 RCTs, with three trials on reiki (So et al 2008). Overall, participants in touch intervention groups had 0.83 units (on a 0-to-10 scale) lower pain intensity than non-touch therapy participants (95%CI -1.16 to -0.50). Participants receiving reiki had an average 1.24 units lower pain intensity (95%CI -2.06 to -0.42). Trials conducted by more experienced practitioners showed better pain reduction, but there is a need for higher quality trials.

A protocol has been published for a Cochrane review to examine the efficacy of reiki for anxiety and depression (Joyce and Herbison 2007). No results have been published yet.

A search in PubMed returned no other results for reiki.

12.3 Clinical trials

A search of clincaltrials.gov yielded six clinical trials for reiki. There are three ongoing (not recruiting) clinical trials:

- effects of reiki on stress
- reiki/energy healing in prostate cancer
- complementary therapies in men receiving radiation therapy for prostate cancer (including reiki).

In addition, three completed trials were found, although they may not yet have published results:

- reiki for treating fibromyalgia
- use of reiki for patients with advanced AIDS
- efficacy of reiki in painful neuropathy and cardiovascular risk factors in noninsulin dependant diabetes.

12.4 Adverse effects

No or very few adverse effects are reported for reiki.

12.5 References

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13 Tai chi

13.1 What is it?

Tai chi is a Chinese martial art that can be practised as a self-defence technique and for its health benefits. Tai chi exists in many forms, and can be a meditative form of exercise using slow movements that may provide spiritual and health benefits.

13.2 What is the evidence?

Summary

Tai chi helps to reduce the rate of falls and risk of falling for elderly people who live at home (but not for those in hospitals or nursing homes).
Level I

Tai chi may also help to improve sleep quality, and quality of life for people with fibromyalgia.
Level II

Evidence for the effect of tai chi on different types of arthritis is mixed. A Cochrane review of rheumatoid arthritis found no significant effects, except for an improvement in plantar flexion, but more trials involving larger numbers of people are needed.
Level I

Several small trials found that tai chi improved symptoms of osteoarthritis (pain, physical function, bone density and fear of falling), but these effects may only last up to six weeks, and more trials (involving greater numbers of people) are needed.
Level II

Indications for which tai chi is effective	
• Rate and risk of falls for older people who live at home	
• Sleep quality	
• Quality of life for people with fibromyalgia	
Indications for which tai chi is not effective	
• Rate or risk of falls in the hospital or aged care facility settings	
Indications for which there is not enough evidence	
• Diabetes	• General quality of life in elderly people
• Chronic musculoskeletal pain	• Rheumatoid arthritis
• Osteoarthritis	

We found three Cochrane reviews and one non-Cochrane systematic review and meta-analysis of the effects of tai chi for a range of indications. These are summarised below, along with eight additional RCTs that were not included in the reviews.

13.2.1 Falls

A Cochrane review by Gillespie et al (2009) reviewed interventions for preventing falls in older people in the community, with primary outcomes of rate of falls and risk of falling. The review included 111 RCTs (*N*=55 303). Tai chi reduced the rate of falls and the risk of falling (rate ratio [RR] 0.63, 95%CI 0.52 to 0.78; RR 0.65, 95%CI 0.51 to 0.82).

A similar Cochrane review of falls in nursing care facilities and hospitals included 41 RCTs (25 422 participants), with three trials of '3D' exercises, including tai chi (Cameron et al 2010). Pooled data with other single intervention trials showed no reduction in the rate of falls or the risk of falling.

13.2.2 Arthritis

A Cochrane review on tai chi for treating rheumatoid arthritis included four RCTs (*N*=206) (Han et al 2004). Tai chi-based exercise programs had no clinical or statistically significant effect on activities of daily living, tender and swollen joints, or patient overall rating, but did significantly improve ankle plantar flexion. No adverse effects were seen. The included trials did not assess the effects on patient-reported pain.

An RCT investigated the effects of tai chi for 41 elderly people with knee osteoarthritis (Brismee et al 2007). The intervention group attended six weeks of group tai chi lessons, followed by six weeks of home-based tai chi, then six weeks of no tai chi. The control group attended health information lectures for six weeks, followed by 12 weeks of no activity. The tai chi group showed significant improvement in overall knee pain ($P<0.0078$), maximum knee pain ($P<0.0035$), physical function ($P=0.0075$) and stiffness ($P=0.0206$) compared to baseline levels. Tai chi participants reported lower overall pain and better physical function than the control group, who did not change significantly from the baseline in any parameters. All improvements were lost after the six week period of no tai chi. The sample size was small.

Song et al (2010) conducted an RCT of six months of tai chi on knee muscle strength, bone mineral density and fear of falling in 82 older women with osteoarthritis. The tai chi group had significantly greater knee extensor endurance (pre- to post-test mean increase=36.4 W/kg, compared to 1.1 W/kg for the controls); and significantly greater bone mineral density in the femur (mean change=0.09, versus -0.10 for the controls), Ward's triangle (mean change=0.04, versus -0.04 for the controls) and trochanter (mean change=0.07, versus -0.05 for the controls). Fear of falling was also reduced in the tai chi group. The sample size of this trial was small.

