SHIATSU

A review of the evidence

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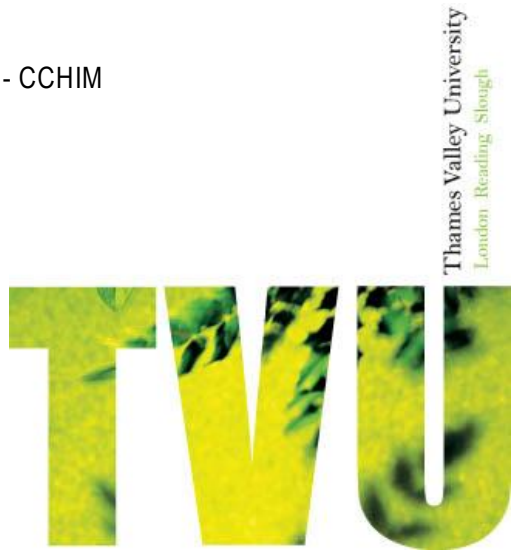

Contents

Glossary of terms

Attrition rate: The rate at which participants are 'lost' during the course of a study. (Also called 'loss to follow up'). Participants that are 'lost' during a study are often called dropouts and are usually untraceable.

Bias: When a point of view prevents impartial judgment on issues relating to the subject of that point of view. In clinical studies, bias is controlled by blinding and randomisation.
A systematic distortion of research results due to the lack of objectivity, fairness, or impartiality on the part of the evaluator or assessor. Alternatively, there are disparities in research or test results due to using improper assessment tools or instruments across groups.
A systematic error or deviation in results or inferences from the truth. In studies of the effects of health care, the main types of bias arise from systematic differences in the groups that are compared (**selection bias**), the care that is provided, exposure to other factors apart from the **intervention** of interest (**performance bias**), withdrawals or exclusions of people entered into a study (**attrition bias**) or how outcomes are assessed (**detection bias**). Reviews of studies may also be particularly affected by **reporting bias**, where a biased subset of all the relevant data is available.

Blinded study: A study done in such a way that the patients or subjects do not know (is blinded as to) what treatment they are receiving to ensure that the results are not affected by a placebo effect (the power of suggestion).

Blinding: The process of preventing those involved in a trial from knowing to which comparison group a particular participant belongs. The risk of bias is minimised when as few people as possible know who is receiving the experimental intervention and who the control intervention. Participants, caregivers, outcome assessors and analysts are all candidates for being blinded. Blinding of certain groups is not always possible, for example surgeons in surgical trials.

Bonferroni correction for Type 1 error: This is an example of a multiple comparison techniques. It adjusts the Type 1 error level to compensate for multiple comparisons between three or more groups or two or more response variables.

Carryover effect: The persistence, into a later period of treatment, of some of the effects of a treatment applied in an earlier period.

Control group: The subjects in a controlled study who do not receive the treatment.

Controlled study: A study that uses the method of comparison to evaluate the effect of a treatment by comparing treated subjects with a control group, who do not receive the treatment. (See also uncontrolled study)

Convenience sample: A group of individuals being studied because they are conveniently accessible in some way. This could make them particularly unrepresentative, as they are not a random sample of the whole population. A convenience sample, for example, might be all the people at a certain hospital, or attending a particular support group. They could differ in important ways from the people who haven't been brought together in that way: they could be more or less sick, for example**.**

Double-blind: In a double-blind study, neither the subjects nor the people evaluating the subjects know who is in the treatment group and who is in the control group. This mitigates the placebo effect and guards against conscious and unconscious prejudice for or against the treatment on the part of the evaluators.

Duplicate bias: A study that has been published more than once using the same data but written as a separate study.

Hawthorne effect/bias: This can be summarized as "Individual behaviours may be altered because they know they are being studied." This means that the act of measurement, itself, impacts the results of the measurement. In science, dipping a thermometer into a vial of liquid can affect the temperature of the liquid being measured. In the same way, the act of collecting data, where none was collected before creates a situation that did not exist before, thereby affecting the results**.**

Intention to treat analysis: A strategy for analysing data from a randomised controlled trial. All participants are included in the arm to which they were allocated, whether or not they received (or completed) the intervention given to that arm. Intention-to-treat analysis prevents bias caused by the loss of participants, which may disrupt the baseline equivalence established by randomisation and which may reflect non-adherence to the protocol. The term is often misused in trial publications when some participants were excluded.

Inter-rater reliability: The degree of stability exhibited when a measurement is repeated under identical conditions by different raters. Reliability refers to the degree to which the results obtained by a measurement procedure can be replicated. Lack of inter-rater reliability may arise from divergences between observers or instability of the attribute being measured.

Intervention group: A group of participants in a study receiving a particular health care intervention. Parallel group trials include at least two intervention groups.

Intra-rater reliability: The degree of stability exhibited when a measurement is repeated under identical conditions by the same rater. Reliability refers to the degree to which the results obtained by a measurement procedure can be replicated. Lack of intra-rater reliability may arise from divergences between instruments of measurement, or instability of the attribute being measured.

Language bias: Exclusion, in a meta-analysis of controlled trials, of those published in languages other than English.

Mean: The sum of a list of numbers, divided by the number of numbers. This is also often referred to as the average.

Meta-analysis: A statistical procedure to combine a number of existing studies. Through such a procedure, effects which are hard or impossible to discern in the original studies because of a too small sample size can be made visible, as the meta-analysis is (in the ideal case) equivalent to a single study with the combined size of all original studies. A weakness of the method is that problems with any of the studies will affect the result of the meta-analysis, so a good meta-analysis of bad studies will still result in bad data.

Null hypothesis: A statement concerning one or more parameter(s) that is subjected to a statistical test; a statement that there is no relationship between the two variables of interest; the belief that any apparent relationship between or among variables in one or more research samples has been caused by sampling error; the hypothesis that is tested when seeking to gain statistical support for a research hypothesis.

Order effects: Where the effects of two different interventions (A, B) are both being studied for all participants divided into two groups (1, 2). The order in which these interventions are administered may have an effect on the outcome e.g. group 1 has intervention A followed by B and group 2 has intervention B followed by A.

Placebo: An inactive substance or procedure administered to a participant, usually to compare its effects with those of a real drug or other intervention, but sometimes for the psychological benefit to the participant through a belief that s/he is receiving treatment. Placebos are used in clinical trials to blind people to their treatment allocation. Placebos should be indistinguishable from the active intervention to ensure adequate blinding.

Placebo effect: The belief or knowledge that one is being treated can itself have an effect that confounds with the real effect of the treatment. Subjects given a placebo as a pain-killer report statistically significant reductions in pain in randomised studies that compare them with subjects who receive no treatment at all. This very real psychological effect of a placebo, which has no direct biochemical effect, is called the placebo effect. Administering a placebo to the control group is thus important in studies with human subjects; this is the essence of a blind experiment.

Powered sample size: The sample size calculated for a study will ensure that it is sufficient in order to detect a significant difference.

Practice effect: The effect of receiving an intervention for a second time. This can also be referred to as a learning effect. When you split the subjects, the group that gets the control first has the practice effect added to the intervention, whereas the group that gets the intervention first has the practice effect added to the control treatment. So when you average the difference scores, the practice effect disappears and you are left with the treatment effect, provided the two groups have the same number of subjects.

Pragmatic design: A trial that aims to test a treatment policy in a 'real life' situation, when many people may not receive all of the treatment, and may use other treatments as well. This is as opposed to an explanatory trial, which is done under ideal conditions and is trying to determine whether a therapy has the ability to make a difference at all (i.e. testing its efficacy).

P-value: The probability (ranging from zero to one) that the results observed in a study (or results more extreme) could have occurred by chance if in reality the null hypothesis was true. In a meta-analysis, the P-value for the overall effect assesses the overall statistical significance of the difference between the intervention groups, whilst the P-value for the heterogeneity statistic assesses the statistical significance of differences between the effects observed in each study.

Probability samples: Samples in which each element in the population has a known chance of being selected into the sample.

Purposive sample: A non probability sampling technique wherein investigators use their judgment and prior knowledge to choose people for the sample who would best serve the purposes of the study.

Random Sample: A random sample is a sample whose members are chosen at random from a given population in such a way that the chance of obtaining any particular sample can be computed. The number of units in the sample is called the sample size, often denoted as ‘n’.

Randomised block experiment: This study design splits the experiment into a number of "mini-experiments" or blocks for convenience, or to increase power. Typically, each block has one experimental unit of each treatment.

Randomised control trial (RCT): A clinical trial in which chance is deliberately introduced in assigning subjects to the treatment and control groups. For example, write an identifying number for each subject on a slip of paper, stir up the slips of paper, and draw slips without replacement until half of them have been drawn. The subjects identified on the slips drawn could then be assigned to treatment, and the rest to control. Randomising the assignment tends to decrease confounding of the

treatment effect with other factors, by making the treatment and control groups roughly comparable in all respects but the treatment.

Sample with low attrition rate: This indicates that there was a low level of drop outs from the group of study participants (See **Attrition rate**)

Single blind study: A study in which one party, either the investigator or participant, is unaware of what medication the participant is taking; also called single-masked study.

Single-group pretest posttest design: There is no control group in this type of study. The results are therefore measured by:
Pretest - a means to measure existing knowledge or ability prior to the implementation of an instructional activity, innovation or program
Posttest - a means to measure knowledge or ability after an instructional activity, innovation or program is implemented, using one or more research methods . Also sometimes referred to as a "post-assessment."

Three armed RCT: A randomised clinical trials where there are three groups receiving different treatments / interventions for comparison.

Type I error: Error that occurs when the null hypothesis is rejected when a true relationship between variables does not exist; also called alpha (α) error.

t–distribution: A statistical distribution describing the distribution of the means of samples taken from a population with unknown variance.

t-test: The t-test employs the statistic (t) to test a given statistical hypothesis about the mean of a population (or about the means of two populations). The most common t-test is a test for a difference of two means

Uncontrolled study: A study in which there is no control group; i.e., in which the method of comparison is not used: the experimenter decides who gets the treatment, but the outcome of the treated group is not compared with the outcome of a control group that does not receive treatment.

Nomenclature of points

It is necessary in an academic report of this kind to name points strictly as they appear in published papers. This is why the same points appear with different abbreviations across this report; for example Pericardium 6 appears as P6, PC6, Pc6 and HP6.

The various abbreviations as they appear in the report are listed below:

Heart meridian points are abbreviated as: Ht; HT

Small Intestine meridian points are abbreviated as: Si; SI

Pericardium meridian (also known as Heart Protector, Heart Governor and Heart Constrictor) points are abbreviated as: P; Pc; PC; HP

Triple Heater meridian (also known as Triple Warmer) points are abbreviated as: TH; TW

Spleen meridian points are abbreviated as: Sp; SP

Stomach meridian points are abbreviated as: ST; St

Lung meridian points are abbreviated as: L; LU; Lu

Large Intestine meridian points are abbreviated as: LI; Li

Kidney meridian points are abbreviated as: K; KI; Ki

Bladder meridian (also known as the Urinary Bladder) points are abbreviated as: UB; BL; BI; B

Liver meridian points are abbreviated as: Liv; LIV; LR

Gall Bladder meridian points are abbreviated as: GB

Conception Vessel meridian (also known as Ren Mai) points are abbreviated as: Ren; CV

Governing Vessel meridian (also known as Du Mai) points are abbreviated as: Du; GV

Chinese point names are given in some abstracts and the meridian/number format has been inserted where appropriate.

The “Third Eye Point” between the medial ends of the eyebrows on the bridge of the nose has no meridian/number format associated with it. It is named in the following ways in the text: Yintang; Extra 1

1. Executive Summary

The aim of this evidence review was to identify and appraise scientific publications on the practice of Shiatsu in order to determine the direction of future research for the Shiatsu profession.

Comprehensive searches were conducted (Feb 1990-June 2006) of databases; MEDLINE, Cochrane, EMBASE, CINAHL, AMED, PsycINFO, BNI, Blackwell Synergy, Ingenta, Science Direct and Index to Theses. Acupressure and Shiatsu use the same points and are based on the meridian system of Traditional Chinese Medicine, but Shiatsu techniques cover more than just acupressure. On this basis, it was agreed that acupressure studies should be included in the review.

Initial search results identified 602 studies. After applying exclusion criteria and quality assessment, 5 Shiatsu and 41 acupressure publications remained for review and appraisal. The Shiatsu studies comprised three uncontrolled studies and two quasi-experimental studies. For acupressure, three were systematic reviews, 23 randomised controlled trials (RCTs), 14 quasi-experimental studies and one uncontrolled study.

The Shiatsu studies provide very limited evidence on a diverse range of health issues (angina, low back pain, fibromyalgia, chemotherapy side effects/anxiety and inducing labour). The methodological quality of these studies was generally poor.

Studies on acupressure provided fairly strong evidence for its use in the treatment of pain. Evidence for acupressure for nausea and vomiting was inconsistent, with the strongest evidence for post-operative nausea. Weak evidence for renal symptoms and COPD/asthma was found. The remaining acupressure studies provided evidence of variable quality on psycho-social health issues, consciousness/anaesthesia and other disparate health issues.

The methodological quality of studies and the health issues investigated were heterogeneous and therefore study results could not be pooled. The main methodological limitations of the studies identified included: small sample sizes, insufficient details on sampling and follow up, high drop out rates, uncontrolled design, and lack of blinding.

The research base for Shiatsu is very much in its infancy and the profession will need to work closely with its practitioners and researchers in order to build up evidence of effectiveness. Well-designed efficacy studies are needed on Shiatsu as an intervention.

Recommendations following this review include:

- Conduct further research on the effectiveness of Shiatsu as an intervention
- Encourage practitioners to engage in research using well designed studies
- Clarification of the relationship between Shiatsu and acupressure for marketing and public awareness
- Consider the development and piloting of an adverse event reporting system for Shiatsu
- Explore clinical and the cost effectiveness of Shiatsu in an integrated setting
- Identify specific topic areas for initial research investment
- Develop an evaluative framework for integrated Shiatsu practice
- Develop a research resource for the profession
- Investigate the appropriateness of various research methodologies for Shiatsu research

2. Introduction

The word SHIATSU is Japanese and means pressure ("ATSU") with fingers ("SHI"), i.e. "finger pressure". The term has been used over the last 200 years to describe the practice of a massage therapy which incorporates gentle manipulations and stretches combined with pressure techniques exerted through the fingers, thumbs, elbows, knees and feet. Shiatsu is an oriental medicine which has its roots in Chinese medicine and may even have pre-dated acupuncture. It embraces the philosophy of Yin and Yang, the energy meridians, the five elements and the concept of Ki, or energy. Practitioners use points on the meridians to rebalance the body's energy. These pressure points are known as "tsubos" in Japanese and are points that allow the therapist to act on the energy meridians. The concept of affecting the balance of energy through tsubos on the meridians is similar to that of acupuncture where needles are placed at these specific points or where heat is applied to chosen points on the meridians, and in Shiatsu where pressure is applied on both points and meridians.

However, more recently Shiatsu is known as a form of bodywork which primarily developed in Japan. It has been recognized by the Japanese Government as a therapy in its own right during the last 50 years[1]. It is now practiced in many European countries and was one of eight non-conventional, complementary medicine disciplines named in the Collins Report.[2]

Shiatsu has a number of different styles, philosophical approaches and theoretical bases. The Shiatsu Society UK encourages an eclectic outlook so that practitioners and students become familiar with and respect the different forms and styles of Shiatsu, The approaches most commonly found in Britain are Zen Shiatsu (most common), Macrobiotic Shiatsu, Healing Shiatsu, Tao Shiatsu, Seiki, Namikoshi Shiatsu and Hara Shiatsu.

Shiatsu aims is to balance, restore and maintain the body's energy balance and prevent the build-up of stress. It is used to treat a wide range of conditions, from specific injuries to more general symptoms of poor health, and is a deeply relaxing experience. Shiatsu is complementary to mainstream Western medicine, not an alternative. Some of the most common syndromes which may be amenable to treatment by Shiatsu include: headaches; migraine; stiff necks and shoulders; backaches; coughs; colds; menstrual problems; respiratory illnesses including asthma and bronchitis; sinus trouble and catarrh; insomnia; tension; anxiety and depression; fatigue and weakness; digestive disorders and bowel trouble; circulatory problems; rheumatic and arthritic complaints; sciatica and conditions following sprains and injuries.

Acupressure is the treatment through massage of specific pressure points as defined within with meridian system of Traditional Chinese Medicine (TCM). Acupressure is embedded within Shiatsu training, theory and practice. Shiatsu practitioners are trained in the anatomical location, functions and uses of over 150 pressure points on the body. Shiatsu and acupressure are not identical, since Shiatsu training and practice covers more than acupressure and includes diagnosis from the Hara, and the treatment of entire meridians as well as points. However, Shiatsu incorporates acupressure, and there is an argument to be made that evidence for the efficacy of acupressure can validly be used to support claims about the efficacy of Shiatsu for specific conditions. [3]

3. Aim

The aim of this report was to systematically review the current evidence base for Shiatsu by identifying relevant scientific publications and appraising the quality of the research published to date.

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[1] Lundberg .P (1992) *The New Book of Shiatsu*. New York: Fireside Books.

[2] European Parliament (1997*). The Collins Report, Resolution on the Status of Non-Conventional Medicine.* Strasbourg (disseminated by the European Parliament, May 1999).

[3] Bewley D (2006) Director Shiatsu Society, letter to Committee of Advertising Practice, June 2006.

4. Objective

To inform future research directions for the Shiatsu profession in order to build their evidence base.
To support evidence driven practice, marketing and advertising of Shiatsu.
To support the development of Shiatsu training and education.

5. Methods and search strategy

5.1 Databases

Comprehensive searches were conducted for publications from February 1990 to June 2006. No date restrictions were set therefore initial results included publications prior to this date. The initial searches were conducted in February 2006. The MEDLINE searches were updated in March, April and June 2006 with a final update in August 2006 in preparation for reviewing the evidence. All search results were collated in individual Reference Manager® databases for review.

Search engines and journal databases accessed are listed below (Table 1)

Table 1 - Search engines and journal databases accessed:

Via PubMed:
MEDLINE
Via OVID:
EBM reviews (includes all Cochrane Library resources)
Allied and Complementary Medicine (AMED)
British Nursing Index (BNI)
Cumulative Index to Nursing & Allied Health Literature (CINAHL)
EMBASE
MEDLINE in process & non indexed
OVIDMEDLINE
PsycINFO
Journal databases:
Science Direct
Blackwell Synergy
Ingenta Select
Wiley Interscience

The following databases were also searched:

1. Index to Theses
http://www.theses.com/

2. ZETOC (British Library electronic table of contents)

The Shiatsu Society UK provided a copy of a commissioned report[4]

[4] Mackay H & Long A (2003) The Experience and Effects of Shiatsu: Findings from a Two Country Exploratory Study. University of Salford, UK

In addition, information and unpublished data was collected from the Shiatsu Society UK. The references of retrieved information were checked to identify any further studies. Any duplicates identified by systematically searching the database were removed.

5.2 Definition of search terms

Shiatsu was used as the main search term for most searches as it is included in the MeSH term 'acupressure' in MEDLINE. MeSH is the National Library of Medicine's (NLM) "controlled vocabulary used for indexing publications for MEDLINE/PubMed. MeSH terminology provides a consistent way to retrieve information that may use different terminology for the same concepts" See Appendix 1
More information on MeSH – Medical Subject Headings can be found at:

http://www.nlm.nih.gov/mesh/meshhome.html

The full details of searches carried out are given in Appendix 2.

5.3 Assessment of the evidence

The stages used to assess the evidence are given in Appendix 3 and are shown graphically in the Flow Chart Figure 1. Abstracts were retrieved and reviewed against the inclusion criteria (Appendix 3) and if accepted into the review they were retrieved for classification and appraisal. Studies could be classified into one of the following: a systematic review, randomized controlled trial, and uncontrolled studies. Two reviewers independently categorized the evidence and an independent adjudicator used if there was any disagreement about inclusion.

As part of the review process, the references of any systematic or literature reviews and meta-analyses were checked against the search results to ensure accuracy of searches. It was during this process, that it was found that a small number of these references, relating to acupressure studies that had not been captured in any of the above searches. By obtaining MEDLINE abstracts in citation format, it became clear that acupressure was also included in a second MeSH tree and therefore not all of the acupressure citations in MEDLINE had been included in the initial searches in February 2006. See Appendix 4 for the second MeSH tree description and subsequent search details.

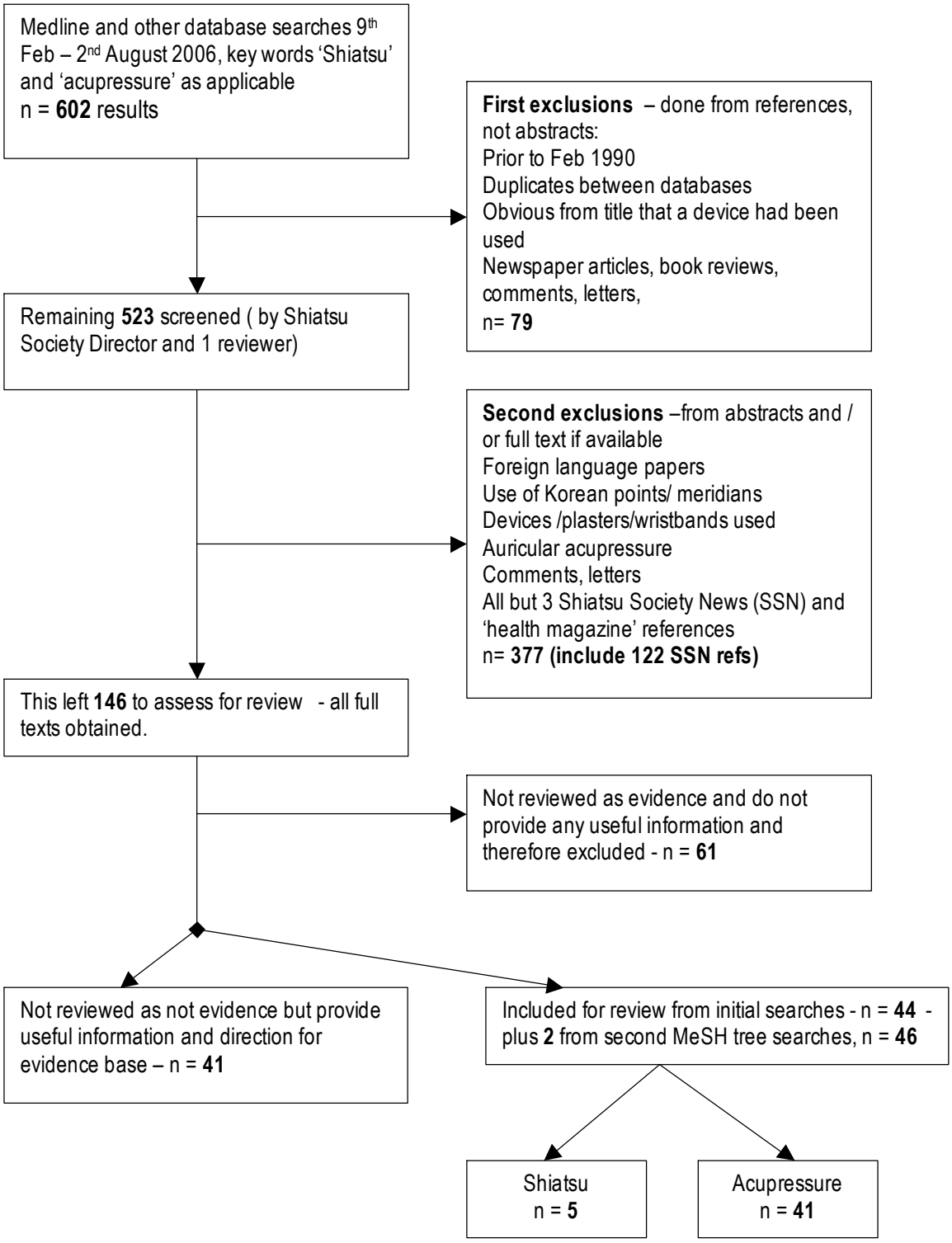
All relevant studies were appraised and their methodological quality assessed. The categorisation of the quality, weight and direction of evidence for each study was graded using criteria developed and adapted from Waddell[5].

Category 1: Generally consistent finding in a range of evidence from well-designed experimental studies
Category 2: Either based on a single acceptable study, or a weak or inconsistent finding in some multiple acceptable studies.
Category 3: Limited scientific evidence, which does not meet all the criteria of acceptable studies, or an absence of directly applicable studies of good quality. This includes published and unpublished expert opinion.

Relevant information was extracted independently by 2 reviewers using a standardised extraction form. See Appendix 5 and Figure 1.

[5] Waddell G, Feder G, McIntosh A, Lewis M, Hutchinson A. (1996) Clinical Guidelines for Management of Acute Low Back Pain (Low Back Pain Evidence Review). Royal College of General Practitioners. London.

5.4 Figure 1: Flowchart of evidence review process



6. Results and Analysis

After carrying out the initial database searches, a total of 602 publications were identified which had a keyword of 'Shiatsu' and/or 'acupressure' (Figure 1) After duplicates between databases, comments, newspaper articles and letters were excluded (79), 523 publications were screened online using published abstracts and full articles where available. A further second screening using agreed exclusion criteria (Appendix 3) resulted in 146 publications for review. Full texts of the 146 publications were further screened by two reviewers.

After applying exclusion criteria and quality assessment, 5 Shiatsu and 39 acupressure publications remained for review and appraisal. Two acupressure studies were further added after the second MeSH term searches, leaving a total of 46 studies to review, 5 Shiatsu and 41 acupressure (Figure 1 and Appendices, 4, 6, 7.). The 46 included studies were critically appraised by two reviewers using the checklist in Appendix 8. Evidence tables of these publications were constructed (Appendix 9). Data collected on each study included: study design, setting, sample, health issue, analysis of results, conclusions and comments on quality.

A total of 13 Shiatsu and 48 acupressure publications were excluded as a result of screening the 146 publications. Details of the excluded publications can be found in Appendix 10. Note: two acupressure publications were excluded after the second MeSH tree searches.

Of the remaining 41 publications which were considered useful for background information, 22 referred to Shiatsu and 19 to acupressure. Details of these can be found in Appendix 11.

Reference Manager® databases for included, excluded publications and those providing background information were also constructed (Appendices 12, 13, 14). No further publications were included for review from the Index to Theses and ZETOC searches. Details of these searches can be found in Appendix 15.

The Shiatsu publications comprised three uncontrolled studies and two quasi-experimental studies (without a randomised control group). For acupressure, three were systematic reviews, 23 randomised controlled trials (RCTs), 14 quasi-experimental studies (without a randomised control group) and one uncontrolled study. The majority of studies used a standardised acupressure/Shiatsu procedure, only five studies were pragmatic.

It was felt inappropriate to combine the Shiatsu and acupressure studies in case there were differences in the techniques. Pooling of data or a meta-analysis of all included studies could not be carried out due to heterogeneity in study methodology, the range of health conditions studied, variety of interventions and outcome measures employed.

Tables 2 and 3 give the number of included Shiatsu and acupressure articles by health issue.

Table 2: Shiatsu studies by health issue

Health Issue	Number of studies
Angina	1
Low back pain	1
Fibromyalgia	1
Chemotherapy side effects/anxiety	1
Inducing labour	1
Total	**5**

Table 3: Acupressure studies by health issue			
Health Issue – Initial search results	**Sub sections**		**Number of studies**
Pain	Dysmenorrhoea	3	11
	Labour pain	3	
	Lower back pain	3	
	Minor trauma	1	
	Neck pain	1	
Nausea & vomiting	Post-operative	4	9
	Chemotherapy	3	
	Pregnancy	2	
Renal Symptoms			5
Chronic obstructive pulmonary disease/asthma			4
Anxiety/stress/sleep problems			3
Measures of anaesthesia/ Consciousness			3
Angina			1
Gastrointestinal motility			1
Gagging			1
Nocturnal enuresis			1
		Subtotal	**39**
Health Issue – Subsequent search			
Angina			1
Nausea & vomiting (pregnancy)			1
		Total	**41**

Full details of each included study, comprising methodology, design, sample, intervention, results, conclusion and critical appraisal comments, can be found in Appendix 9. A narrative summary of the studies is given below, which discusses the evidence found for Shiatsu and acupressure grouped according to the health condition investigated.

6.1 Shiatsu

The Shiatsu studies identified investigated quite separate health issues and did not use comparable methodology and therefore could not be pooled. These studies appear in alphabetical order in Appendix 9 and are discussed and summarised individually below.

Ballegaard et al (1996) investigated the effect of Shiatsu, with acupuncture and lifestyle adjustment, on patients with angina pectoris. The focus of this study was on cost benefit rather than efficacy. 69 consecutive patients were treated and compared with those from a separate trial of two invasive treatments for angina[6]. Incidence of death/myocardial infarction (MI) was 7% in this sample, compared to 21% and 15% in the comparison group (undergoing coronary-artery bypass grafting and percutaneous transluminal coronary angioplasty respectively). There was no significant difference in pain relief between groups. Additionally a cost-saving of $12000 per patient was estimated. This was a convenience sample and was not powered. The main flaws were the absence of an equivalent control group and lack of blinding. The comparison group were from the USA and the study was done in Denmark, additionally 56% of the participants would have been excluded from the one of the comparison groups. Also, due to the pragmatic design, it is difficult to isolate the effects of acupressure from co-interventions of acupuncture and lifestyle adjustments.

[6] King SB, Lembo N J, Weintraub W S et al (1994) A randomised trial comparing coronary angioplasty with coronary bypass surgery. *New England Journal of Medicine,* 331(16):1044-50

Brady et al (2001) administered Shiatsu massage to a convenience sample of 66 volunteers complaining of lower back pain. This was a single-group pretest-posttest design. Pain and anxiety significantly decreased after treatment ($p<0.001$), which did not change when demographic variables were controlled for. The absence of a control group and use of a volunteer sample who paid for treatment limits the validity of these results. 13 patients had previously received Shiatsu, further limiting the generalisability of findings.

Faull (2005) conducted a pilot study to compare the effectiveness of Watsu (water Shiatsu) to Aix massage for fibromyalgia syndrome (FMS). 17 female participants were randomly assigned to receive either Watsu then Aix or vice versa, with a 3 week break between treatment blocks. A significant improvement was seen after treatment with Watsu ($p=0.01$) for SF-36 subscales of physical function, bodily pain, vitality and social function, but not for Aix. This was only a pilot study and used a very small volunteer sample, only 13 of whom completed the study. No control group was used, although the counterbalanced design should reduce carryover effects of using repeated measures design. However, order effects may have occurred due to high dropout rate from Watsu first group (4 out of 8).

Iida et al (2000) investigated the relaxation effects of Shiatsu on anxiety and other side effects in patients receiving cancer chemotherapy. Nine patients were divided into strong anxiety or weak anxiety groups and all were given Shiatsu massage on the hands and feet. The strong anxiety group showed a significant decrease in anxiety after intervention ($p=0.09$). The weak anxiety group showed a significant increase in the relaxation score ($p=0.01$). There was a slight relief of physical symptoms in both groups but significance is not stated. This is a very small study, limiting the validity of results, aggravated by the further division of the sample into two groups, reasons for which are not clear. The use of the t-test on such a small sample will only detect differences that are huge, and may be the reason why few effects were seen. No control group was used.

Ingram et al (2005) investigated the effects of Shiatsu on post-term pregnancy in 142 women attending a consultant clinic appointment at 40 weeks gestation. Two groups were used, a Shiatsu group who received thumb pressure on points GB21, Li4 and Sp6 and who were taught breathing techniques and exercises. The control group received no intervention. The Shiatsu group was significantly more likely to labour spontaneously than the control ($p=0.038$) and had a longer labour ($p=0.03$). The main flaw was that groups were selected according to which midwife was on duty (only one midwife was trained in Shiatsu), although groups were homogenous for maternal age, parity and delivery details. The frequency of use of self-administered Shiatsu was not monitored. As a preliminary audit this study gives some useful results, although Shiatsu was not compared to a sham treatment.

There was insufficient evidence both in quantity and quality on Shiatsu in order to provide consensus.

6.2 Acupressure

The studies described as giving acupressure as an intervention form the second part of Appendix 9 and are in alphabetical order and summarised below.

6.2.1 Pain

Pain was the most common issue addressed by acupressure studies. These included studies on dysmenorrhoea (3 studies), labour pain (3 studies), lower back pain (3 studies), one study on minor trauma and one on neck pain. Seven of the 11 studies were RCTs, with control groups and random assignment; the remainder did not have a control and/or random assignment.

Dysmenorrhoea

Chen and Chen (2004) randomised 69 students with primary dysmenorrhoea into an intervention group who received acupressure at Sp6 and a control group who rested. Acupressure significantly reduced menstrual pain ($p<0.05$). The sample size was powered and 72% completed the study. The placebo effect was not controlled for as a sham treatment arm was not included. The generalisability of the findings is limited as the participants were volunteers and aged 17-19.

Jun et al (2006) carried out a controlled trial of acupressure compared to light touch at Sp6 for primary dysmenorrhoea, also on a sample of students. Sample size (58) was powered. The severity of dysmenorrhoea was significantly reduced in the acupressure group compared to control ($p=0.000$) and this effect lasted for up to 2 hours after treatment ($p=0.032$). Allocation to study groups was performed sequentially not randomly, although groups were homogenous in their baseline demographics and the factors affecting dysmenorrhoea. Students and data collectors were blinded. In both this and the study above, Hawthorne bias may be present as it is possible (although not stated) that the participants were students of the researchers.

Pouresmail and Ibrahimzadeh (2002) carried out a three-armed RCT of 216 high school students (aged 14-18 years), to compare the effects of acupressure, acupressure at sham points and Ibuprofen on primary dysmenorrhoea. Results indicated that all three techniques significantly reduced pain ($p<0.01$). Both acupressure and Ibuprofen were better than placebo. This is a high quality study with random group assignment and a large sample with a low attrition rate. However, the validity of the outcome measures was not disclosed and it is not clear if blinding was used.