Wang et al (2009) conducted an RCT of tai chi on knee osteoarthritis symptoms in 40 elderly people. Participants undertook one hour of either tai chi or wellness education and stretching, twice weekly for 12 weeks. Outcomes were measured using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scale. The tai chi group significantly improved on the WOMAC pain scale (mean difference at 12 weeks –118.80 mm [95%CI –183.66 to –53.94; $P=0.0005$]), WOMAC physical function scale (–324.60 mm [95%CI –513.98 to –135.22; $P=0.001$]), patient global visual analog scale (VAS; –2.15 cm [95%CI –3.82 to –0.49; $P=0.01$]), physician global VAS (–1.71 cm [95%CI –2.75 to –0.66; $P=0.002$]), chair stand time (–10.88 seconds [95%CI –15.91 to –5.84; $P=0.00005$]), Center for Epidemiologic Studies Depression Scale (–6.70 [95%CI –11.63 to –1.77; $P=0.009$]), self-efficacy score (0.71 [95%CI 0.03 to 1.39; $P=0.04$]), and Short Form 36 physical component summary (7.43 [95%CI 2.50 to 12.36; $P=0.004$]).

13.2.3 Diabetes

Two small RCTs studied the health benefits of tai chi for older adults with type II diabetes (Tsang et al 2007, Tsang et al 2008). Compared to sham exercise, tai chi did not affect insulin resistance at 72 hours postexercise, long-term glucose control, fitness, self-reported activity, or quality of life. The intervention was unlikely to have been of sufficient intensity, duration or frequency to produce observable effects.

13.2.4 Quality of life

Dechamps et al (2010) ran a multicentre RCT on exercise for improving health-related quality of life in 160 elderly people. Interventions were tai chi, a cognition-action program, or usual care, performed over six months, with outcomes measured at 12 months. The control group had a nonsignificant decline in ability to perform activities of daily living over 12 months compared to the intervention groups. The total neuropsychiatric inventory score worsened significantly in the control group, but was either unchanged or improved in the intervention groups.

The efficacy of tai chi to improve sleep quality in 112 adults with moderate sleep complaints was investigated in an RCT by Irwin et al (2008). The trial included 16 weeks of tai chi teaching followed by practice, or a health education program, with follow-up nine weeks later. Outcomes were measured using the Pittsburgh Sleep Quality Index (PSQI). The tai chi group showed significant improvements in PSQI than the health education group ($P<0.05$).

A non-Cochrane systematic review and meta-analysis examined the efficacy of tai chi for chronic musculoskeletal pain (Hall et al 2009a). Seven small, low-quality RCTs were included (six on arthritis, one on tension headaches). The pooled effect size for arthritis was 10.1 (range 6.3–13.9) points for pain reduction, and 9.6 (range 5.2–14.0) points for disability reduction, on a 0-to-100 scale.

An RCT of tai chi for fibromyalgia compared 33 participants undertaking hour-long tai chi sessions twice weekly for 12 weeks with 33 control participants undertaking wellness education and stretching (Wang et al 2010). Outcomes included a change in fibromyalgia impact questionnaire (FIQ) score (ranging from 0 [no symptoms] to 100 [severe symptoms]), or summary scores on the physical and mental components of the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36). The tai chi group's mean FIQ score was 62.9 ± 15.5 at baseline and decreased to 35.1 ± 18.8 after 12 weeks. The control group's mean FIQ score at baseline was 68.0 ± 11 and decreased to 58.6 ± 17.6 after 12 weeks. This difference was significant ($P<0.001$). The tai chi group also significantly improved in physical component ($P=0.001$) and mental component scores ($P=0.03$). Significant improvements were maintained at 24 weeks.

13.3 Clinical trials

A Cochrane review protocol for tai chi for treating and preventing depression has not yet published results (Chi et al 2008). RCT protocols have been published for:

- tai chi for long-term low back pain (Hall et al 2009b)
- green tea polyphenols and tai chi for bone health (Shen et al 2009)
- tai chi for osteopenic women (Wayne et al 2010).

A search for 'tai chi' on clinicaltrials.gov found 55 trials on tai chi for a wide variety of indications. These trials are at various stages of completion.

13.4 Adverse effects

Very few adverse effects of tai chi were reported.

13.5 References

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14 Yoga

14.1 What is it?

Yoga is a traditional Indian practice that includes breathing exercises, postures and meditation. It is believed to alleviate stress and induce relaxation. There are many types of yoga that focus on different aspects of body, mind and spirit.

14.2 What is the evidence?

Summary

Many trials have looked at the effects of yoga on health and psychological outcomes, and although yoga often appears to be beneficial, few trials are of a high enough quality to draw conclusions.

It is likely that yoga helps to improve psychological outcomes (including anxiety) in women with breast cancer, although larger trials are still needed.
Level II

Indications for which yoga is effective	
• Psychological outcomes (including anxiety) in women with breast cancer (although larger trials are needed) • Chronic low back pain	
Indications for which there is not enough evidence	
• Epilepsy • Depression • Metabolic syndrome • Migraine • Haemodialysis	• Cardiovascular disease • Kyphosis • Menopausal symptoms • Asthma

14.2.1 Epilepsy

A Cochrane review on yoga for epilepsy was first published in 2002 and assessed as up to date in November 2009 (Ramaratnam and Sridharan 2002). The review included two unblinded trials, one of which was quasi-randomised. A total of 50 people were enrolled (18 treated with yoga, 32 with control interventions); all people taking antiepilepsy medication continued their medication during the study. One study compared yoga to sham yoga and no yoga; the other compared yoga to acceptance and commitment therapy. The trials found conflicting and inconsistent results, and had a high risk of bias. No reliable conclusions can be drawn regarding the efficacy of yoga as a treatment for epilepsy.

14.2.2 Cardiovascular disease

A Cochrane review by Innes et al (2005) examined the efficacy of yoga on risk indices of cardiovascular disease (such as insulin resistance syndrome) and related end points. They included 70 trials (22 RCTs [*N*=1214], 15 non-randomised controlled trials [*N*=692], 32 uncontrolled trials [*N*=930] and one cross-sectional study [*N*=105]). Overall, the trials were poor quality with a number of methodological problems. Various trials showed that yoga has a beneficial effect on insulin resistance (13 trials, including two RCTs, showed varying levels of benefit), lipid profiles (11 of 14 trials showed improvement in lipid profiles; 5 RCTs had inconsistent results), body weight or composition (four of five RCTs showed improvement), blood pressure (37 trials measured blood pressure; 27 of these, including 11 RCTs, showed yoga had a beneficial effect), coagulopathy (two trials showed a beneficial effect), oxidative stress (five trials, including one RCT, showed a beneficial effect of yoga), heart and respiratory rate (25 of 27 trials, including 6 of 7 RCTs showed yoga had a beneficial effect), or clinical end points (14 trials, including 6 RCTs, showed evidence of benefit). The methodological limitations of these trials prevent firm conclusions being drawn.

14.2.3 Psychological indications

A Cochrane review of the effects of yoga on anxiety included eight RCTs of poor quality (Kirkwood et al 2005). The evidence base was insufficient to draw conclusions about the efficacy of yoga for anxiety or anxiety disorders.

A small RCT compared the effects of yoga (*N*=18) with supportive therapy (*N*=20) on anxiety in breast cancer patients before surgery, radiotherapy and chemotherapy (Rao et al 2009). The yoga group showed significantly lower self-reported state anxiety and trait anxiety, which correlated with decreased stress and symptom severity during treatment. Two other RCTs looked at the psychological indications in breast cancer patients (Vadiraja et al 2009a, Vadiraja et al 2009b). Both trials showed some benefit from yoga, for both physiological and psychological measures, and it would be useful to investigate these effects further in larger trials with better defined control groups.

Yoga was found to be as effective as relaxation in reducing stress and anxiety, and improving health status, in a randomised comparative trial of 131 South Australians with mild to moderate stress (Smith et al 2007). However, more research is needed to compare yoga with other (or no) interventions.

A Cochrane review looked at the effects of yoga on depression (Pilkington et al 2005). The review included five RCTs (*N*=183), but it was unclear how people were randomised in these trials. Three trials reported that yoga was more effective than control or no intervention. Two trials examined Sudarshan Kriya yoga (SKY): one found that full SKY was more effective than partial SKY; the other found that SKY was less effective than electroconvulsive therapy and similar to drug therapy. The authors concluded that yoga shows potential evidence of benefit, but the variations in interventions and limitations in trial reporting mean that no conclusions can be made from these data.

A small randomised pilot trial of meditation with yoga and psychoeducation, group therapy with hypnosis and psychoeducation, and psychoeducation alone for long-term depressed mood included 46 participants (Butler et al 2008). At nine months' follow-up, significantly more people in the meditation plus yoga group had experienced a remission compared to controls. There were no significant differences between groups in reduction

of symptoms or depressive episodes during the trial. The small size of this trial means that no conclusions could be drawn.

Smith and Pukall (2009) systematically reviewed the effect of yoga on psychological functioning in cancer patients. Ten trials were included (*N*=905; six RCTs, three non-controlled trials and one program evaluation study). In the RCTs, yoga was associated with improvements in measures of anxiety (ES range 0.04 to 4.67; three RCTs), depression (ES range 0.17 to 7.44; three RCTs), stress (ES range 1.24 to 2.25; two RCTs), fatigue (ES range 0.00 to 0.05; two RCTs), quality of sleep (ES 0.98; one RCT), mood (ES range 0.27 to 0.74; two RCTs), quality of life (ES range 0.28 to 1.51; three RCTs) and spiritual wellbeing (ES 0.39; one RCT). No conclusions can be made due to heterogeneity between the trials and methodological weaknesses.

Chen et al (2009) investigated sleep disturbances, depression and perceived health status in 128 elderly people after six months of 'silver yoga' exercises (cluster randomised trial). The yoga group significantly improved in mental health indicators over the course of the trial. In contrast, an RCT comparing six months of yoga, walking exercise and wait list controls in 135 elderly people found that yoga or walking did not improve cognitive or alertness outcomes, but yoga did significantly improve physical outcomes and quality of life measures compared to controls (Oken et al 2006).

In an RCT of yoga in addition to antipsychotic drugs to treat schizophrenia, 41 participants were assessed after either yoga or physical therapy for four months (Duraiswamy et al 2007). The yoga group showed significantly less psychopathology, and significantly greater social and occupational functioning and quality of life; however, this trial was most likely too small for reliable results.

14.2.4 Menopausal symptoms

A preliminary RCT evaluated the effects of eight weeks of yoga or wait-list control on menopausal symptoms in 37 survivors of early-stage breast cancer (Carson et al 2009). After the intervention, the yoga group significantly improved in hot-flash frequency, severity, and total scores and in levels of joint pain, fatigue, sleep disturbance, symptom-related bother, and vigour. The yoga group maintained these improvements three months after treatment, and also significantly improved in negative mood, relaxation and acceptance.

Yoga therapy was compared with simple physical exercises over eight weeks in 120 menopausal women (Chattha et al 2008a, Chattha et al 2008b). The yoga group showed a significant ($P<0.001$) reduction in hot flushes, night sweats and sleep disturbance. Methods for analysing changes in the six-letter cancellation test for attention and concentration and Punit Govil Intelligence Memory Scale were unclear (Chattha et al 2008a). A separate publication of what appears to be the same trial reported on symptoms, perceived stress and personality (Chattha et al 2008b). The yoga group showed decreased symptoms, perceived stress and neuroticism.