Labour pain

Chung et al (2003) randomly assigned 127 parturient women to an intervention group who received acupressure at Li4 and BL67, placebo group who received light skin stroking at these points and a control group (conversation only). All groups showed a significant decrease in labour pain during the active first phase of labour ($p=0.041$) and acupressure was significantly more effective than control ($p=0.017$) but not compared to light stroking. This indicated that effects of acupressure may be due to tactile stimulation rather than meridian effects. Additionally a third of women receiving acupressure qualitatively reported that it had reduced their pain. This is a high quality three-armed RCT, with homogenous groups, although sample size in each group was only 42/43 and response rate was very low at the transitional phase of labour (31 out of 127). Both the outcome measure (VASs) and the acupressure procedure were shown to be reliable and valid by the researchers. The three steps to ensure validity and reliability of the acupressure were 1) Protocol was established by experienced Chinese physicians and using a pilot study; 2) Intrarater reliability test was used to control pressure force, measured for each practitioner and three experts evaluated the accuracy of the acupoint location for each practitioner; 3) Practitioners underwent a 2 hour training session and monthly meetings.

Lee et al (2004) conducted a double-blind RCT of acupressure compared to touch on Sp6 acupoint for labour pain. A volunteer sample of seventy-five women in labour were matched for five characteristics of labour and randomly assigned. There were significant differences between the groups in subjective labour pain scores immediately after the intervention ($p=0.012$), 30 mins after ($p=0.021$) and 60mins after ($p=0.012$). Anxiety was also significantly lower in the acupressure group compared to the control ($p=0.03$). Groups were homogenous. Bias may be introduced by using a volunteer sample. Blinding was used where possible (patients and data collectors) and the use of a placebo treatment controlled for the emotional supportive effects of human touch.

Waters and Raisler (2003) used ice massage on acupoint Li4 during labour contractions in a one-group pretest-posttest study. As measured by the visual analogue scale (VAS), pain was reduced

after the intervention. This study had a number of methodological limitations, the main flaw being the absence of a control group. In addition, no sample size is given, convenience sampling was used, and only early labour pain was investigated due to the limitations of the outcome measure.

Lower back pain

Hsieh et al (2004) conducted an RCT of acupressure compared to physical therapy for chronic low back pain. 146 participants were randomly assigned to receive four weeks of either acupressure or physical therapy (thermotherapy, infrared, electrical stimulation, exercise and traction). Mean post-treatment pain scores were significantly lower in the acupressure group ($p=0.0002$) and also after 6 months ($p=0.0004$). This is a high quality trial with a powered sample (although convenience), homogenous groups, valid outcome measures and using intention to treat analysis to protect against attrition bias. Blinding was used where possible; practitioners and patients were blinded to pretest scores and follow-up staff were blind to treatment allocation. Although no placebo treatment was used, it can be assumed that physical therapy is usual care in Taiwan. This study was pragmatic as acupressure treatment was individualised rather than using a standardised protocol.

Hsieh et al (2006) conducted another RCT of acupressure compared to physical therapy for chronic low back pain, on 129 orthopaedic outpatients. The methodology was very similar to Hsieh et al 2004, comparing acupressure to physical therapy in randomised groups. This study also showed significantly lower pain and disability scores in the acupressure group compared to physical therapy ($p<0.05$). Again, no placebo treatment was used and the treatment was pragmatic rather than standardised. As it used the same methodology, this study is of a similarly high quality to Hsieh et al (2004).

Yip and Tse (2004) randomly assigned 61 adults with sub-acute or chronic low back pain into an intervention or control group (usual care only). The intervention consisted of acupoint stimulation using an electronic device on acupoints Li10, Li11, Si10, TW15 and BL10 and acupressure with lavender oil on UB 22, 23, 25 and 40. The intervention group showed a significant reduction in pain intensity compared to the control ($p=0.0001$) but not for duration of pain. The sample size was powered, however participants were volunteers, 16% dropped out and these were older which may cause bias. It is difficult to isolate the effect of acupressure in this study, due to co-interventions of electrical stimulation and lavender oil, and due to the lack of a control treatment.

Neck pain

Yip and Tse (2006) used the same protocol as above to treat 28 adults with sub-acute non-specific neck pain. The acupressure group showed a significantly greater reduction in pain than control ($p=0.001$). Although group assignment was random, this trial used a very small sample and no blinding or placebo. Again, it is difficult to isolate the acupressure effect.

Minor trauma

Kober et al (2002) conducted a double-blind RCT with 60 minor trauma patients who were randomly allocated to acupressure, sham acupressure or control groups. All were treated for 3 minutes during transportation in ambulances. At the end of transport they found significantly less pain, anxiety and heart rate in the acupressure group but not in either sham or control groups. Sampling bias may be present as eligible patients were purposively selected by paramedics. All groups were homogenous, the trial was truly double blinded (paramedic giving treatment and patient) and intention to treat analysis was used, although there were no dropouts.

Overall, the evidence for the efficacy of acupressure for pain is fairly strong and can be graded as category 1 evidence (*generally consistent findings in a range of evidence from well-designed experimental studies*) (see p. 3). Although some studies have methodological flaws, a number of RCTs consistently show that acupressure is more effective than control for reducing pain, namely dysmenorrhoea (Chen & Chen 2004; Jun et al 2006; Pouresmail & Ibrahimzadeh 2002), lower back pain (Hsieh et al 2004; Hsieh et al 2006; Yip & Tse 2004) and labour pain (Chung et al 2003; Lee et al 2004).

6.2.2 Nausea & vomiting

Nausea and vomiting was the second most common health issue to be studied. We found 10 studies, which investigated nausea and vomiting in three main situations; post-operative including caesarean (four studies), as a side effect of chemotherapy (three studies) and during pregnancy (three studies). Nearly all studies used the P6 acupoint.

Post-operative

Chen et al (2005) investigated the use of acupressure at P6 on reducing nausea, vomiting, anxiety and pain in 104 post-caesarean women. They found that acupressure significantly reduced nausea, vomiting and retching up to 10 hours post-caesarean compared to a control group who received standard care. Anxiety and pain were also reduced. Although this study had a fairly large sample and a control group, a convenience sample was used and group assignment was not random (first 52 recruited were in intervention group). Although this may introduce seasonal/time-related bias, this was in order to prevent participants discussing the study and groups were shown to be homogenous for demographic and physiological variables and pre-test scores.

Two reviews for postoperative nausea and vomiting were found, one systematic review (Lee & Done 2004) and one meta-analysis (Shiao & Dune 2006). Lee & Done found 26 trials specifically using P6. Although studies were heterogeneous, they concluded that acupressure reduced the risk of both nausea and vomiting compared to sham treatment, and reduced the risk of nausea but not vomiting compared to antiemetic medication. As a Cochrane review this is a high quality systematic review, which used comprehensive search terms and combined data from the trials. It was limited to acupoint P6. Shiao and Dune pooled the data on 33 trials using some form of acupoint stimulation versus placebo or control, 30 of which used the P6 acupoint. Two further trials compared acupoint stimulation to medication. Their results showed that all modalities of acupoint stimulation were effective in reducing postoperative nausea and vomiting compared to controls, and as effective as medication. This is a well conducted meta-analysis using comparable studies and a good selection process. 18 of the trials were for acupressure, providing a large body of evidence in this area, although most of these used bands to apply pressure. The pooled data from these studies showed that acupressure reduced nausea ($p<0.0001$) and there was no evidence of bias.

Ming et al (2002) conducted a randomised block experiment comparing finger-pressing, wrist-band and control (conversation only) in a sample of 150 patients undergoing endoscopic sinus surgery. They found that post-operative nausea and vomiting were significantly different between the three groups ($p=0.001$ and $p<0.001$ respectively). This study has a good sample size and very low attrition (98.7% follow up) but was not blinded. Patients were matched for motion-sickness before being randomly assigned (it is unclear why this was variable was used) and groups were homogenous. Although internal validity was high, the study was not blinded which may have introduced placebo/observer bias.

Chemotherapy

Acupressure for nausea as a side-effect of chemotherapy was investigated by Dibble et al (2000), Ezzo et al (2006) and Shin et al (2004).

Dibble et al (2000) conducted a pilot RCT of 17 women undergoing chemotherapy for breast cancer in oncology outpatient clinics. Patients were randomised (stratified based on setting and treatment regimen) to receive usual care or usual care plus acupressure at P6 and ST36. Nausea experience and intensity were significantly reduced in the acupressure group ($p<0.01$ and $p<0.04$ respectively). Results of this study are inconclusive due to the very small sample size and the lack of a placebo treatment (discussed as unethical), although groups were homogenous. Also, the Hawthorne effect may have been present due to the extra attention given to the treatment group.

Ezzo et al (2006) conducted a Cochrane Systematic review on 11 trials of acupoint stimulation for chemotherapy-induced nausea and vomiting. Pooled data showed that all methods combined reduced the incidence of acute vomiting ($p=0.04$), but not severity of nausea compared to control. Acupressure reduced mean acute nausea severity ($p=0.04$) but not acute vomiting or delayed symptoms, although studies did not use placebo controls. This is a well conducted review which reports all methodological details. Data was pooled using intention to treat analysis and using original data where possible. Additionally duplicate bias and language bias were controlled for. Evidence for acupressure is however limited as the review included all acupoint stimulation (including acupuncture) only three of which were acupressure trials and which include those which used bands.

Shin et al (2004) compared the effects of self-acupressure on P6 with antiemesis medication to medication alone, in a sample of 40 postoperative gastric cancer patients receiving the first cycle of chemotherapy. A significant reduction was found between intervention and control groups in the severity of nausea and vomiting, duration of nausea and frequency of vomiting (all $p<0.01$). Although these results are highly significant, a number of methodological issues are present. The sample is small and convenience sampling was used, group allocation was also not random (allocation used, first 20 patients in control group), although groups are homogenous for demographic, disease and treatment variables. Again, the intervention group had additional attention, which may have introduced the Hawthorne effect.

Pregnancy

Three studies investigated nausea and vomiting in pregnancy; Habek et al (2004) looked at hyperemesis gravidarum (HG), which is a more severe and rare form of the nausea and vomiting investigated by Markose et al (2004) and Belluomini et al (1994).

Habek et al (2004) randomised 36 pregnant women with HG to four groups; acupuncture, placebo acupuncture, acupressure and placebo acupressure. Results showed that acupressure significantly reduced the occurrence of HG ($p<0.01$). This study was double-blinded which is unusual in these studies. Sampling was not given, but group allocation was random. Statistical analysis of group composition was not performed. The main flaw with this study is the small sample, which is then divided into four groups, so the power in each group is very low. Also, the outcome measure appears to be simply the disappearance of nausea and vomiting as assessed by the patient and gynaecologist, which is subject to bias. The acupressure protocol was not controlled and was self-administered.

Markose et al (2004) conducted a one group uncontrolled study of acupressure on P6 for nausea, vomiting and dry retches in 35 women pregnant under 12 weeks. After treatment (day 7) there was a significant reduction in the frequency of nausea from day 3 (before treatment) ($p=0.008$), vomiting ($p=0.000$) and retching ($p=0.016$). This study was of poor quality as it was uncontrolled and used a very small sample. In addition, only 17 of the 35 women completed the study. Sampling procedure is not given.

Belluomini et al (1994) randomised 90 pregnant women (12 weeks gestation or less) to receive either acupressure at Pc6 or sham acupressure at a non acupoint. Both groups showed significant reduction

in nausea and emesis over time, but this improvement was significantly greater in acupressure group (p=0.0021) than control. There were no differences in severity or frequency of emesis between groups. The sample was selected from referred patients, details of this are not clear. Only 60 out of 90 completed the study and intention to treat analysis was not used. Drop out was however similar between study groups. A randomised block design was used which can give more powerful treatment effects, but criteria for blocking were not given (may be gestational age). Groups homogenous for pregnancy characteristics and pre-test scores. Maternal age was associated with nausea and vomiting score. Gestational age was controlled for. This study was single blind and used a sham treatment arm. Acupressure was self administered acupressure and reliability of the procedure was not checked.

In summary, the evidence for acupressure for nausea and vomiting is somewhat inconsistent and varies with type of nausea investigated. Studies investigating post-operative nausea provide the strongest evidence, which can be as graded as Category 1 evidence (see protocol 3b) as the studies are generally well designed (Chen 2005; Ming 2002), and include a systematic review (Lee & Done 2004) and a meta analysis (Shiao & Dune 2006). The two trials reviewed for chemotherapy-induced nausea and vomiting (Dibble 2000; Shin 2004) give little reliable evidence, mainly due to small sample size, and although the Cochrane review (Ezzo 2006) gives quality evidence, little of it is on true acupressure. The three studies of acupressure for nausea in pregnancy are of poor quality with small samples and/or uncontrolled study design (Belluomini et al 1994; Habek 2004; Markose 2004)

6.2.3 Renal Symptoms

Five studies were identified which investigated the use of acupressure for renal symptoms. All of these studies have a number of similarities as Tsay SL was lead researcher in four and co-researcher in the fifth study.

Cho and Tsay (2004) randomly assigned 62 haemodialysis patients to acupressure and control groups to test the effect of acupressure on fatigue and depression on End-Stage Renal disease (ESRD). Acupressure group received acupoint massage on zusanli (St36), sanyinjiao (Sp6), taixi (Ki3) and yung chuan (Ki1) while the control group received routine care. Results showed a significantly greater reduction in fatigue ($p<0.004$) and depression ($p=0.045$) in the acupressure group than the control. Sample size was powered, group assignment random, and treatment groups were homogenous except for age. Differences in pre-test scores and age were also controlled for. The extra attention the treatment group received may have had an effect as a sham treatment arm was not included.

Two articles by Tsay & Chen (2003) and Tsay et al (2003) appear to be based on the same RCT of acupressure for quality of sleep in ESRD patients, but are included as separate studies as they were published as individual papers. However, we have only described the methodology/quality once below, as details are identical. 98 ESRD patients from four hospitals were randomly assigned into three groups, acupressure (on points H17 and K11), sham (massage not on acupoints) and control (standard care). Results indicate that improvement in quality of sleep was significantly greater in acupressure compared to control ($p<0.01$). However there were no differences between the acupressure and the sham group, or the sham and control group, except that subjective sleep quality was improved in the sham group compared to the control ($p=0.003$). Blinding was used, for interviewer/data collector, usual care provider and participant, but not acupressure nurse. The outcome measures and acupressure procedure were reliable. Bonferroni correction controlled for type 1 error. Group assignment was random, and groups were homogenous for demographics, sleep affecting behaviour and ESRD related factors. Attrition was low (98 from 105).

Tsay (2004) conducted an RCT of 106 ESRD patients, investigating acupressure for fatigue. Again, patients were randomised to three groups, acupressure, sham and control. Acupoints Ki1, St36, GB34 and Sp6 were used. Results, adjusted for differences in baseline fatigue, showed that patients in the acupressure group ($p=0.01$) and sham group ($p=0.003$) both had significantly lower fatigue

scores than control. Although reduction of fatigue was greater in acupressure than sham groups, this difference was not significant, indicating that non acupoints massage also had an effect on reducing fatigue. Participants were not blinded; the researchers stated that participants knew which group they were in. Control and intervention groups were demographically and clinically homogenous and co-variables of depression and quality of sleep were controlled for in analyses. The reliability and validity of the procedure was evaluated by expert validation, and the internal consistency of the outcome measures was good.

Tsay et al (2004) tested the effects of acupuncture or transcutaneous electrical acupoint stimulation (TEAS) on fatigue, sleep quality and depression in a prospective RCT. They randomly assigned 106 haemodialysis patients to three groups to receive either acupressure or TEAS on points Ki1, St36, GB34 and Sp6 or control who received routine care only. Acupressure and TEAS patients had significantly lower fatigue (p=0.05 and p=0.016 respectively) and less depressed moods (p=0.009 and p=0.008 respectively) than control, adjusted for baseline differences. There were no differences between acupressure and TEAS groups. This study used random group assignment and three arms, with homogenous groups. It also had a powered sample size and low attrition rate (2 out of 108). The reliability and validity of the procedure was evaluated by expert validation, and the internal consistency of the outcome measures was good. However, no details of blinding are given and results are limited to haemodialysis patients.

These five studies provide category 2 evidence for the use of acupressure for renal symptoms (*evidence based on a single acceptable study, or a weak or inconsistent finding in multiple acceptable studies*) (see p. 3). This categorisation has been chosen mainly because they do not represent a range of studies, as all are fairly similar in design and setting and mainly led by one researcher. The individual studies provide some evidence for the efficacy of acupressure for ESRD/haemodialysis patients, but this is limited in generalisability. Although they did control for a number of factors and biases, most studies were not blinded which reduces the quality of the evidence.

6.2.4 Chronic obstructive pulmonary disease/asthma

Three studies on chronic obstructive pulmonary disease (COPD) and one on chronic obstructive asthma were identified (Maa et al 1997; Maa et al 2003; Tsay et al 2005; Wu et al 2004).