14.2.5 Metabolic syndrome

The effects of yoga were studied in a small RCT of 24 underactive, overweight adults with metabolic syndrome (Cohen et al 2008). Participants were assigned to 15 yoga sessions over 10 weeks, or a wait-list control. The yoga group showed a significant increase in energy levels (P<0.009), a non-significant improvement in wellbeing, and non-significant decreases in stress and blood pressure. This trial was possibly too small for reliable results.

14.2.6 Pain management

A non-Cochrane systematic review of several physical exercises for chronic low back pain included six high-quality RCTs (Slade and Keating 2007). Yoga was comparable to trunk strengthening for pain (standardised mean difference [SMD]: short-term: 0.13 [-0.46, 0.71]; medium-term 0.51 [-0.08, 1.11]) and function (SMD: short-term: 0.51 [-0.08, 1.10]; medium-term 0.38 [-0.22, 0.97]). The effects of yoga were large for medium-term pain and function compared to education (pooled SMDs: 0.92 [0.47, 1.37]; 0.95 [0.50, 1.40]).

An RCT with 72 participants investigated the effects of yoga therapy or self-care for three months on migraine frequency, severity and pain (John et al 2007). The yoga group showed a significant reduction in migraine intensity (P<0.001) frequency (P<0.001) and associated clinical features (P<0.001). The authors noted that more trials would be beneficial.

14.2.7 Other indications

Additional RCTs have been done on yoga for:

- kyphosis (some small improvements but unclear whether these are clinically meaningful) (Greendale et al 2009)
- asthma (some improvements in physiological and psychological measures; however, there are not enough data to make conclusions) (Vempati et al 2009)
- haemodialysis patients (some improvements, but based on 37 people only) (Yurtkuran et al 2007).

14.3 Clinical trials

Cox et al (Cox et al 2010) and Sherman et al (Sherman et al 2010) describe RCT protocols to investigate the efficacy of yoga for chronic low back pain in the UK and the US. These results are yet to be published. The search term ‘yoga’ on clinicaltrials.gov returns 107 trials for numerous indications and at various stages of recruitment or completion.

14.4 Adverse effects

Breathlessness and fatigue were reported in one of five RCTs in the systematic review by Pilkington et al (2005). No other adverse effects were reported in any trials.

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Part C — Results of Search 2
Qualifications and training of therapists

15 Training, qualifications and regulation of therapists

Complementary and alternative medicine (CAM) is a largely unregulated industry in Australia. There are variations in registration requirements across the states and territories; for example, Chinese medicine and acupuncture have registration only in Victoria (McCabe 2008, Xue et al 2009).

Medical practitioners may be unlikely to refer patients to an unlicensed health practitioner, for fear of legal repercussions if harm is caused. However, if the industry is regulated, medical practitioners may feel more secure in making referrals to CAM practitioners. In addition, patients may be more likely to tell their medical practitioner if they are seeing a CAM practitioner (McCabe 2005).

15.1 Naturopathy

The practice of naturopathy and western herbal medicine is currently unregulated in Australia, despite research indicating regulation is warranted (Lin et al 2009). There is a lack of clarity concerning how 'naturopath' is defined and, in the absence of statutory regulation or accreditation, anyone in Australia can legally practise as a naturopath (Canaway 2009). This is in spite of the fact that naturopathy is taught at bachelor and postgraduate levels in Australian tertiary institutions, including RMIT University, Macquarie University, La Trobe University, Southern Cross University, University of Technology Sydney, Victoria University and the University of Western Sydney (Baer 2006).

A survey sent to 43 providers of naturopathy and western herbal medicine education found substantial variations between the content and length of courses, as well as the contact hours and clinical education required (McCabe 2008). The total combined undergraduate and postgraduate courses of providers was 104, and under half (49%) of the courses began after 2000, with 19 campuses planning to introduce new courses over the next five years (Lin et al 2009). This anticipated growth in education, and therefore workforce, underlies the importance of investigating the statutory regulation of naturopathy and western herbal medicine.

Interviews conducted between March and June 2006 with seven senior naturopaths elicited a range of perceptions concerning the potential impacts of introducing statutory regulation. Arguments against it included the perception that natural therapies are 'safe'; that registration offers no guarantee of safety; that Chinese medicine practitioners have registration in their professions, but 'do not enjoy it'; and that self-regulation of the industry is sufficient, because most natural therapists belong to professional associations that have monitoring standards. Arguments in favour of statutory regulation included the perception that it would improve patient safety by increasing awareness of drug–herb interactions; that it would be more in line with increased public expectations of health care practitioners; and that it would improve interactions with the medical profession (Canaway 2009).

Perceived negative impacts of introducing statutory regulation included restriction or loss of freedom of practice; increase in professional indemnity costs; and increase in emphasis on scientific understandings of natural therapies, which would detract from a holistic approach, and lead to standardisation of practice (Canaway 2009).

Perceived positive impacts of introducing statutory regulation included an increase in status, legitimacy and acceptance, possibility for Medicare rebates to be introduced; consistency in the quality of education; and access to herbal products currently listed on the medicines and poisons schedule (Canaway 2009).

15.2 Chinese medicine

Statutory registration of Chinese medicine practitioners has been required in Victoria since 2000. RMIT University has adopted a capability-based curriculum approach in their programs, requiring Chinese medicine practitioners to meet 28 capabilities, which fall under four broad categories: technical, communication, sustainability and research.

In October 2005, all registered Chinese medicine practitioners ($N = 714$) were invited to rate the importance (using five-point Likert scales) of each of 28 capabilities. Just under a third of questionnaires (32.5%; $N = 228$) were completed and returned. Respondents clearly perceived the technical capabilities of a Chinese medicine practitioner to be either important or very important, with all the 12 capabilities in this category receiving ratings of four or above (Xue et al 2008b).