Maa et al (1997) investigated the effects of self-administered acupressure on reducing dyspnoea and other associated symptoms in 31 patients with COPD. Patients were those beginning a pulmonary rehabilitation program at two private hospitals and acupressure was used as an adjunct to standard care. The study was a pretest-postest crossover design; group 1 had 6 weeks of acupressure followed by sham acupressure and group 2 vice versa. Real acupressure was more effective than sham for reducing dyspnoea (p=0.009) and minimally effective for reducing decathexis (p=0.044) but had no effect on any other symptoms. This study had a small sample, although sensitivity analysis was performed and did not identify any idiosyncratic individuals. Also, dropout was high (20 of 51), and mostly due to medical reasons, which may have biased the results. Also the study was only single-blind and many patients could identify sham from real acupressure. The crossover design should reduce effects of retesting, carryover or time-related effects of patients acting as their own controls, which controls for heterogeneity. Outcomes were valid and reliable.

Maa et al (2003) conducted a pilot randomised trial of acupuncture and acupressure for improving the quality of life of patients with chronic obstructive asthma. 41 outpatients were randomly assigned to receive acupuncture, acupressure or control, all groups received standard care. Acupressure patients had a significantly greater reduction in health related quality of life (p=0.05) and in irritability (p=0.06) but not in any other scores. Again, this study had a small and purposive sample, although again, sensitivity analysis was performed and did not identify any idiosyncratic individuals. There was also a very high attrition rate (41%), which was again mostly due to medical reasons and dropout was also

greater from the acupuncture group. Intention to treat analysis was not used. The study was not blinded.

Tsay et al (2005) used a two group experimental blocking design to investigate acupressure (at points Li4, PC6 and HT7) for dyspnoea, anxiety, heart rate and respiratory rate in patients with COPD. 52 patients, all on mechanical ventilation support, were matched for sex, age and length of ventilation use then randomly assigned to acupressure or control (massage and handholding) groups. Dyspnoea ($p=0.009$), anxiety ($p=0.011$), heart rate ($p=0.005$) and respiratory rate ($p<0.0001$) improved significantly in the acupressure group compared to control. This study had a powered sample although there was no information about dropout. The groups were homogenous for demographic and clinical factors. Clinical outcome measures were used and the procedure was reliable and validated by experts. Patients, data collectors and usual care givers were blinded, but not acupressure nurses or researchers.

Wu et al (2004) matched 44 outpatients with COPD for age, sex, pulmonary function, smoking and steroid use then randomly assigned them to receive acupressure (points GV14, CV22 , B13, B23, L10) or sham acupressure (Sp5, Sp3, Li1). Scores from the Pulmonary Status and Dyspnoea Questionnaire modified scale showed that the true acupressure group improved significantly more than the sham group for all three subscales; dyspnoea ($p<0.05$), fatigue ($p<0.01$) and activity ($p<0.001$). Tolerance for activity also significantly improved ($p<0.001$) as did anxiety ($p<0.001$). Although this study used a small sample, the randomised block design should give more powerful treatment effects. The sham points were on different meridians and ganglionic sections, indicating the efficacy of the specific acupoints chosen. The acupressure protocol was highly reliable and validated by the researchers, using three tests: 1) independent rating for validity to achieve 100% agreement, 2) observation of accuracy of points by TCM practitioner and 3) true and sham points compared on video for homogeneity in timing. The outcome measures were also reliable and valid.

Overall, the evidence for acupressure for COPD/asthma is category 2 evidence (see p. 3) as there are only a small number of studies and these have a number of methodological flaws. All studies had fairly small samples, and two of the identified studies had a high dropout rate which is likely to have biased their results (Maa et al 1997; Maa et al 2003).

6.2.5 Anxiety/stress/sleep problems

Three studies were identified which investigated psycho-social aspects of health, specifically pre-operative anxiety, quality of sleep and alertness.

Agarwal et al (2005) conducted an RCT with 76 adults undergoing elective surgery. Patients were randomised to receive acupressure at Extra 1 point or sham acupressure at an inappropriate site. Anxiety decreased in both groups, but both returned to baseline after 30 minutes. The decrease in anxiety was greater in the Extra 1 group ($p<0.05$). Bispectral index values were also lower during treatment in both groups, and were lower for Extra 1 group ($p<0.05$). The sample size was powered, group allocation was random and groups were homogenous. A sham treatment arm was included, although there was no other control group. The study was single-blinded (patient).

Chen et al (1999) performed a three armed RCT testing the effectiveness of acupressure in improving the sleep quality of institutionalised residents. 246 elderly residents with sleep disturbances were matched for hypertension, hypnosis, naps and exercise then randomly assigned to acupressure (points baihui (GV20), fengchi (GB20), anmian (BL18) and shenmen (Ht7) x2), sham (1cm-3cun from real points) or control (conversation) groups. Quality of sleep improved in all three groups and improvements were significantly greater in acupressure group (scheffes post hoc comparison). This was a high quality trial, with a large sample size, systematic random sampling and random group assignment, matched to give more powerful treatment effects. The control and intervention groups were homogenous for a huge range of factors (demographics age, gender, living conditions, drug use,

chronic disease, time at facility, naps, exercise, time in bed, milk tea and coffee consumption, smoking, sleep indices). The internal validity of the procedure was extensively controlled by inter-rater reliability and expert validation. However, the study was only single-blind and the principal investigator, who knew the participants, both administered treatment and collected data, which may introduce Hawthorne effect and researcher bias. Generalisability is limited as setting was a very specific home for elderly people with low income and without a son.

Harris et al (2005) used a crossover design to test acupressure to modify alertness in the classroom. They randomly assigned 39 students to two acupressure treatment sequences: stimulation-relaxation-relaxation or relaxation-stimulation-stimulation. Compared to relaxation, stimulation acupressure gave a greater alertness score ($p=0.019$). Day of study and hours of overnight sleep also significantly affected the score. The study was single-blind (subjects), although the majority of students could correctly discern the treatment. This did not significantly affect the results, although it came close, raising p to 0.0484. There is a chance that participants were students of the researchers, it which case it would appear that Hawthorne effect may be present. Small sample size (39) and low generalisability as all medical students (well educated, scientific researchers who were highly motivated to comply) were also issues. Group allocation was random and control and intervention groups were homogenous. Crossover design should reduce effects of retesting, carryover or time-related effects, although participants acting as their own controls can cause practise effect (especially with self-report). Validity of the outcome measure was not given. Nine students provided missing data retrospectively which may cause recall bias. Statistical analysis was very comprehensive, accounting for effects of sequence, period, treatment and 'other covariates', masking, and co-variates, including caffeine, sleep, medication, anxiety and compliance.

The quality of studies for acupressure for psycho-social health issues is variable; reliable conclusions cannot be drawn from the existing evidence base, although evidence for improving sleep quality in institutionalised elderly is strong (Chen et al 1999).

6.2.6 Anaesthesia/consciousness

Three studies have investigated the effects of acupressure on levels of anaesthesia or consciousness. These levels include the acoustic evoked potential (AEP), changes in which reflect the depth of anaesthesia and transition from awake to anaesthetised (Dullenkopf et al 2004); bispectral index (BIS) and spectral edge frequency (SEF) which are measures of the level of consciousness during anaesthesia/sedation (Fassoulaki et al 2003; Litscher 2004).

Dullenkopf et al (2004) used a repeated measures, counterbalanced design to investigate the influence of acupressure at Extra 1 point on the AEP of unsedated adult volunteers. 15 volunteers received acupressure at Extra 1 point followed by acupressure on a control point the following day or vice versa, the order was chosen randomly. Subjects acted as their own controls and results showed that AEP reduced significantly after 10 minutes of pressure on Extra 1 point ($p=0.0044$), but this effect only lasted for 5 minutes. Stress levels were also reduced ($p=0.0066$). This study had a very small sampling and no details of sampling were given. Patients acted as their own controls, which can cause danger of attrition, and practice effect. It can also cause carryover effects but these should be addressed by counterbalancing, as there were no differences in changes in AEP between participants who had Extra 1 or sham acupressure first.

Fassoulaki et al (2003) used a similar repeated measures design to give 25 volunteers acupressure on extra 1 point or a control on alternate days in a randomised manner, with the aim of reducing self-reported stress levels. BIS was significantly reduced during pressure on extra 1 point ($p<0.001$) but returned to baseline after pressure release. Pressure on the control point also reduced BIS but reductions from extra 1 were greater ($p<0.001$). Sample size is small, although it was powered. Again, sampling/follow-up details are not given. Participants were excluded if they believed in Traditional Chinese Medicine theory, which may well bias results. Acupressure was given for 10

minutes at Extra 1 and for only 5 minutes in the control group, which is a major flaw. Again, patients acting as their own controls can cause danger of attrition, practice and carryover effects.

Litscher (2004) conducted a crossover trial of acupressure on yintang, acupuncture, laserneedle acupuncture and sham acupressure on the BIS and SEF in 25 healthy volunteers. Participants each received all four interventions, the order of which was randomised for each patient. Results showed a significant reduction of BIS and SEF during acupressure ($p=0.001$). Stress was also reduced by acupressure ($p<0.001$) but also by sham acupressure ($p<0.012$). This was a volunteer sample and quite small, also participants were paid to take part. Subjects and data collectors were blinded. Again, the use of subjects as their own controls raises issues of bias, especially as subjects only had 20 minutes between treatments so treatment effects may overlap.

Overall, the evidence for the effects of acupressure on consciousness/anaesthesia is weak, rated as category 3 (see protocol 2b) as only three studies have been identified, all of which use a repeated measures design rather than RCT and small sample size (Dullenkopf et al 2004; Fassoulaki et al 2003; Litscher 2004).

6.2.7 Other conditions

The remaining five articles on acupressure investigated distinct health conditions which were not grouped but are considered separately below.

Ballegaard et al conducted two studies of acupressure for angina (1999 and 2004). The 1999 study was mainly a cost-benefit analysis of using acupressure as part of a self-care program for outpatients with angina pectoris. 105 patients were given acupressure at CV17, UB14 and UB15, along with acupuncture and a range of other lifestyle modifications based on self-care. Three groups were used for comparison of risk; published data on invasive treatments[7][8], a random sample of the Danish population and the group used for this study. The intervention group had a 90% reduction in hospitalisation and a 70% reduction in needed surgery. Medication intake and degree of disease were significantly reduced and quality of life improved after treatment (all $p<0.0001$). The risk of cardiac death or myocardial infarction was lower in the treatment group than general population (significance not given). As this study was designed as a cost benefit analysis rather than an efficacy study, a different study design may have given different results, the main problem being the use of non equivalent control groups. Also the sample was volunteer and convenience. It is difficult to isolate the effects of acupressure from co-interventions of acupuncture and the self-care program.

Ballegaard et al (2004) investigated the long-term effects of acupressure, as part of integrated rehabilitation (IR), to reduce the risk of angina pectoris sufferers dying from myocardial infarction (MI). 168 patients (103 candidates for surgery, 69 inoperable) with angina in a private clinic in Denmark received 12 sessions of IR which included acupressure at CV17, UB14 and UB15. 3 historical controls were used; 1) General Danish population, 2) New York clinical database[9] and 3) Patients who underwent surgery from a study in New York[10]. The 3 year accumulated risk of death was 2% (confidence limits 0 - 4.7%) for the 103 surgery candidates, compared to 6.4% (confidence limits 4.7 – 6.1%) for the Danish population and 8.4% (confidence limits 7.7 – 9.1%) for New York surgery patients. Risk of death was 7.7% (3.9-11.5%) for the 69 inoperable patients, compared to 16% (10-34%) and 25% (18-36%) for American patients treated with laser surgery or medication respectively.

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[8] Yusef et al (1994) Effect of coronary artery bypass graft surgery on survival: Overview of 10-year results from randomised trials by the Coronary Artery Bypass Graft Surgery Trialists Collaboration. *Lancet,* 344:563-570

[9] Hannan, Racz M, McCallister B et al (1999) A Comparison of 3 year survival after coronary artery bypass graft surgery and percutaneous transluminal coronary angioplasty. *Jour Am Coll Cardiol*, 33(1):63-72

[10] Schofield P M, Sharples L D, Caine N et al (1999) Transmyocardial laser revasculisation in patients with refractory angina: A randomised controlled trial. *Lancet,* 353:519-524

The accumulated risk of operation/MI/death was reduced in groups who had undergone treatment for longer ($p<0.05$ for trend). In addition, the IR program resulted in cost savings of $36000 and $22000 for surgical/inoperable patients respectively, although these costs were based on an American study. This study had a good sample size although sampling was not random and a very long follow-up period. The main flaws are the absence of an equivalent control group and lack of blinding. Also, due to the pragmatic design, it is difficult to isolate the effects of acupressure from co-interventions of acupuncture, self-care program including Chinese health philosophy, stress management and lifestyle adjustments. The sample was not significantly different in baseline variables to Scandinavian heart patients. The researchers described this study as a quality control review, which is subject to selection bias, expectation bias and social bias as patients have chosen and are paying for the treatment. However, evidence is cited which claims that no bias is introduced by patients choice of a particular treatment or paying for treatment[11].

Chen et al (2003) conducted an RCT using acupressure to improve gastrointestinal (GI) motility in women after trans-abdominal hysterectomy. 41 patients were randomly assigned to intervention (acupressure on Pc6, St36, Sp6) and control (acupressure on sham points) groups. The acupressure group had significantly improved GI motility ($p<0.05$), higher self-awareness of GI motility ($p<0.05$) and satisfaction ($p<0.001$) compared to control. The sample was small and not powered and the study was only single-blind. However, groups were homogenous for a wide range of factors (identified from previous research) (demographics, bowel movements, GI history, surgery history, duration of surgery, blood loss, analgesics, pain, post-surgical activities, leaving the bed and food intake patterns). The reliability of the procedure was verified by training, expert verification of point location and GI motility.

Lu et al (2000) investigated the anti-gagging effects of acupressure in 109 dental patients. Patients were randomly assigned to three groups; acupuncture (P6 or sham point), acupressure (P6 or sham) and pharmacological sedation with either acupressure or acupuncture. Acupressure was additionally performed with either thumb, device or Sea-band. There was a significant reduction in gagging with acupuncture (team evaluation $p=0.047$, patient $p=0.009$) and with device acupressure (team $p=0.002$, patient $p=0.001$) at P6 versus sham point, but no other significant differences for acupressure (using thumb or Sea-band). The study was described as double-blind although blinding procedures are not evident. The use of so many comparison groups results in very small group size (between 9 and 18). The outcome measure (subjective rating by the dental team and patient) was not validated and may not be reliable. Groups were not compared for homogeneity in baseline characteristics.

Yuksek et al (2003) randomised 24 patients to receive either acupressure or oxybutinin for nocturnal enuresis. Acupressure was applied to points Gv4, Gv15, Gv20, B23, B28, B32, H7, H9, St36, Sp4, Sp6, Sp12, Ren2, Ren3, Ren6, K3 and K5. There were no significant differences in incidence of bed-wetting between groups after treatment. No bed-wetting was seen in 83.3% of children who received acupressure and 58.3% who received oxybutinin. The main flaw was the very small sample size, with no details of sampling, comparison of groups or randomisation. Additionally selection bias was introduced from moving 3 patients who had previously unsuccessful pharmacological treatment from oxybutinin to acupressure group. Acupressure was not compared to a placebo/sham group.

Studies retrieved and collated as background information on Shiatsu (Appendix 11), identified four single case reports of adverse events occurring following Shiatsu massage (Herskovitz et al 1992; Mumm et al 1993; Tsubo 2001; Wada et al 2005). This is an important area for the profession regarding safety issues and possible causal links between Shiatsu and adverse events. Note, these may not have been the only case reports.

[11] Morrison D A, Sethi G, Sacks J et al (2002) The VA AWESOME (angina with extremely serious operative mortality evaluation) Multicenter Registry. Percutaneous coronary intervention versus coronary bypass graft surgery for patients with medically refractory myocardial ischemia and risk factors for adverse outcomes with bypass: the VA AWESOME multicenter registry: comparison with the randomised clinical trial. *J Am Coll Cardiol,* 39:266-273

A limited number studies assessed qualitative aspects of Shiatsu as a therapy (Cheesman et al 2001; Long & Mackay 2003) but the data was either not presented scientifically or was not carried out in controlled circumstances. Other studies mentioned acupuncture massage techniques and it is unclear if this was about acupressure (Furlan et al 2002). There were also general articles mentioning Shiatsu as an intervention (Galantino et al 2003) and some mentioned Shiatsu as part of a service provision (Peace & Manasse 2002; Sommers et al 2002; Yates 2005). A survey was funded by the Research Council for Complementary Medicine (Harris & Pooley 1998) to investigate what conditions practitioners currently treated and to ascertain the direction of future research into the efficacy of Shiatsu. The survey found that the most common conditions presenting for treatment were musculo-skeletal and psychological problems and concluded that future efficacy research should focus on these areas, in particular neck/shoulder, lower back problems, arthritis, depression, stress and anxiety. Two studies referred to Watsu but one was a personal account (Davis 2003) and the other a series of case reports (Vogtle et al 1998).

Background information on acupressure mainly included acupressure and its effects on nausea and vomiting and literature reviews (Collins & Thomas 2004; Harris 1997). The articles on nausea and vomiting included some reviews (Oates & Whitehead 2003; Oates & Whitehead 2004; Jewell 2003; Aikins 1998) but tended to be very broad and included either various types of intervention or were non systematic or related to devices or combinations of interventions (Anderson & Aikins 1998; Johnson 2005). Non-pharmacological management was shown to be effective for post operative and chemotherapy induced nausea and vomiting but Shiatsu was not specifically mentioned (Lee & Done 1999; King 1997; Pan et al 2000).