All six capabilities in the research category were rated lower than four, indicating capabilities such as keeping up-to-date with Chinese medicine research, developing a research protocol and disseminating research outcomes, were not perceived as important (Xue et al 2008b). However, the establishment of the Chinese Medicine Clinical Research Centre (CMCRC) at Liverpool Hospital (a publicly funded health facility in New South Wales) challenges any perception that research into Chinese medicine is not valued. There, qualified Chinese medicine practitioners work within research protocols to treat patients participating in research trials (Zhu et al 2009).

15.3 Acupuncture

The *Chinese Medicine Registration Act 2000* mandates the registration of anyone practising acupuncture in Victoria. Training of acupuncturists in Australia began in private training colleges, and is now also taught in universities including Victoria University, RMIT University, University of Technology Sydney and University of Western Sydney. The latter three institutions offer research acupuncture programs at a postgraduate level. Further evidence of acupuncture's acceptance within Australian tertiary circles was the 2006 launch of the *Australian Journal of Acupuncture and Chinese Medicine,* a peer-reviewed publication. Acupuncture treatment is claimable through Medicare; however, only if it is provided by a registered medical practitioner (Xue et al 2009).

15.4 Complementary and alternative medicine therapists and attitudes towards evidence-based practice

One attempt in Australia to assess attitudes of evidence-based practice held by CAM practitioners is the development of the Evidence-Based practice Attitude and utilisation SurvEy (EBASE). EBASE measures the following constructs: (A) opinion of evidence-based practice, (B) skills in evidence-based practice, (C) level of practitioner training in five areas, (D) use of evidence-based practice, (E) barriers to evidence-based practice, (F) preferences regarding a proposed evidence-based practice intervention and (G) demographic details. The validity of EBASE was assessed by a panel of reviewers that included academics in CAM, heads of CAM associations and CAM practitioners. EBASE achieved good internal consistency (Cronbach's alpha = 0.84) and acceptable test–retest reliability (ICC = 0.578–0.986) (Leach and Gillham 2008).

Despite randomised controlled trials being so highly valued in evidence-based practice, case series studies are often the only study type available. However, a critical appraisal tool is required to evaluate the quality of such studies. With this in mind, a group of Australian researchers developed and validated an instrument to assess the quality of case series studies into herbal medicine. Items were generated by herbal medicine practitioners, and researchers and other academics, resulting in a final version of 13 items. The items were categorised into four clusters; (i) aims and design related, (ii) treatment protocol related, (iii) methods and therapeutic or side effects related and (iv) study conduct related (Yang et al 2009).

15.5 Integrating complementary and alternative medicine into mainstream practice

The Australasian Integrative Medical Association (AIMA) represents medical practitioners and nurses who incorporate complementary therapies into their practice. Integrative clinics in Australia include the Perth Natural Medicine Clinic, which comprises biomedical physicians, podiatrists, osteopaths, naturopaths and other practitioners (Baer 2008). A survey conducted in 2005 revealed that general practitioners (GPs) believe it is appropriate to practise some, but not all, CAM therapies. Appropriateness ratings were highest for acupuncture and hypnosis (93% and 87% of respondents, respectively), and lowest for spiritual healing, such as reiki (19%).

Government regulation was strongly preferred by the GP respondents for acupuncture (87%), Chinese herbal medicine (80%), hypnosis (79%), herbal medicine (77%) and naturopathy (73%). Regulation was not seen as important for therapies not involving the use of medicines, such as yoga (33%), meditation (37%) and spiritual healing (39%) (Cohen et al 2005). General practitioners are not adverse to referring patients to some CAM therapists; a telephone survey with 1067 respondents reported GPs had made the referral for acupuncture in 20.7% of referrals (Xue et al 2008a).

Regulation of CAM has been discussed particularly in relation to the treatment of cancer. However, while integrative medicine is seen as a 'holistic approach to cancer care' (p 377), there is still work to be done in opening dialogue between CAM and mainstream cancer medicine (Robotin and Penman 2006). Interviews with 25 oncology doctors and nurses at two Australian hospitals revealed both positive and negative perceptions of the role of CAM in oncology management. Acceptance appeared to be higher for CAM

therapies that did not involve the patient ingesting a product, such as reiki, meditation or relaxation (Broom and Adams 2009).

It can be argued that integrative medicine serves clients well, in that it includes them in the negotiation process of their own health care. A hermeneutic phenomenological approach was used to explore the experiences and meanings of practitioner–client relationships in three Sydney integrative medicine clinics. Case studies and interviews conducted with clients and the GPs of the clients revealed that integrative medicine was seen as allowing more client-centred care by encouraging high levels of client agency. However, two GPs practising integrative medicine at the clinic reported that the approach required them to provide more explanation and justification to highly engaged clients, and added pressure to remain up-to-date with latest research (Grace and Higgs 2010).

Podiatrists may also refer to CAM therapists or use CAM themselves to treat patients. Four hundred and sixty-six podiatrists from six Australian states and territories completed a questionnaire regarding their personal and professional use of CAM. One-third (33%) reported that they had participated in CAM training. Of those who had no CAM training, 63% indicated that they would be interested in undertaking training in the area. Most respondents (67%) reported that they felt CAM had a place in podiatric medical practice, and most (76%) believed CAM training should be included in undergraduate podiatry training. Sixty per cent of respondents believed that statements regarding CAM should be incorporated into the podiatry professional code of conduct (Wilkinson and Tinley 2009).

In-depth interviews with 13 midwives revealed that midwives are supportive of CAM therapies being used in hospitals. However, whilst the midwives interviewed revealed that they sometimes incorporated CAM into their work, they perceived obstetricians as not embracing CAM, which can create power struggles in the care of pregnant women (Adams 2006).