A thesis on delivering Shiatsu in general practice (Pirie 2003) looked at the impact of Shiatsu on GP consultations and whether frequency of prescriptions for medications were reduced (Appendix 15). This was a qualitative study and the researcher was also the practitioner. The research concluded that complementary medicine could be effectively delivered in general practice and that further research in clinical and cost effectiveness was warranted.

These findings provide an important addition to the existing knowledge base on Shiatsu but are very limited.

7. Discussion

The research base for Shiatsu is very much in its infancy and the profession will need to work closely with practitioners and researchers in order to build up a larger body of evidence. This evidence review has considered and included research studies which have a conventional RCT design. The methodological limitations of the studies reported in this systematic literature review included small sample sizes, non reporting of follow up, insufficient details on sampling, high drop out rates, uncontrolled design, lack of blinding etc. Many studies were also underpowered i.e. their sample size at the outset was insufficient to detect a significant difference.

Complementary medicine is under pressure to provide scientific evidence of efficacy if they are to be accepted and integrated within the prevailing framework of conventional medicine. The relevance of evidence based medicine depends on the quality of the research carried out. While much of the research carried out with Shiatsu or acupressure as an intervention is of insufficient quality to provide consensus on its use, some high quality (Category 1) clinical research (particularly around pain) does exist. This provides a model for future research.

Contention is slowly emerging about how complementary medicine should be evaluated[12,13,14,15,16,17]. The complexity of interventions and their potential synergistic effect requires innovative evaluative approaches using whole systems research that include qualitative and quantitative methods.[18,19] Analysis of the literature indicates that important refinements are being generated in complementary medicine research and clinical trial design in response to the challenges posed by the forced encounter of the paradigms of holistic and conventional medical practice.

Shiatsu is no different to other complementary therapies in that a pragmatic RCT approach (reflecting normal practice) should be an inherent part of study design. In addition, qualitative data provides additional information on patients' and/or practitioners' views on the effectiveness of treatment. Many studies are including such qualitative data as part of their design to provide a broader picture of patient outcomes.

If Shiatsu is to be evaluated at least in part through RCTs, these must be appropriately designed. A recent paper concluded that RCTs would be more effective in studying acupuncture if participants were randomised to groups based on acupuncture diagnosis, not solely on conventional western criteria[11]. This may be true for other complementary therapies including Shiatsu which uses elements of Traditional Chinese Medicine diagnosis as well as Hara diagnosis. The authors felt that although treatments must be standardised to ensure replicability of the study, blinding was not absolutely necessary for a good quality RCT, however, if used, control groups need to be standardised. They felt that homogeneity of groups based on specific acupuncture diagnostic criteria (which takes into account the different philosophy and Chinese medicine system) could be used as evidence of efficacy of the intervention and satisfy both acupuncture and conventional medicine critics.

Future clinical research on Shiatsu and acupressure also needs to take into account practitioner variability in terms of point selection (based on differences in their education and training). The issue of blinding, which involves "sham" or placebo treatments, is also difficult to resolve. Shiatsu (as distinct from acupressure) presents futher complexities as treatments are based on Hara diagnosis and rarely if ever "standardised".

In the case of acupuncture there has been controversy about the use of sham acupuncture and it is now generally felt that it cannot be used as an inert control though it could be one arm of an RCT[12] The strength of any conclusions from research will depend on the quality of the evidence included and even with gold standard RCT there can still be bias[20]. As the included studies have shown, "sham"

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[12] Walji R, Boon H (2006). Redefining the randomised controlled trial in the context of acupuncture research. *Complement Ther Clin Pract.*

[13] Shea J. (2006) Applying evidence-based medicine to Traditional Chinese Medicine: Debate and strategy. *J Altern Complement Med* 12(3): 255-263.

[14] Walker LG, Anderson J. (1999)Testing Complementary and alternative therapies within a research protocol. *European J Cancer* 35(11) 1614-1617

[15] Herman PM, D'Huyvetterk . Mohler MJ ((2006) Are health services research methods a match for CAM. *Altern Ther* 12(3): 78-83.

[16] Broom A. (2005) Using qualitative interviews in CAM research: A guide to study design, data collection and data analysis. *Complement Ther Med* 13: 65-73.

[17] Walach H, Falkenberg T, Fonnebo V, Lewioth G, Jonas WB. (2006) Circular instead of hierarchical: methodological principles for the evaluation of complex interventions. 6: 29. <http://www.biomedcentral.com/1471-2288/6/29. doi 10.1186/1471-2288-6-29>.

[18] Verhoef MJ, Lewith G, Ritenbaugh C, Boon H, Fleishman S & Leis A. (2005) Complementary and alternative medicine whole systems research: Beyond identification of inadequacies of the RCT. *Complement Ther Med* 13(3): 206-212

[19]Giordano J, Garcia MK, Strickland G.(2004) Integrating Chinese Traditional medicine into a US Public Health Paradigm. *J Altern Complement Med* 10(4): 706-710.

[20] Leibovici L. (1999) Alternative (complementary) medicine: a cuckoo in the nest of empiricist warblers. *BMJ (Clinical Research ED.);* 319: 1629 -32.

acupressure including light touch at acupoints does have an effect. This means that “sham” acupressure may not be an appropriate control unless a study is very carefully designed.

Safety is best established with prospective studies and the four reports identified in this review highlighted the importance of having good evidence on safe practice. The type and frequency of adverse events and any transient reactions after Shiatsu therapy needs exploration as although this was not the focus of this review, several incidences of adverse reactions to Shiatsu were found.

8. Conclusions

The summaries of the best quality evidence to date suggest that, due to the small number of studies specifically relating to Shiatsu, well designed research in any area would be a welcome addition to the current evidence base. For acupressure and pain, the evidence is generally consistent and has demonstrated that acupressure can control pain. Acupressure studies for nausea and vomiting have been somewhat inconsistent and may merit further research. Similarly the studies on COPD and asthma, psycho-social aspects of health, anaesthesia and other health conditions are generally weak due to study design. From these studies reviewed only pain, nausea and vomiting have provided some evidence of benefit but are too heterogeneous and therefore cannot be amalgamated.

9. Recommendations

- Significant research needs to be carried out if Shiatsu is to develop an evidence base
- Further research is needed to investigate the effectiveness of Shiatsu as an intervention
- Encourage practitioners to engage in research using well designed studies
- The relationship between Shiatsu and acupressure needs clarification for marketing and public awareness
- Consider the development and piloting of an adverse event reporting system for Shiatsu
- Explore clinical and the cost effectiveness of Shiatsu in an integrated setting
- Identify specific topic areas for initial research investment
- Develop an evaluative framework for integrated Shiatsu practice
- Develop a research resource for the profession
- Investigate the appropriateness of various research methodologies for Shiatsu research

Appendix 1 - Search Terms and definitions

In order to ensure that the correct search term was used, a MeSH search was carried out for the term '**Shiatsu**' with the following result (copied from MeSH) for the option '**Shiatsu [Multi]**' exploded into the MeSH tree:

Acupressure
A type of massage in which finger pressure on specific body sites is used to promote healing, relieve fatigue, etc. Although the anatomical locations are the same as the ACUPUNCTURE POINTS used in ACUPUNCTURE THERAPY (hence acu-), no needle or other acupuncture technique is employed in acupressure. (From Random House Unabridged Dictionary, 2d ed). Shiatsu is a modern outgrowth that focuses more on prevention than healing.

Year introduced: 1996
Entry Terms:

- Shiatsu
- Shiatzu
- Zhi Ya
- Chih Ya

Previous Indexing:

- Acupuncture Points (1990-1995)
- Pressure (1983-1995)

All MeSH Categories
Analytical, Diagnostic and Therapeutic Techniques and Equipment Category
Therapeutics
Complementary Therapies
Acupuncture Therapy
Acupressure

All MeSH Categories
Analytical, Diagnostic and Therapeutic Techniques and Equipment Category
Therapeutics
Complementary Therapies
Musculoskeletal Manipulations
Massage
Acupressure

All MeSH Categories
Analytical, Diagnostic and Therapeutic Techniques and Equipment Category
Therapeutics
Musculoskeletal Manipulations
Massage
Acupressure

All MeSH Categories
Analytical, Diagnostic and Therapeutic Techniques and Equipment Category
Therapeutics
Physical Therapy Modalities
Musculoskeletal Manipulations
Massage
Acupressure

Appendix 2 - Database searches and terms used

Pub/Med search terms

The following search terms were used for 3 initial MEDLINE searches (09.02.06) with no limits set for search criteria:

1. **'Shiatsu AND nursing'** – to update a previous search that the Shiatsu Society UK had undertaken.

2. '**Shiatsu**' – MeSH term to capture any omissions from the first search.

3. **'Shiatsu NOT acupressure'** - to restrict results to Shiatsu.

OVID searches

OVID is an online biomedical data service which comprises of a number of databases. Access can be limited dependant on subscription e.g. EMBASE. This facility allows for a single search to be performed over a number of databases which is then screened for duplicates between databases to produce a final result. Some of these databases include 'popular' health publications such as Here's Health and articles published by organisations for newsletters e.g. the Shiatsu Society News. The following databases were used:

- EBM Reviews - Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews, Cochrane Central Register of Controlled Trials.
- AMED (Allied and Complementary Medicine) <1985 to February 2006> (154)
- British Nursing Index (BNI) <1985 to February 2006> (12)
- CINAHL - Cumulative Index to Nursing & Allied Health Literature.
- EMBASE
- Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations
- Ovid MEDLINE(R) <1966 to present
- PsycINFO
- Journals@Ovid (this includes the former Core Biomedical, Nursing and Mental Health full text collections).

OVID search terms

The majority of OVID databases use a MeSH system for indexing therefore the term **'Shiatsu'** was used for the search (28.02.06). It was only possible to update this search once, 22.03.06. with no new results, as EMBASE was no longer accessible for any further searches therefore the same search could not be repeated.

Other sources

The search terms '**Shiatsu'** and **'acupressure'** were used for searches in journal databases, Index to Theses and ZETOC (23.02.06)

Appendix 3 - Screening of search results

Inclusion criteria

Shiatsu or acupressure administered manually /bodily
Primary research
Secondary research
Systematic review
Review of effectiveness
Literature review with described methodology

Studies in preferred study design hierarchy:
Randomised controlled trial (RCT)
Cohort
Case/Control
Before and after
Cost – comparison / effect / benefit / economics
Audit

Further details of hierarchy of study design and grading of evidence can be found at:

http://www.york.ac.uk/inst/crd/pdf/crd4_ph5.pdf pg 5 of 20 shows hierarchy of study designs for studies of effectiveness. (Centre for Reviews and Dissemination)
http://www.york.ac.uk/inst/crd/pdf/crd4_ph8.pdf pg 10 of 16 shows grading re level of evidence – A1-D5

Exclusion criteria

The exclusion criteria were built up in stages as until search results and abstracts were available for initial screening this could not be finalised. For the purpose of this review, qualitative studies, case reports, case series and grey literature were not included for appraisal as these were not considered as scientific evidence of effectiveness.

Stage 1 – initial screening of results
Published prior to February 1990
Duplicated in other searches
Obvious from title that a device has been used
Newspaper articles, book reviews, 'popular' health publications.
General comments, letters

Stage 2 – from abstracts
Foreign language papers
Use of Korean points/meridians
Use of plasters, devices, wristbands
Auricular acupressure
General comments, letters

Stage 3 – from full text articles.
This includes Stage 2 exclusion criteria as it may not have been obvious from the abstracts.

Foreign language papers

Use of Korean points/meridians
Use of plasters, devices, wristbands
Auricular acupressure
Anecdotal evidence
Personal experience
Shiatsu / acupressure are mentioned as therapies in general complementary medicine publications and there is no section which relates specifically to either therapy.
Guidelines for treatment
Reports of possible adverse events
Surveys
Case reports
Case series
Qualitative studies
Conference abstracts / posters

Appendix 4 - Second MEDLINE MeSH tree and subsequent searches

Acupuncture Therapy
Treatment of disease by inserting needles along specific pathways or meridians.
The placement varies with the disease being treated. It is sometimes used in conjunction with heat, moxibustion, acupressure, or electric stimulation.
Year introduced: 1990
Entry Terms:

- Therapy, Acupuncture

Previous Indexing:

- Acupuncture (1966-1989)

See Also:

- Medicine, Chinese Traditional
- Acupuncture

All MeSH Categories
Analytical, Diagnostic and Therapeutic Techniques and Equipment Category
Therapeutics
Complementary Therapies
Acupuncture Therapy
Acupressure
Acupuncture Analgesia
Acupuncture, Ear
Electroacupuncture
Meridians
Acupuncture Points
Moxibustion

The term 'acupuncture therapy' was introduced in 1990 and the MeSH tree terms included 'acupressure' and 'acupuncture points'. 'Acupressure', where 'Shiatsu' is included, was introduced as MeSH term in 1996'. It was not clear from the information in MEDLINE, whether all citations for acupressure had been re-indexed when the term was introduced.
Further searches were therefore carried out on 24th August 2006 to ascertain how many additional publications needed to be reviewed. The search terms used and results were as follows:

Code	Search term	Result	Comment
A	'Shiatsu' – to verify the final 'Shiatsu' search on 1st August	259	18 not in 'acupressure' (259 – 18 = 241 = C
B	'acupressure'	360	119 not in 'Shiatsu' (360 – 119 = 241 = C)
C	'Shiatsu' AND 'acupresssure'	241	
D	'Shiatsu' OR 'acupressure'	378	(= B + 18 Shiatsu from A)
E	'acupoint' AND acupressure'	100	All found in 'acupressure'
F	'acupuncture point' AND 'acupressure'	87	All found in 'acupressure'
G	'acustimulation'	24	10 not found in 'acupressure'

The 10 new results in the 'acustimulation' search did not refer to manually applied acupressure and therefore were not considered for inclusion.

Of the 119 new results in the 'acupressure' search, 15 were duplicated in other searches and 25 were before 1990. Following the exclusion criteria protocol, a further 77 publications were excluded and full text copies were requested for the two remaining publications.

1. Belluomini,J., Litt,R.C., Lee,K.A., and Katz,M. (1994). Acupressure for nausea and vomiting of pregnancy: a randomized, blinded study. *Obstet Gynecol* 84:245-248.
This was added to the evidence tables and appraised.

2. Matsumura,W.M. (1993). Use of acupressure techniques and concepts for nonsurgical management of TMJ disorders. *J Gen Orthod.* 4:5-16.
There was no abstract available for this publication and it was not possible to obtain a full text copy, it was therefore excluded.

Other

As a result of checking the references of the 146 publications that were left for screening, two publications were considered for review.

One was included for review at this final stage:

Ballegaard,S., Johannessen,A., Karpatschof,B., and Nyboe,J. (1999). Addition of acupuncture and self-care education in the treatment of patients with severe angina pectoris may be cost beneficial: an open, prospective study. *J Altern Complement Med* 5:405-413.

This was listed in the references of an included publication by the same first author, but did not appear in any of the MEDLINE searches, as it had been indexed under 'acupuncture therapy':
Ballegaard,S., Borg,E., Karpatschof,B., Nyboe,J., and Johannessen,A. (2004). Long-term effects of integrated rehabilitation in patients with advanced angina pectoris: a nonrandomized comparative study. *J Altern Complement Med* 10:777-783.

One was excluded:
Vickers,A.J. (1996). Can acupuncture have specific effects on health? A systematic review of acupuncture antiemesis trials. *J R Soc Med* 89:303-311.
This was referred to in an excluded letter :
Hoo,J.J. (1997). Acupressure for hyperemesis gravidarum. *Am J Obstet.Gynecol.* 176:1395-1397.
It was found to be indexed under 'acupuncture therapy ' and did not appear in any searches, original or those carried out on 24th August as the key words of the publications included 'acupuncture'. 34 studies were reviewed, seven of which referred to manual acupressure, three were before 1990, three were excluded from this evidence review and one was subsequently included from the MEDLINE 'acupressure' search of 24th August. (Belluomini,J., Litt,R.C., Lee,K.A., and Katz,M. (1994). Acupressure for nausea and vomiting of pregnancy: a randomized, blinded study. *Obstet Gynecol* 84:245-248.)