Survey responses from 36 actively practising rehabilitation physicians also indicated acceptance and use of CAM in their work. Acupuncture, tai chi and yoga were the most commonly prescribed CAM by survey respondents (Mak et al 2009). A literature review by Wiese et al (Wiese et al 2010) published in 2010, examined the relationship between CAM and mainstream healthcare in detail, and discusses the implications for practitioners and patients.

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Part D — Results of Search 3
How Australia compares internationally

16 Australian and overseas guidance on alternative therapies

This section presents the results of our literature review of national and overseas guidance (eg guidelines, regulation and consensus statements) on complementary and alternative therapies.

16.1 Background

In Australia, complementary medicines are regulated under the *Therapeutic Goods Act 1989*. The Therapeutic Goods Administration (TGA) developed the Australian Regulatory Guidelines for Complementary Medicines[1] to ensure these medicines meet appropriate safety and quality standards. Australia is also a member of the International Regulatory Cooperation for Herbal Medicines.[2]

The TGA has 'Guidelines for levels and kinds of evidence to support indications and claims' (Therapeutic Goods Administration (TGA) 2001). Indications and claims can be based on evidence of traditional use or scientific evidence, and the guidelines specify the type and level of evidence necessary to support different levels of claims or indications.

The Australian Medical Association (AMA) released a position statement on complementary medicine in 2002.[3] The AMA recognises that the evidence-based aspects of complementary medicines and therapies are part of patient care and may have a role in mainstream medical practice. It emphasises the importance of a scientific evidence base to assess safety, quality and efficacy.

The UK has national guidelines for the use of complementary therapies in supportive and palliative care (Tavares 2003). These are defined as therapies that are used alongside conventional health care, including aromatherapy, massage, reflexology, reiki, spiritual healing, therapeutic touch, hypnosis and hypnotherapy, acupuncture, and homeopathy. The guidelines include a nonsystematic review of the evidence for each therapy, which outlines the evidence base, when these therapies may be useful (eg to relieve pain), contraindications and precautions, and regulation and training required for each therapy.

More recently in the United Kingdom, the Complementary and Natural Healthcare Council was established to regulate complementary therapies (Federal Working Group 2008). Registered professions include aromatherapy, massage therapy, nutritional therapy, reflexology, shiatsu, Alexander technique teaching, yoga therapy, Bowen therapy, and sports and remedial therapy. In 2010–11, the register will also open to professionals in cranial sacral therapy, naturopathy, reiki, hypnotherapy, microsystems acupuncture and healing. The council has a code of conduct, performance and ethics, and registration is voluntary.

In the US, the White House Commission on Complementary and Alternative Medicine Policy (White House Commission on Complementary and Alternative Medicine Policy 2002) recommends coordination and support for research and programs on

[1] See http://www.tga.gov.au/docs/html/argcm.htm
[2] See http://www.who.int/medicines/areas/traditional/irch/en/index.html
[3] See http://ama.com.au/node/2214

complementary and alternative medicine (CAM). It discusses the importance of education and training, disseminating accurate and easily accessible information, ensuring safety and accountability, improving access to services, and the role of CAM in health promotion in terms of the nation's health goals. The policy states that 'the coverage and reimbursement policies of public and private organizations that pay for, provide or insure conventional health care services have played a crucial role in shaping the health care system — and they will play an increasingly important role in determining the future of CAM and its place in the nation's health care system'.

The World Health Organization (WHO) conducted a global survey on policy and regulation for traditional medicine (TM) (World Health Organization (WHO) 2005). The survey revealed that 45 of the 141 responding member states reported having a national policy on TM/CAM, and 51 member states were in the process of developing one. WHO recognises that countries face major challenges in developing and implementing regulation of TM/CAM. These challenges relate to regulatory status, safety and efficacy, quality control, safety monitoring, and a lack of knowledge about TM/CAM within national drug regulatory authorities.

WHO held its first Congress on Traditional Medicine in November 2008, attended by more than 70 member states. The congress adopted the 'Beijing Declaration', which promotes the safe and effective use of traditional medicine, and calls on member states to take steps to integrate TM/CAM into national health services.[4]

16.3 Services funded by veterans' affairs departments overseas

To assess how the DVA compares internationally in their arrangements for alternative therapies, we reviewed the benefits available to veterans in other countries.

16.3.1 Canada

Veterans Affairs Canada (VAC) provides benefits under 14 programs of choice, including ambulance and medical travel, audio and vision, dental, inpatient and outpatient hospital and medical services, and some prescription drugs.[5] Veterans are eligible to receive various benefits depending on the condition for which they have a disability entitlement, based on demonstrated need.

Acupuncture and massage therapy are covered by VAC. These services must be provided by licensed health professionals, and usually must be prescribed by a physician in order to be approved for VAC funding. VAC may also provide any benefit that is considered to be the appropriate response to an assessed health need. These requests are considered on an individual patient basis.

16.3.2 New Zealand

Veterans' Affairs New Zealand (VANZ) is a unit of the New Zealand Defence Force. Recipients of War Disablement Pensions are entitled to fully funded health care for themselves and their families, including general practitioner or specialist consultations, access to private hospital care if the public hospital has a waiting list, prescriptions and

[4] See http://www.who.int/medicines/areas/traditional/congress/beijing_declaration/en/index.html
[5] http://www.vac-acc.gc.ca/clients/sub.cfm?source=services/vip/benefits-services

medical equipment. VANZ provides funding for other specialist treatments, including acupuncture, and also reviews requests for treatments on an individual patient basis.

16.3.3 United Kingdom

In the United Kingdom, veterans can seek support through the Service Personnel and Veterans Agency in the Ministry of Defence. All veterans are entitled to hospital services from the National Health Service (NHS) for any condition related to their service. Veterans with service-related conditions receive priority over other patients with the same clinical need, but are not given priority over patients with more urgent needs. Veterans who are concerned about their physical or mental health can be referred to the Medical Assessment Programme (MAP), an assessment service specialising in veterans' health that recommends treatment and management options through the NHS. The MAP provides general medical examinations only.

Through the NHS, veterans have the same access to complementary therapies as other members of the public, and these services may be subsidised to varying degrees. The availability of some healthcare services is determined nationally by the National Institute of Health and Clinical Excellence, an independent organisation that provides advice and recommendations on drugs and treatments. Individual trusts within the NHS have their own policies for funding services, to enable trusts to meet the needs of the local population.

Complementary therapies are generally not funded by NHS trusts due to a lack of information on their clinical effectiveness, although some procedures are available through hospices and hospitals as part of a palliative care package.[6] Health care professionals may apply for NHS funding for complementary therapies on an individual patient basis.

16.3.4 United States

The United States Department of Veterans Affairs provides a standard package of medical benefits to veterans. This includes preventative care services (such as immunisations, physical assessments and examinations, and screening tests), outpatient and inpatient diagnostic and treatment services (such as emergency care, medical and surgical treatments, chiropractic, mental health, bereavement counselling and substance abuse), and medications and surgical supplies. Additional limited benefits are provided to certain veterans (for example, those exposed to agent orange or who participated in certain operations) and veterans or their families in special circumstances.

Alternative therapies are not included in these benefits. In addition, the department states that it does not fund services not ordered and provided by licensed or accredited professional staff. It also does not fund health club or spa membership, even for rehabilitation.

[6] For example, see http://www.brightonandhovepct.nhs.uk/healthprofessionals/generalpractice/policies/priorapprovalsgps.asp

16.4 Services funded by private health insurers overseas

Subsidised complementary therapies can also be accessed through private health insurance. In Australia, the leading private health insurer, Medibank Private, offers a maximum rebate of $500 per year for alternative therapies on its most expensive health care plan, with sublimits of $400 per therapy type. Another large health insurance company, MBF, offers benefits of up to $400 per year for natural therapies on its most expensive plan, with sublimits of $200 per therapy type. Like healthcare systems themselves, private health insurance policies vary widely between different countries.

16.4.1 Canada

In Canada, the provinces provide public hospital and medical care under the *Canada Health Act 1984*. Pacific Blue Cross, a large health insurance company, pays benefits for treatment by naturopaths, massage therapists, physiotherapists, chiropractors, speech pathologists, chiropodists or podiatrists, osteopaths, psychologists, audiologists, acupuncturists and registered dieticians. They pay a maximum of CAN$500 per year or $25 per visit for up to 20 visits. Patients must be referred to a massage practitioner or registered dietician by a GP.[7]

16.4.2 New Zealand

The health system in New Zealand is similar to that in Australia, with a mix of public and private health care providers. Southern Cross Healthcare Group, New Zealand's leading private health insurance organisation, pays benefits of up to NZ$500 per year for complementary therapies (such as acupuncture, homeopathy or naturopathy, and remedial massage). Practitioners must be registered with their professional association.[8]

16.4.3 United Kingdom

In the United Kingdom, complementary therapies are not usually subsidised by the NHS, although health care professionals may apply for NHS funding for complementary therapies on an individual patient basis.

A large health insurance company, Bupa, offers benefits for complementary therapies only in its most expensive plan, with a total benefit of £250 per year. The therapy must be conducted by a Bupa-recognised complementary medicine practitioner as the result of a GP or Bupa-recognised specialist referral.[9]

Aviva health insurance offers benefits for GP-referred treatment for injury by a physiotherapist, chiropractor, osteopath or acupuncturist for up to 10 sessions per year.[10]

PruHealth offers benefits for complementary therapies of up to £600 per year, only on its most expensive health care plan and only where the therapy is performed to treat an acute

[7] http://www.pbchbs.com/Corp/individual/bluechoice.aspx
[8] http://www.southerncross.co.nz/society/buying-health-insurance/our-plans/wellbeing.aspx
[9] http://www.bupa.co.uk/individuals/health-life-cover/health-insurance
[10] http://www.aviva.co.uk/healthcarezone/document-library/files/ge/gen2762.pdf

condition after GP or specialist referral. The practitioner must be insured and a member of their professional specialty organisation.[11]

16.4.4 United States

Private health insurance policies in the United States are diverse and vary significantly from state to state. Many people have private health insurance plans that are sponsored by their employer, and these plans are more likely to cover at least some complementary and alternative therapies, such as massage and acupuncture. Employees can also buy complementary therapy 'top-ups' for their standard plans; this may involve subsidised fees rather than full cover.

Benefits for complementary therapies in the United States are usually limited. The increasing consumer interest in complementary and alternative therapies is likely to prompt more health insurance providers to include proven safe and efficacious therapies in their health plans.[12]

16.5 Summary

Overall, this review found a variety of different entitlements for veterans in different healthcare and regulatory systems. Similarly, private health insurance companies provide a range of benefits for complementary therapies, but these are usually limited compared to conventional therapies. Australia is not significantly different to other countries in its decisions regarding complementary therapy entitlements for veterans, for either government funding or private health insurance.

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[11] http://www.pruhealth.co.uk/insurance/plan_comparison/plans
[12] http://nccam.nih.gov/health/financial

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Appendix 1 Search results

Search 1: Efficacy of therapies

Where searches were too specific (that is, they returned too few papers), we left out the study type component of the search string. This retrieved greater numbers of papers (including many that were irrelevant, and that we discarded during the winnowing stage).