Appendix 5 - Abstract screening form

Date:
Author:
Publication date:
RefMan database:
ID (from database):

Inclusion criteria	
Primary research	Yes/No
Secondary research	Yes/No
Systematic review	Yes/No
Review of effectiveness	Yes/No
Literature review with described methodology	Yes/No
Shiatsu	Yes/No
Acupressure	Yes/No
Exclusion criteria	
Foreign language papers	Yes/No
Qualitative	Yes/No
Case series	Yes/No
Case reports	Yes/No
Grey literature	Yes/No
Inclusion criteria - preferred study design hierarchy	
Randomised controlled trial (RCT)	Yes/No
Other acceptable designs	
Cohort	Yes/No
Case/Control	Yes/No
Before and after	Yes/No
Cost – comparison / effect / benefit / economics	Yes/No
Audit	Yes/No
Exclusion criteria	
Use of Korean points/meridians	Yes/No
Plasters, devices, wristbands	Yes/No
Auricular acupressure	Yes/No
Comments	
Include study	**Yes/No**

Appendix 6 - Initial search results

Pub/Med searches:

Shiatsu AND nursing	**44** results, 2 before 1990 leaving **42** for review
Shiatsu	**235** results, 5 before 1990, 41 included in above, leaving **189** to review
Shiatsu NOT acupressure	**9** results all included in above or before 1990, leaving **none** to review

OVID search
269 results after duplicates within databases were removed (via OVID search engine) in search result order

EBM reviews (incl all Cochrane Library)	5
AMED – includes Shiatsu Society News –	154
BNI	12
CINAHL	43
EMBASE	14
MEDLINE in process & non indexed	2
OVID MEDLINE	34
PsycINFO	5
Total	**269**

Exclusions:

Prior to 1990	19
Book reviews, newspaper clips	13
Shiatsu Society News collated into a separate database for Society to review	**110**
Natural Health, Here's Health etc included with above	**15**
Acupuncture	4
Total left to compare with 3 Pub/Med searches	**108**
Duplicates between Pub/Med & OVID searches	36
Final OVID search results to be reviewed	**72**
Total initial exclusions from OVID	**197**

Other searches

There were **9** new results from the journal databases searches as detailed below:

Science Direct	17 – **6** of which were new results
Blackwell Synergy	51 (only 4 of these referred to 'Shiatsu' others referred to various complementary therapies) **1** of which was new
Ingenta Select	**2** both new
Wiley Interscience	0

A loan copy of one thesis was ordered for review and the ZETOC search (see Appendix 15) could not be downloaded for review and included multiple duplicates and conference abstracts.

Follow up searches

A number of additional searches were carried out between March and August 2006 to ensure that the most recent publications were captured. Searches included 4 additional MEDLINE 'Shiatsu' searches and a search for 'acupressure' in Science Direct journal database.

After Stage 1 and 2 exclusions had been completed, 146 publications were left for full text screening and appraisal.

A summary of searches, downloaded to Reference Manager® databases for review, and exclusion stages is shown below:

Reference Manager® Database	Code	Search results - new only	Stage 1	Stage 2	Full text to screen
Shiatsu and Nursing Medline Feb 06	SNM0206	44	2	30	12
Shiatsu Medline Feb 06	SM10206	235	46	109	80
Shiatsu Medline 21.03.06 new only	SM20306	7		4	3
Shiatsu Medline 26.04.06 new only	SM30406	4		2	2
Shiatsu Medline 21.06.06 new only	SM40606	9		6	3
Shiatsu Medline 01.08.06 new only	SM50806	4		2	2
Shiatsu OVID 28.02.06/22.03.06 new after first exclusions	SO10306	72		57	15
Shiatsu Society News (OVID) as requested by DB	SSN0806	125		122	3
Lee & Done search systematic review 27.04.06	SLD0406	1		0	1
Shiatsu from journal databases 22.03.06 new only	SJD0306	9		4	5
Acupressure Science Direct 04.05.06	SDA0506	88	31	39	18
Acupressure Science Direct 27.06.06/ 02.08.06	SDA0606	4		2	2
TOTAL		**602**	**79**	**377**	**146**

Appendix 7 - Retrieved publications for screening

Of the 146 remaining publications, 106 referred to acupressure and 40 to Shiatsu. As acupressure and Shiatsu use the same points, publications on acupressure were included. Further exclusions for review at this stage included: adverse event reports, Shiatsu as part of multiple interventions, treatment guidelines, and surveys, case report and series and qualitative studies. A number of publications although not evidence, were used for background and historical information.

Summaries of the screening process are shown below:

First screening - not all full text available

Database	To screen	Include (Inc)	Exclude (Exc)	Background (Bg)/ waiting for full text	Shiatsu (S)	Acupressure (A)
SNM0206	12	10	1	1	2	10
SM10206	80	42	26	12	15	65
SM20306	3	1	2			3
SM30406	2	1		1		2
SM40606	3	3				3
SM50806	2			2		2
SO10306	15	8	1	6	15	
SSN0806	3			3	3	
SLD0406	1	1				1
SJD0306	5	4		1	5	
SDA0506	18	13		5		18
SDA0606	2			2		2
Total	**146**	**83**	**30**	**33**	**40**	**106**

Second screening – all full text available

Database	To screen	Inc	Bg	Exc	SInc	AInc	SBg	ABg	SExc	AExc
SNM0206	12	10	1	1	2	8		1		1
SM10206	80	26	18	36	1	25	7	11	7	29
SM20306	3	1		2		1				2
SM30406	2	1	1			1		1		
SM40606	3	2	1			2		1		
SM50806	2		1	1				1		1
SO10306	15	1	9	5	1		9		5	
SSN0806	3		3				3			
SLD0406	1	1				1				
SJD0306	5	1	3	1	1		3		1	
SDA0506	18	1	4	13		1		4		13
SDA0606	2			2						2
Total	**146**	**44**	**31**	**61**	**5**	**39**	**22**	**19**	**13**	**48**

Appendix 8 - Critical Appraisal checklist

The following form was used to assess the quality of each study and was compiled from checklists in Greenhalgh T & Donald A, Evidence Based Health Care Workbook, BMJ Books 2000 and Centre for Reviews and Dissemination (http://www.york.ac.uk/inst/crd/report4.htm)

Sample	Sample size - powered? - adequate size? Sampling – random? How were participants recruited? Are results generalisable?
Group assignment	Were participants randomly assigned to groups? Were groups homogenous for baseline variables and in which variables?
Blinding – single/double?	Were the following blinded to which group they were in: - Participants? - Care givers? - Assessors? If not, was double blinding technically not possible? Was a placebo treatment used? Were details given?
Co-interventions	Can the effects of acupressure/Shiatsu be isolated or were co-interventions used?
Outcomes	Were the outcomes appropriate, valid and reliable? clinical are best
Follow up/attrition rate	Were all participants accounted for? Was follow-up over 80%? Was intention to treat analysis used?
Intervention	Intervention described? Valid & reliable?
Results	Are statistics clear and appropriate?
Patients paying for treatment?	May bias results
Finance/ethics	How was study financed? Was ethical approval given?

Appendix 9 - Evidence tables studies included

Shiatsu

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Ballegaard,S., Norrelund,S., and Smith,D.F. (1996). Cost-benefit of combined use of acupuncture, Shiatsu and lifestyle adjustment for treatment of patients with severe angina pectoris.	**Design**: Follow-up controlled trial with non-equivalent control group (see intervention below) **Setting**: Denmark **Sample**: Sixty-nine consecutive patients with severe angina pectoris Forty-nine patients were candidates for coronary-artery bypass grafting (CABG), whereas bypass grafting was rejected in the remaining 20 patients. **Health issue**: Angina pectoris **Intervention**: Patients were treated with acupuncture, Shiatsu and lifestyle adjustments, and were followed for 2 years. Shiatsu was self/spouse administered at point CV17. Endpoint findings (incidence of death +/ myocardial infarction and pain relief) with those of a different study, a large prospective, randomized trial comparing CABG with percutaneous transluminal coronary angioplasty (PTCA).	The incidence of death and myocardial infarction was 21% among the patients undergoing CABG, 15% among the patients undergoing PTCA and 7% among our patients. No significant difference was found concerning pain relief between the three groups. Invasive treatment was postponed in 61% of our patients due to clinical improvement, and the annual number of in-hospital days was reduced by 90%, bringing about an estimated economic saving of 12,000 US $ for each of our patients. Despite the fact that the men in the present study, had significantly less positive expectations towards the outcome of the treatment, when compared to the women, there was no significant difference concerning the effect.	The study suggests that the combined treatment with acupuncture, Shiatsu and lifestyle adjustment may be highly cost effective for patients with advanced angina products and may reduce the risk of dying and/or myocardial infarction more than coronary bypass surgery and PTCA	Convenience sampling, no power calculation No Shiatsu practitioner (self/spouse administered). Main flaw is use of findings from a previous study as a control group, and there is no statistical comparison of differences between the groups. Also, 56% of participants would have been excluded from one of the 'control' groups. Control group study is from the USA. Shiatsu is *additional* intervention, co-interventions of acupuncture and lifestyle adjustment. Good two year follow-up. Focus on cost benefit not efficacy. No blinding.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Brady,L.H., Henry,K., Luth,J.F., and Casper-Bruett,K.K. (2001). The effects of Shiatsu on lower back pain.	**Design**: Quasi-experimental, Pre-test – post test, single group design **Setting**: Shiatsu clinic and school (USA) **Sample**: Convenience sample. 66 individuals/volunteers complaining of lower back pain **Health issue**: Low back pain **Intervention**: Random assignment to Shiatsu massage provided by 2 therapists. Each individual measured on state/trait anxiety and pain level before and after 4 Shiatsu treatments (50-60 min) within an 8 week period. Each subject called 2 days following each treatment and asked to quantify the level of pain.	Pain using the VAS decreased after 4 treatments. P<0.001 Anxiety measured by Trait Anxiety Inventory showed no significant differences. State Anxiety Inventory showed a significant reduction P<.0001. Demographic variables; gender, age, gender of therapist, length of history with lower back pain, and medications taken for lower back pain did not alter the significant results.	Both pain and anxiety decreased significantly over time.	Volunteer patients. Absence of control group. Repeated measures (regression towards the mean) can cause carryover effects. Patients had to pay for treatment which may create bias by limiting access to a higher socio-economic group. 13 patients had previously had Shiatsu before the study (it is unclear whether they were being treated at the time they were recruited).

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Faull,K. (2005). A pilot study of the comparative effectiveness of two water-based treatments for fibromyalgia syndrome: Watsu and Aix massage	**Design**: Two-condition, repeated measure with reverse order counterbalancing comparative study. **Setting**: New Zealand **Sample**: Seventeen recruited, thirteen completed study, females diagnosed with FMS **Health issue**: Fibromyalgia syndrome (FMS) **Intervention**: The effectiveness of holistic therapy (Watsu, WATer ShiatSU) was compared to the water-based therapy, Aix massage. Two treatment blocks each of four sessions over two weeks. Participants randomly assigned to receive either Watsu then Aix or vice versa, with a 3 week break between treatment blocks. Short-Form-36 General Health Survey (SF-36) data were collected at the start and completion of treatment. Each SF-36 subscale was tested with a two-way, repeated measure analysis of variance.	Significant change (p=0.01) in treatment and interaction effects were found for Watsu on the SF-36 subscales of physical function, bodily pain, vitality and social function, but not for Aix treatment.	Watsu was supported as an effective holistic intervention compared to Aix massage. A study with a larger sample and a control group is required before it can be inferred that the change is due to this therapy	Pilot study for a larger study of Watsu. Volunteer sampling and very small sample size (n=13). No control, although counterbalanced to reduce carryover effects of using repeated measures design. However, order effects may have occurred due to high dropout rate from Watsu first group (4 out of 8). Variables other than Watsu may have caused the significant result.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Iida,M., Chiba,A., Yoshida,Y., Shimizu,K., and Kanda,K. (2000). Effects of Shiatsu massage on relief of anxiety and side effect symptoms of patients receiving cancer chemotherapy.	**Design**: One group pre-test post-test quasi-experimental **Setting**: Gunma Hospital, Japan **Sample**: Nine patients scheduled for cancer chemotherapy were grouped into two; the strong anxiety group and the weak anxiety group. **Health issue**: Anxiety and side effect symptoms of cancer chemotherapy. **Intervention**: The relaxation effects of Shiatsu massage for these two groups of patients were compared using state trait anxiety inventory (STAI), physical and psychological relief of side effect symptoms scale, relaxation (RE) scale and skin temperature. Shiatsu given to hands and feet for 30 minutes morning and night for 4 days. Scores compared before and after treatment using t-test.	The strong anxiety group showed significant decline in anxiety score after intervention ($p=0.09$), indicating slight relaxation effects. Both groups had big expectation for psychological relaxation effects of massage. There was a slight relief of physical symptoms in both groups but significance is not stated. In the weak anxiety group, Shiatsu massage significantly increased RE score ($p=0.01$), showing relaxation effects. There was little change in peripheral skin temperature.	Results proved that Shiatsu massage may relieve anxiety. Suggested that Shiatsu massage is used in addition to attentive listening to relieve anxiety in the clinical settings	Very small study (n=9). In addition this was analysed in two groups, giving n=4 and n=5, giving inconclusive evidence. A t-test on a sample this small will only detect differences that are huge and may be the reason why few effects were seen. Sample were 89% male. No control group. Unclear why group was divided into weak and strong anxiety. No sampling process given.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Ingram,J., Domagala,C., and Yates,S. (2005). The effects of Shiatsu on post-term pregnancy.	**Design**: A pilot audit with control group **Setting**: St. Michael's Hospital, Bristol **Sample**: 142 women, who attended a consultant clinic hospital appointment at 40 weeks gestation. 66 were in intervention group (when midwife who had learned Shiatsu was on duty) and 77 comparison women were those who attended similar clinics when the midwife was not on duty. **Health issue**: Post-term pregnancy **Intervention**. Women were taught the massage techniques by one midwife, who had completed the Shiatsu course. Thumb pressure was applied to points GB21, LI4, Sp6. Women used the techniques as often as felt comfortable. Some partners were also taught techniques. Breathing techniques and exercises on all fours were also taught. The audit extracted outcome information from the Stork hospital database including induction, type of delivery, length of labour and analgesia used and a an audit questionnaire was sent out.	Chi squared and t-tests were used. Post-term women who used Shiatsu were significantly more likely to labour spontaneously than those who did not (p=0.038). Of those who had used Shiatsu, 17% more went into spontaneous labour compared to those who were not taught Shiatsu Shiatsu group had a significantly longer labour (p=0.03), although analgesia use was similar. However, if emergency caesarean sections are excluded, spontaneous labour occurs even more in Shiatsu group (22%; p=0.012) and labour length is not significantly different (p=0.19). Maternal age, gestation and baby weight were not statistically significant between groups. 30 (45%) women completed audit questionnaire; 87% of those taught used Shiatsu and 80% found the techniques useful.	Raises the hypothesis that specific Shiatsu techniques on post term women by midwives can decrease the number of labours which need to be induced pharmacologically.	Group assignment not random (depends on which midwife was on duty), although no significant differences between groups in maternal age, parity or delivery details. Relatively small sample size. Self administered Shiatsu (taught by midwife who was taught by study researcher). Also direct effects of Shiatsu unclear as no control over how often/how much pressure was used. Preliminary audit. Co-intervention of breathing techniques and exercises.