Topic grid — PubMed searches (22 September 2010)

Intervention	Outcome	Study type	Total hits	Relevant papers
acupuncture or acupressure	(treatment outcome, or rehabilitation outcome or treatment effectiveness or treatment efficacy or efficacy or prognosis) or (cost effectiveness or cost-effectiveness or cost or cost-benefit or cost benefit) or (pain or anxiety or depression or well-being or well being or wellbeing or quality of life)	clinical or trial* or controlled or randomised or non-randomised or systematic review* or qualitative or study or research or project or audit or evaluation or pilot or patient* survey* or consumer choice	15	12
aromatherapy			0	0 (4 papers added from a general web search)
massage or healing or therapeutic touch			29	2
CHANGED to: massage OR massage therapy			359	90 (but excluded those on neonates)
reflexology or relaxation			22	2
homeopathy or homoeopathy			54 (Note: searched without the study type string; otherwise only returned 4 papers)	31 (papers on children excluded)
hypnotherapy or hypnosis			112 (Note: searched without the study type search string, otherwise only retrieved 1 paper)	46
meditation			128 (based on first two components of study string only)	43
reiki			0	0
music therapy			182 (based on first two components of study string only)	45
tai chi			68 (based on first two components of study string only)	21

yoga	108 (based on first two components of study string only)	33

Note that the searches above were supplemented by a general web search.

Broad search string
(alternative therap* or alternative medicine or complementary medicine or complementary therap* or herbal medicine or Chinese medicine or Chinese herbal medicine) or (acupuncture or aromatherapy or massage or reflexology or homeopathy or homoeopathy or acupressure or hypnotherapy or hypnosis or meditation or relaxation or healing or therapeutic touch or reiki or music therapy or tai chi or yoga)
AND
(treatment outcome or rehabilitation outcome or treatment effectiveness or treatment efficacy or efficacy or prognosis) or (cost effectiveness or cost-effectiveness or cost or cost-benefit or cost benefit) or (pain or anxiety or depression or well-being or well being or wellbeing or quality of life) or health
AND
(clinical or trial* or controlled or randomised or non-randomised or systematic review* or qualitative or study or research or project or audit or evaluation or pilot or patient* survey* or consumer choice)
Number of retrieved papers: 204 **Number of relevant papers: 32**

Cochrane library (23 September 2010)

Intervention	Relevant papers (excluding protocols, withdrawn papers, children)
acupuncture or acupressure	38 CR
aromatherapy	4 CR
massage or healing or therapeutic touch	14 CR
CHANGED to: massage OR massage therapy	as above
reflexology or relaxation	16 CR (1 protocol)
homeopathy or homoeopathy	9 CR (1 protocol)
hypnotherapy or hypnosis	10 CR
meditation	2 CR (10 other SRs)
reiki	3 CR (1 protocol)
music therapy	10 CR
tai chi	5 CR (1 protocol)
yoga	1 CR (4 other SRs}

Notes: CR = Cochrane review; SR = systematic review

clinicaltrials.gov

Intervention	Retrieved trials
acupuncture or acupressure	13 (23 Sep 10)
aromatherapy	5 (23 Sep 10)
massage or therapeutic touch	7 (23 Sep 10)
reflexology	3 (23 Sep 10)
homeopathy or homoeopathy	42 (23 Sep 10)
hypnotherapy or hypnosis	50 (23 Sep 10)
meditation	147 (5Oct10)
reiki	6 (5Oct10)
music therapy	68 (5Oct10)
tai chi	55 (5Oct10)
yoga	107 (5Oct10)

Note that some trials were excluded if they did not enrol adults, or meet other criteria.

Search 2: Practitioners and services

Papers were limited to those published in English during the past five years (since 2005). The search was augmented by a general web search.

alternative therap* or alternative medicine or complementary medicine or complementary therap* or herbal medicine or Chinese medicine or Chinese herbal medicine
AND
(teaching or training or practitioner training or practitioner education or medical education quality or provider training) or (standards or professional standards or professional practices or qualification*) or (therapis* or servic*) or (regulation or registration or industry regulation or self-regulation or competency) or (herbal medicine/education or herbal medicine/standards) or (professional autonom* or professional competenc*) or (quality of health care or safety of health care)
AND
Australia
NOT
(trial or clinical trial) or (intervention or cost effectiveness)
Papers retrieved: 60
Papers included: 22

Glossary

alternative medicine	[also called alternative therapy] Alternative medicine offers an alternative, and is used instead of, conventional diagnosis and therapies.
complementary medicine	[also complementary and alternative medicine — CAM]. Complementary medicine complements, or is used alongside, conventional diagnosis and therapies.
Cochrane Collaboration	An international review group that produces Cochrane reviews.
Cochrane review	A Cochrane review is a systematic investigation of health care research.
effectiveness	How well an intervention works in real-world conditions (eg reported as patient outcomes to treatment). Effectiveness takes into account factors such as how easy an intervention is to administer, and possible adverse effects.
efficacy	How well an intervention works in an ideal or controlled setting, such as a clinical trial.
evidence-based medicine	The use of current best evidence to make a decision about an individual patient.
meta-analysis	A systematic review that uses statistical techniques to join and summarise the results of a number of research trials.
placebo	A treatment that has no physiological function but may have a psychological function.
randomised controlled trial	A trial that randomly allocates different treatments within a trial group to assess the efficacy of a healthcare treatment.
systematic review	A systematic review systematically gathers and reviews relevant research trials to compare and comment on results.