Acupressure

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Agarwal,A., Ranjan,R., Dhiraaj,S., Lakra,A., Kumar,M., and Singh,U. (2005). Acupressure for prevention of pre-operative anxiety: a prospective, randomised, placebo controlled study.	**Design**: Prospective Randomised Controlled Trial **Setting**: Hospital, possibly India. **Sample**: Seventy-six adults, ASA grade I and II, undergoing elective surgery. Group 1 (control) received acupressure at an inappropriate site and group 2 (acupressure) received acupressure at extra 1 point. **Health issue**: Pre-operative anxiety (characterised by increased analgesic and anaesthetic requirement, postoperative pain and prolonged hospital stay) **Intervention**: On morning of surgery, following arrival in pre-operative area, patients relaxed for 15 mins then acupressure was applied for 10 min and patients were observed for another 30 min.. The effects of acupressure on pre-operative anxiety and bispectral index (BIS) values (this is a measure of the level of consciousness during anaesthesia) were investigated. Anxiety was recorded on a visual stress scale (VSS) at the start of the study and thereafter at 10 and 40 min. BIS was recorded at 0, 2, 5, 10, 12, 15, 30 and 40 min.	Anxiety (measured by VSS) decreased in both groups following pressure application for 10 min: median VSS (interquartile range) were 5 (1) vs. 8 (1) in the acupressure and 7 (0) vs. 8 (1) in the control groups ($p < 0.001$). However, after 30 mins both groups returned to baseline ($p>0.05$). The decrease in anxiety after 10 mins was greater in the extra 1 point group ($p<0.05$). BIS values were significantly lower during acupressure application than baseline or after release of treatment in both groups ($p<0.05$). During acupressure, BIS values were lower for extra 1 point than control group ($p < 0.05$).	Acupressure is effective in decreasing both pre-operative anxiety and BIS. The effects are not sustained 30 min following release of acupressure. Further studies are needed to elucidate the duration for which acupressure is effective.	Randomised group allocation, although not clear about sampling procedure. Power calculation performed for sample size. Control and intervention groups are homogenous (no significant differences in demographics). Placebo used but details of 'inappropriate site' for sham acupressure not given. May have had effect. Reduction in anxiety and BIS in control group may be due to massage/attention effects, although extra 1 group did show a greater reduction. Single blinded (patient). Used instead of usual care (sedative premedication) not as adjunct.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Ballegaard,S., Borg,E., Karpatschof,B., Nyboe,J., and Johannessen,A. (2004). Long-term effects of integrated rehabilitation in patients with advanced angina pectoris: a nonrandomized comparative study.	**Design**: Nonrandomised comparative study. (reported by authors as a quality control review) **Setting**: The treatment was carried out as an ambulatory treatment in a private clinic, Denmark **Sample**: 168 patients with angina pectoris, of whom 103 were candidates for invasive treatment and 65 for whom this had been rejected. Comparison groups: 1) General Danish population matched for age, gender, and observation period, medical and invasive treatments, 2) New York clinical database and 3) American study Schofield et al 1999. **Health issue**: Angina pectoris **Intervention:** 12 sessions over 3-4 weeks of Integrated rehabilitation (IR); acupuncture, a self-care program including acupressure, Chinese health philosophy, stress management techniques, and lifestyle adjustments. Acupressure self/spouse administered at CV17 and UB14 and 15. OUTCOME MEASURES: Follow-up until death or surgery. Data collected from patient database on death rate from any cause, the need for	The 3-year accumulated risk of death was 2.0% (95% confidence limits: 0.0%-4.7%) for the 103 candidates for invasive treatment, 6.4% for the general Danish population, 5.4% (4.7%-6.1%), and 8.4% (7.7%-9.1%) for patients who underwent percutaneous transluminal balloon angioplasty and coronary artery bypass grafting, respectively, in New York. For the 65 inoperable patients the risk of death due to heart disease was 7.7% (3.9%-11.5%), compared to 16% (10%-34%) and 25% (18%-36%) for American patients, who were treated with laser revascularization or medication, respectively. Accumulated risk (of operation, MI, death) improved significantly over time (p for trend <0.05) Of the 103 candidates for invasive treatment, only 19 (18%) still required surgery. Cost savings over 3 years were US $36,000 and US $22,000 for surgical and nonsurgical patients, respectively. These were mainly achieved by the reduction in the use of invasive treatment and a 95%	Integrated rehabilitation was found to be cost effective, and added years to the lives of patients with severe angina pectoris. The results invite further testing in a randomized trial	Good size (168) but consecutive not random sample. Acupressure treatment was not standardised, as part of IR program, for which the 'main philosophy behind the treatment is self-care'. Therefore a pragmatic design. Results cannot be conclusive as compared to non-equivalent groups. Improvement in accumulated risk increased with time since onset of treatment, indicating independent treatment effect. Long follow up period. Costs based on an American study but study performed in Denmark. Patients seem to be paying for treatment, although they give a ref that this does not affect prognosis. Social selection bias not present as sample did not differ from other Scandinavian heart patients. Unclear who financed the study (KID foundation). Treatment not blinded, but they say bias is avoided as

	invasive treatment, and health care expenses.	reduction in in-hospital days.		patients had very little contact with doctor.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Ballegaard,S., Johannessen,A., Karpatschof,B., and Nyboe,J. (1999).	**Design**: An open prospective study and cost-benefit analysis **Setting**: outpatient basis in a private research clinic, Denmark? **Sample**: 105 patients with angina pectoris, 73 candidates for invasive treatment, and 32 for whom this was rejected. **Health issue**: Angina pectoris **Intervention:** Acupuncture and self-care education including acupressure at CV17, UB14, UB15 was added to the pharmaceutical treatment. OUTCOME MEASURES: Healthcare expenses, a satisfactory medical status defined as New York Heart Association (NYHA) classification 0-I and/or no use of antianginal medication, and risk measured as cardiac death or myocardial infarction.	The estimated cost savings during 5 years were $32,000 (U.S.) per patient, mainly due to a 90% reduction in hospitalization and 70% reduction in needed surgery. Compared to 8% before treatment, 53% of the patients achieved a life without limitations (NYHA 0-I) 1 year after treatment, as did 69% after 5 years. No increased risk for myocardial infarction or cardiac death was observed.	The addition of acupuncture and self-care education was found to be cost beneficial in patients with advanced angina pectoris. The results invite further testing in a randomized controlled trial	Mainly a cost-analysis, study design may have varied if this was primarily an efficacy study. Results cannot be conclusive as compared to non-equivalent groups. Volunteer, consecutive sample. Pragmatic design. Effects of acupressure cannot be isolated from co-interventions of acupuncture and lifestyle modification, all based on a theory of self-care. Long follow up period.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Belluomini,J., Litt,R.C., Lee,K.A., and Katz,M. (1994). Acupressure for nausea and vomiting of pregnancy: a randomized, blinded study	**Design**: RCT **Setting**: Physician and midwife practices, California? **Sample**: 90 pregnant women with nausea with/without vomiting, gestation of 12 weeks or under **Health issue**: Nausea and vomiting of pregnancy. **Intervention:** women were randomized to one of two acupressure groups: one treatment group using an acupressure point (PC-6) and one sham (non acupoint) control group using a placebo point. Subjects were blind to the group assignment. Each evening for 10 consecutive days, the subjects completed an assessment scale (Rhodes inventory of N&V) describing the severity and frequency of symptoms that occurred. Data from the first 3 days were used as pre-treatment scores. Beginning on the morning of the fourth day, each subject used acupressure at her assigned point for 10 minutes four times a day. Data from day 4 were discarded to allow 24 hours for the treatment to take effect. Data from days 5-7 were used to measure treatment effect.	Sixty women completed the study. There were no differences between groups in attrition, parity, fetal number, maternal age, gestational age at entry, or pre-treatment nausea and emesis scores. Analysis of variance indicated that both groups improved significantly over time, but that nausea improved significantly more in the treatment group than in the sham control group ($F_{1,58} = 10.4$, $P = .0021$). There were no differences in the severity or frequency of emesis between the groups. There was a significant positive correlation ($r = 0.261$, $P = .044$) between maternal age and severity of nausea.	Our results indicate that acupressure at the PC-6 anatomical site is effective in reducing symptoms of nausea but not frequency of vomiting in pregnant women	The sample was selected from referred patients, details of this are not clear. Only 60 out of 90 completed the study and intention to treat analysis was not used. Dropout was however similar between study groups. Randomised block design but criteria for blocking not given (could be gestational age?). Groups homogenous for pregnancy characteristics and pre-test scores. Maternal age was associated with N&V score. Controlled for gestational age and placebo effect. Single blind (patient) Self administered acupressure and reliability not checked. Outcome measure is reliable and valid.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Chen,H.M. and Chen,C.H. (2004). Effects of acupressure at the Sanyinjiao point on primary dysmenorrhoea.	**Design**: RCT **Setting**: Medical Technology College, Taiwan **Sample**: 69 female adolescent students (aged 17 – 19). **Health issue**: symptoms of primary dysmenorrhoea among adolescent girls. **Intervention**: The experimental group (n = 35) received acupressure at Sanyinjiao (Sp6) (above the ankle) while the control group (n = 34) rested for 20 min, without receiving acupressure. Fifty participants (30 experimental, 20 control) completed the 4-6-week follow-up session (self administered acupressure). Five instruments were used to collect pretest and post-test data at each session: (1) Visual Analogue Scale for pain; (2) the Short-Form McGill Pain Questionnaire; (3) the Menstrual Distress Questionnaire; (4) the Visual Analogue Scale for anxiety; and, for the experimental group only, (5) the Acupressure Self-Assessment Form. Data were analysed using repeated measures two-way ANOVA.	Acupressure at Sanyinjiao during the initial session reduced the pain and anxiety typical of dysmenorrhoea but not distress. No p value. In the self-treatment follow-up session, acupressure at Sanyinjiao significantly reduced menstrual pain. No p value but not anxiety or distress. Thirty-one (87%) of the 35 experimental participants reported that acupressure was more than moderately helpful, and 33 (94%) were satisfied with acupressure in terms of its providing pain relief and psychological support during dysmenorrhoea. Interactions were significant for initial pain ($p=0.04$), initial anxiety ($p<0.001$) and self-treatment follow-u pain ($p=0.003$).	The findings suggest that acupressure at Sanyinjiao can be an effective, cost-free intervention for reducing pain and anxiety during dysmenorrhoea, and we recommend its use for self-care of primary dysmenorrhoea	RCT although not blinded so may create bias. Also no sham treatment so placebo effect may be present. Follow up rate of 72%. Volunteer sample with random group assignment. Sample size calculated using power analysis from pilot study findings. Dysmenorrhoea was self-reported which could be subject to bias, including recall bias, although tools were tested for reliability. The acupressure procedure was validated. Limited generalisability (17-19 year olds) Abstract says chi square and t test were performed but these are not evident in text.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Chen,H.M., Chang,F.Y., and Hsu,C.T. (2005). Effect of acupressure on nausea, vomiting, anxiety and pain among post-caesarean section women in Taiwan.	**Design**: Quasi experimental **Setting**: Two hospitals in Taiwan **Sample**: convenience sample. 104 eligible females awaiting caesarean section and having had spinal anaesthesia **Health Issue**: Nausea, vomiting, anxiety and pain **Intervention**: Participants assigned to experimental group received acupressure, and those assigned to the control group received only postoperative nursing instruction. The experimental group received three acupressure treatments. Pressure was applied to Neigan (P6) for total of 20mins on each arm. The first treatment was performed the night before CS, the second was performed 2-4 hours after CS, and the third was performed 8-10 hours after CS. Control group received standard nursing post operative instruction. The measures included the Rhodes Index of Nausea and Vomiting, Visual Analog Scale for Anxiety, State-Trait Anxiety Inventory, Visual Analog Scale for Pain, and physiologic indices. Statistical methods included percentages, mean with standard deviation, t test, repeated measure ANOVA.	The use of acupressure reduced the incidence of nausea, vomiting or retching from 69.3% to 53.9%, compared with control group (95% confidence interval = 0.11-1.65; p = 0.040) 2-4 hours after CS (although nausea and vomiting were not independently significant) and from 36.2% to 15.4% compared with control group (95% confidence interval = 0.59-0.02; p = 0.024) 8-10 hours after CS (nausea, vomiting and retching all significant). Experimental group showed an increasing reduction compared with controls in anxiety and pain overall therapeutic times for all outcome measures. State Anxiety Inventory p=0.000. VAS for anxiety (p=0000) VAS for pain (P=0.001) Significant difference between experimental and control group for Respiration p=0.000, Pulse p=0.004, systolic p=0.001, diastolic blood pressure p=0.006 ANOVA showed a correlation between time and intervention effects.	The experimental group had significantly lower anxiety and pain perception of caesarean experiences than the control group. Significant differences were found in all physiologic indices between the two groups. The utilization of acupressure treatment to promote the comfort of women during caesarean delivery was strongly recommended	Surgery duration and type and number of procedures not taken into consideration. Convenience sample. Size ok (n=104). Controlled study but group assignment was not random (first 52 recruited were in control group). However groups were homogeneous (p>0.05). Acupressure procedure tightly controlled to be the same each time. Interaction effects tested for.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Chen,L.L., Hsu,S.F., Wang,M.H., Chen,C.L., Lin,Y.D., and Lai,J.S. (2003). Use of acupressure to improve gastrointestinal motility in women after trans-abdominal hysterectomy.	**Design**: Randomised controlled trial **Setting**: Mid-Taiwan teaching hospital **Sample**: 41 patients undergoing Trans-abdominal hysterectomy (TAH) without neoplasm **Health issue**: Gastrointestinal (GI) motility in women after (TAH). **Intervention**: Patients were randomly assigned into two groups. The experimental group (n=21) received acupressure for 3 minutes at each of three meridian points: Neiguan (PC-6), Zusanli (ST-36) and Sanyinjiao (SP-6). The control group (n=20) received 3 minutes of acupressure on sham points. Acupressure was performed twice a day, for at least three days. A questionnaire was used to determine patients' satisfaction prior to and after afternoon acupressure. GI contractions were measured with a multifunctional stethoscope before and after acupressure.	Acupressure of these three meridian points significantly ($p < 0.05$) increased GI motility in the experimental group, but there was little change in the control group ($p > 0.05$). Experimental group also showed higher self-awareness of GI motility after acupressure than control group ($p<0.05$). Experimental group had higher degree of satisfaction than control ($p<0.001$). Anecdotally, 14 patients from experimental group reported increase in GI motility and passing of gas compared to none in control group.	Our conclusions are that non-invasive acupressure of these meridian points can significantly improve GI motility and can be incorporated into the technical curriculum and clinical education program of nursing schools. Patients and their family members can be taught to continue this procedure at home to enhance GI motility in patients who have undergone TAH	Small sample, but random group assignment. Sampling not given, presumably convenience. RCT design controls for placebo effect, Hawthorne effect selection bias etc. May be subject to researcher bias although measures in place to reduce this risk. Controlled for a large number of extraneous variables, which were identified from previous research. Groups were homogenous in all: demographics, bowel movements, GI history, surgery history, duration of surgery, blood loss, analgesics, pain, post surgical activities, leaving the bed and food intake patterns. Single blind (used sham acupuncture on non meridian points) so can assess meridian effects. 3 measures of reliability for procedure/measurements, including verification from specialists.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Chen,M.L., Lin,L.C., Wu,S.C., and Lin,J.G. (1999). The effectiveness of acupressure in improving the quality of sleep of institutionalized residents	**Design**: A randomized block experimental design **Setting**: Public assistance facility for elderly residents, Taiwan. **Sample**: 246 elderly residents with sleep disturbances as screened for using the Pittsburgh Sleep Quality Index (PSQI) questionnaire. 84 participants eligible to take part. **Health issue**: disturbed sleep in elderly people **Intervention:** By matching the effects of hypertension, hypnosis, naps, and exercise, subjects were randomly assigned to an acupressure group, a sham acupressure group, and a control group (28 subjects each). The same massage routine was used in the acupressure group and the sham acupressure group, whereas only conversation was employed in the control group. Acupressure group had pressure applied at 5 points (points baihui (GV20), fengchi (GB20), anmian (BL18) and shenmen (Ht7) Sham points were 1cm - 3cun from real points. Acupressure performed for 15mins a day, 4hours before bedtime, Monday to Friday for 3 weeks, by the Principal Investigator.	There were significant differences in PSQI subscale scores of the quality, latency, duration, efficiency and global PSQI scores (all $p<0.001$) among subjects in the three groups before and after interventions and the improvements were all significantly greater in acupressure group than other two (Scheffes post hoc comparison). There was also a significant improvement in disturbances of sleep for all groups ($p<0.05$) but this did not differ between groups. Daily sleep status records showed all groups improved in time to fall asleep, hours of bed time and frequency of nocturnal awakening ($p<0.01$). Frequencies of nocturnal awakening and night wakeful time were significantly reduced in the acupressure group compared to the other two groups. ANCOVA showed that a greater frequency of nocturnal awakening gave a greater reduction. Qualitative data showed acupressure group were more likely to experience increased body comfort and self-reported sleep quality than sham group	This study confirmed the effectiveness of acupressure in improving the quality of sleep of elderly people and offered a nonpharmacological therapy method for sleep-disturbed elderly people	Three armed RCT; Control group had conversation to control for placebo effect and sham points enable identification of meridian effects. Sham group showed some improvement which may be due to effects of massage, although acupressure group showed greatest improvements. Sampling was systematic random and order of subjects randomly decided. Groups randomly assigned once matched for various factors (block design). This gives more powerful treatment effects but only if factors are true, i.e. blocks are homogenous. No justification for choice of factors given. Control and intervention groups are homogenous (no significant differences in demographics age, gender, linving conditions, drug use, chronic disease, time at facility, naps, exercise, time in bed, milk tea and coffee consumption, smoking, sleep indices). Single-blind. PI administered treatment and collected data which may introduce bias (subjects were reluctant to talk to a stranger), including

	Data collected using PSQI in first (baseline) and fifth week. During intervention information on last nocturnal sleep (LNS) was also collected.	sleep quality than sham group.		to a stranger), including Hawthorne effect and Researcher bias. Only 65.6% follow-up. Internal validity of procedure extensively controlled by inter-rater reliability and expert validation. Limited generalisability as mean age 79 years, and residents had to have low income and have no son. Data subject to recall bias.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Cho,Y.C. and Tsay,S.L. (2004). The effect of acupressure with massage on fatigue and depression in patients with end-stage renal disease.	**Design**: experimental pretest and posttest design **Setting**: two hemodialysis clinics in major hospitals in southern Taiwan. **Sample**: Sixty-two patients with end-stage renal disease (ESRD) receiving hemodialysis treatment. **Health issue**: Fatigue and depressive mood experienced by patients with end-stage renal disease. **Intervention**: Patients in the acupressure group received acupoint massage for 12 minutes per day, three days per week, for four weeks. Subjects in the control group only received routine unit care. The measures included the Revised Piper Fatigue Scale, and Beck ' s Depression Inventory. Descriptive statistics, chi 2 tests, t-test and analyses of covariance were used for data analysis.	The results indicate that subjects experienced a moderate level of fatigue. Nearly 65 % of hemodialysis patients had a depressed mood. T-tests showed a significant reduction in fatigue ($p<0.001$) and depression ($p=0.03$) in experimental group but not in control, confirmed by ANCOVA results indicated that fatigue ($F((1.54)) = 9.05$, $p = .004$) and depression ($F((1.54)) = 4.20$, $p = .045$) among patients in the acupressure group showed significantly greater improvement than patients in the control group.	Acupressure therapy could effectively improve ESRD patients' perceived fatigue and depression, which might provide an interventional model for nurses taking care of ESRD patients	Controlled (compared to routine care) but no sham treatment. Sample size power calculation performed. Convenience sample but random group assignment. Co-intervention of massage, although this was only for 3 out of 15 mins of treatment. Used TCM theory to select points and give reasoning for effectiveness. Treatment clearly defined and reliable Control and intervention groups are almost homogenous (no significant differences in demographics except age). ANCOVA used which controls for differences in pre-test scores and age. Extra attention/interaction with experimental group may have affected mental state (placebo effect not tested for)

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Chung,U.L., Hung,L.C., Kuo,S.C., and Huang,C.L. (2003). Effects of LI4 and BL 67 acupressure on labour pain and uterine contractions in the first stage of labour.	**Design**: Experimental study with a pretest and posttest control group **Setting**: Not clear, may be Taipei National College of Nursing Hospital **Sample**: 127 parturient women were randomly assigned to three groups. **Health issue**: Labour pain and uterine contractions during the first stage of labour. **Intervention**: Each group received only one of the following treatments, LI4 and BL67 acupressure, light skin stroking, or no treatment/conversation only. Data collected from the VAS and external fetal monitoring strips were used for analysis.	Findings indicated that there was a significant difference in decreased labour pain during the active phase of the first stage of labour among the three groups (p=0.041), but not during latent and transitional phases. Wilcoxon showed no significant differences between acupressure and effleurage groups or effleurage and control groups, but did show difference between acupressure and control groups (p=0.017) There was no significant difference in effectiveness of uterine contractions during the first stage of labor among the three groups. Duration of labour was shorter in acupressure group compared to control (p=0.019) but not compared to effleurage group. Qualitative data showed one third of women in acupressure group had positive feeling towards the treatment and felt it had reduced their pain.	Results of the study confirmed the effect of LI4 and BL67 acupressure in lessening labour pain during the active phase of the first stage of labour. There were no verified effects on uterine contractions	Randomised controlled three-armed trial. Sampling and group allocation were both random. Control and intervention groups are homogenous (no significant differences in demographics, obstetrics or attrition). Sample size small for three groups (n=42/43) and v low response at transitional phase (31 out of 127) Placebo effect was tested for by use of 3 groups, to determine if effects of acupressure are from meridian effects or tactile stimulation. Outcome measure (VAS) shown to be valid and reliable. Three comprehensive steps to ensure validity and reliability of acupressure procedure. 23 subjects excluded due to medication/caesarean – reduced generalisbility

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Dibble,S.L., Chapman,J., Mack,K.A., and Shih,A.S. (2000). Acupressure for nausea: results of a pilot study.	**Design**: Single-cycle, randomized clinical trial. **Setting**: Outpatient oncology clinic in a major teaching medical center and a private outpatient oncology practice. Western USA **Sample**: Seventeen women participated in the study, receiving CMF or doxorubicin and suffering nausea. **Health issue**: Nausea experience and intensity in women undergoing chemotherapy for breast cancer **Intervention**: Finger acupressure bilaterally at P6 and ST36, acupressure points located on the forearm and by the knee. Baseline and post-study questionnaires plus a daily log of nausea experience measured by the Rhodes inventory of Nausea, Vomiting, and Retching and nausea intensity were used.	Significant differences existed between the two groups in regard to nausea experience ($p < 0.01$) and nausea intensity ($p < 0.04$) during the first 10 days of the chemotherapy cycle, with the acupressure group reporting less intensity and experience of nausea. The CPC (retrospective measure of nausea) reported no differences.	Finger acupressure may decrease nausea among women undergoing chemotherapy for breast cancer	Pilot study (must be replicated prior to advising patients about the efficacy of acupressure for the treatment of nausea) Small sample (n=17) No placebo (discussed as unethical). Hawthorne effect may be present due to extra attention given to acupressure group (for teaching acupressure) Self-administered acupressure Sampling not described Stratified random group assignment (based on setting and treatment regimen). Control and intervention groups are homogenous (no significant differences in demographics, cancer characteristics and treatment). Two of the tools were not validated (two were) Women rarely used ST36 as they reported that it was difficult to access.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Dullenkopf,A., Schmitz,A., Lamesic,G., Weiss,M., and Lang,A. (2004). The influence of acupressure on the monitoring of acoustic evoked potentials in unsedated adult volunteers.	**Design**: Within subjects (repeated measures) design with counterbalancing **Setting**: Not given **Sample**: Fifteen unsedated adult volunteers **Health issue**: Stress levels in unsedated volunteers **Intervention** Patients received pressure on the acupuncture Extra 1 point (EP) and on a control point for 10 min on different days. A-line Autogressive Index (AAI) was recorded 5 min before, during, and 5 min after the interventions. A random procedure selected whether participants received EP or control point pressure first. Before and after the procedures, the volunteers quantified their level of stress by means of a visual analog stress scale (VSS; 0-100). Corresponding data (differences before and after intervention within subjects, before test values and pre-post differences between subjects) were compared by Wilcoxon's signed rank test (Bonferroni correction, $P < 0.05$) and simple regression tested for correlation between AAI values within subjects on different days.	Data are median (range). AAI decreased from 73 (40-99) to 53 (33-94) after 10 min of pressure on EP ($P = 0.0044$). Five minutes after release of pressure there was no difference compared with initial values. There was a statistically significant difference between VSS before and after pressure on EP (36 [7-67] to 15 [0-44]; $P = 0.0066$), but not on control point. There was no difference in changes in AAI or VSS between participants who had EP first or control first. There was no correlation between AAI and VSS values before intervention.	1) There was a wide range of AAI values in awake volunteers. 2) AAI was influenced by acupressure performed on the EP in unsedated adult volunteers. This indicates that monitoring of level of consciousness by change in EEG is not solely influenced by anaesthetics. 3) Acupressure on this point significantly reduced stress levels. Acupressure deserves attention for potentially being a non-invasive, easy to apply alternative to reduce stress and anxiety.	Very small sample (15). Sampling procedure not given, don't even know where they came from! No control group, patients acted as their own controls. This can cause 1) Danger of attrition 2) Carryover effects (addressed by counterbalancing of participants having either EP or control first) 3) Practise effect (especially likely in self-report such as VSS) But acting as own controls does control for the heterogeneity in AAI which was observed. AAI measurements were consistent within subjects. Bonferroni correction was used to control for repeated measures, which is good but can cause a loss in precision of findings.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Ezzo,J., Richardson,M., Vickers,A., Allen,C., Dibble,S., Issell,B., Lao,L., Pearl,M., Ramirez,G., Roscoe,J., Shen,J., Shivnan,J., Streitberger,K., Treish,I., and Zhang,G. (2006). Acupuncture-point stimulation for chemotherapy-induced nausea or vomiting (review).	**Design**: Cochrane Systematic Review **Setting**: - **Sample**: Randomised trials of acupuncture-point stimulation for chemotherapy-induced nausea or vomiting. **Health issue**: Chemotherapy-induced nausea and vomiting in cancer patients **Intervention**: Trials using acupuncture-point stimulation by any method (needles, electrical stimulation, magnets, or acupressure) was used and chemotherapy-induced nausea or vomiting, or both, was assessed. Data were provided by investigators of the original trials and pooled using a fixed effect model. Relative risks were calculated on dichotomous data. Standardised mean differences were calculated for nausea severity. Weighted mean differences were calculated for number of emetic episodes.	Eleven trials (N = 1247) were pooled. Overall, acupuncture-point stimulation of all methods combined reduced the incidence of acute vomiting (RR = 0.82; 95% confidence interval 0.69 to 0.99; P = 0.04), but not acute or delayed nausea severity compared to control. By modality, stimulation with needles reduced proportion of acute vomiting (RR = 0.74; 95% confidence interval 0.58 to 0.94; P = 0.01), but not acute nausea severity. Electroacupuncture reduced the proportion of acute vomiting (RR = 0.76; 95% confidence interval 0.60 to 0.97; P = 0.02), but manual acupuncture did not; delayed symptoms for acupuncture were not reported. Acupressure reduced mean acute nausea severity (SMD = -0.19; 95% confidence interval -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, and all, except electroacupuncture trials, used state-of-the-art antiemetics.	This review complements data on post-operative nausea and vomiting suggesting a biologic effect of acupuncture-point stimulation. Electroacupuncture has demonstrated benefit for chemotherapy-induced acute vomiting, but studies combining electroacupuncture with state-of-the-art antiemetics and in patients with refractory symptoms are needed to determine clinical relevance. Self-administered acupressure appears to have a protective effect for acute nausea and can readily be taught to patients though studies did not involve placebo control. Noninvasive electrostimulation appears unlikely to have a clinically relevant impact when patients are given state-of-the-art pharmacologic antiemetic therapy	Cochrane review. Only 11 articles included. All methodological details given; selection criteria, etc. Data from studies pooled using Intention to Treat analysis and original data where possible. All acupressure trials together, including those using bands which we would have excluded. Duplicate bias avoided. Language bias avoided. Grey literature not searched.

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Fassoulaki,A., Paraskeva,A., Patris,K., Pourgiezi,T., and Kostopanagiotou,G. (2003). Pressure applied on the extra 1 acupuncture point reduces bispectral index (BIS) values and stress in volunteers.	**Design**: Crossover study **Setting**: Not given **Sample**: 25 healthy volunteers **Health issue**: None, healthy volunteers. To reduce preoperative stress. **Intervention** In each volunteer, pressure was applied on the Extra 1 point for 10 min and on a control point for 5 min on different days and in a randomized manner. The BIS value (this is a measure of the level of consciousness during anaesthesia) was recorded before applying pressure on the Extra 1 point (EP), during pressure application every 30 s for 10 min, and after pressure release. Regarding the control point, BIS values were recorded for 5 instead of 10 min during pressure application because acupressure on that point was associated with an unpleasant feeling. Each volunteer was asked to score stress before and after pressure application from 0 to 10. Friedman test used to compare BIS values. Wilcoxon rank to compare BIS values at different times and for EP/control points and VSS before and after. Mann Whitney to compare EP with control.	The BIS values were significantly reduced 2.5, 5, 7.5, and 10 min during pressure application on the extra 1 point (all $P < 0.001$) and returned to the baseline values after pressure release. Pressure application on the control point decreased BIS values ($P < 0.01$ and $P < 0.05$ at 2.5 and 5 min, respectively). However, these values were maintained close to 90% and were significantly higher than those obtained during pressure on the extra 1 point ($P < 0.001$ and $P < 0.001$ for the 2.5- and 5-min comparisons). The verbal sedation score values obtained after pressure application on the extra 1 point were also lower when compared with the values obtained after pressure application on the control point ($P < 0.001$).	Acupressure applied for 10 min on the extra 1 point significantly reduced the BIS values and the verbal stress score when compared with acupressure applied on a control point	Sampling/follow-up/response not given Small sample but apparently powered from a pilot study. Not clear whether participants were blinded. Control point only used for 5 mins (EP for 10) which is a flaw in the study. This was done because discomfort was experienced at control. However, BIS did reduce in EP after 5mins and not in control. Participants excluded if they believed in TCM, could bias sample and reduces generalisable. No control group, patients acted as their own controls. This can cause 1) Danger of attrition (test for impact of sequence effect showed no effect.) 2) Carryover effects (addressed by counterbalancing of participants having either EP or control first) 3) Practise effect (especially likely in self-report such as VSS) But acting as own controls does control for heterogeneity.

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Habek,D., Barbir,A., Habek,J.C., Janculiak,D., and Bobic-Vukovic,M. (2004). Success of acupuncture and acupressure of the Pc 6 acupoint in the treatment of hyperemesis gravidarum.	**Design**: Prospective, placebo-controlled trial **Setting**: Clinical Hospital Osijek, Croatia. **Sample**: 36 pregnant women with HG. **Health issue**: Pregnant women with hyperemesis gravidarum (HG). **Intervention**: Two methods of acupuncture were used: bilateral manual AP of the Pc 6 (Neiguan) acupoint (group 1, n = 10) and bilateral APr of the Pc 6 acupoint (group 2, n = 11); furthermore, superficial intracutaneous placebo AP (group 3, n = 8) and placebo APr (group 4, n = 7) was carried out. APr was self-administered for 30mins whenever they felt nausea. Outcome criteria was disappearance of nausea and vomiting symptoms and no need for medication for HG, assessed by patient report and independent gynaecologist's evaluation.	The efficiency of the HG treatment with AP of the point Pc 6 was 90%, with APr of the Pc 6 63.6%, with placebo AP 12.5%, and with placebo APr 0%. The results showed that AP and Apr can significantly reduce the occurance of HG ($p<0.0001$ and $p<0.01$ respectively)	Acupuncture ($p < 0.0001$) and acupressure ($p < 0.1$) are effective, nonpharmacologic methods for the treatment of HG	Double-blind to reduce bias. Group allocation was random, but the homogeneity of groups was not statistically assessed, even though data was collected and looks similar. Small sample (36) and divided into four groups so power very low in groups. Also sampling process not given, and not stated how women with HG were identified. No control of reliability of acupressure procedure, especially as self-administered there could be variation in procedure. Outcome measures not given. Results just given as % effective, measuring the disappearance of symptoms as subjectively assessed by patient and gynaecologist. Also % should not be used for such small groups.

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Harris,R.E., Jeter,J., Chan,P., Higgins,P., Kong,F.M., Fazel,R., Bramson,C., and Gillespie,B. (2005). Using acupressure to modify alertness in the classroom: a single-blinded, randomized, cross-over trial.	**Design**: a cross-over (two-treatments; three periods), single-blinded, randomized trial. **Setting**: The University of Michigan School of Public Health **Sample**: 39 Students attending a course in clinical research design and statistical analysis at the University of Michigan **Health issue**: alertness in a full-day classroom setting **Intervention**: Blinded subjects were randomized to two acupressure treatment sequences: stimulation-relaxation-relaxation or relaxation-stimulation-stimulation. Acupressure treatments were 15mins, self administered over 3 consecutive days. Pre- and post-treatment alertness scores were assessed each day using the Stanford Sleepiness Scale (SSS). Changes in the SSS score (afternoon-morning) were analyzed using a mixed regression model of fixed and random effects. Important factors that were expected to affect alertness, such as	Baseline characteristics and protocol compliance were similar between the two sequences. Stimulation acupressure treatment yielded a 0.56-point greater difference in score on the SSS, corresponding to less fatigue, compared to the relaxation acupressure treatment ($p = 0.019$). Day of study ($p = 0.004$) and hours of overnight sleep ($p = 0.042$) also significantly affected the change in SSS scores. Incorporating participants' beliefs as to which treatment they received did not significantly alter the observed treatment effect (although it came close, raising p to 0.0484).	Acupressure at stimulation and relaxation points has differential effects on alertness in a classroom setting. Further research is necessary to confirm these findings and to determine whether stimulation and relaxation acupressure are equally effective in influencing alertness	Single-blind (subjects) and all other researchers except those teaching acupressure. Although majority of students could correctly discern the treatment, this did not significantly affect the results. Small sample (39) and low generalisability as all medical students (well educated, scientific researchers who were highly motivated to comply). Sampling not given – may be all eligible students on course. Random group allocation and control and intervention groups are homogenous (no significant differences in demographics). Crossover design should reduce effects of retesting, carryover or time-related. However, is one day enough to allow treatment effects to subside? Also participants acting as own controls can cause practise effect (especially with self-report). Treatment was empirically designed so not clear if acupressure sites chosen were optimal for the intended purpose.

	caffeine and previous night's sleep, were also assessed.			Validity of SSS not given. Missing data provided retrospectively (n=9) may cause recall bias. Very comprehensive statistical analysis accounting for: – Effects of sequence, period, treatment and 'other covariates' – Masking – Co-variates including caffeine, sleep, medication, anxiety and compliance. Results were affected by day of study and hours of sleep which may bias results. Ethical implication of sedating students in class.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Hsieh,L.L., Kuo,C.H., Yen,M.F., and Chen,T.H. (2004). A randomized controlled clinical trial for low back pain treated by acupressure and physical therapy.	**Design**: Randomized controlled clinical trial **Setting**: Orthopedic referral hospital in Taiwan. **Sample**: 146 participants with chronic low back pain were randomly assigned to the acupressure group (69) or the physical therapy group (77), between December 20, 2000, and March 2, 2001 **Health issue**: with low back pain (LBP) **Intervention**: Acupressure from a senior therapist was compared to routine physical therapy. Both were 6 sessions over 4 weeks. Acupressure was for 15mins per session. Physical therapy includes thermotherapy, infrared, electrical stimulation, exercise and traction. Self-appraised pain scores were obtained before treatment as baseline and after treatment as outcomes using the Chinese version of Short-Form Pain Questionnaire (SF-PQ).	There were no significant differences in baseline characteristics among patients randomized into the two groups. The mean of posttreatment pain score after a 4-week treatment (2.28, SD = 2.62) in the acupressure group was significantly lower than that in the physical therapy group (5.05, SD = 5.11) (P = 0.0002). At the 6-month follow-up assessment, the mean of pain score in the acupressure group (1.08, SD = 1.43) was still significantly lower than that in the physical therapy group (3.15, SD = 3.62) (P = 0.0004). The change of score pre to post treatment was also significantly greater in Acupressure ($p<0.0001$)	Our results suggest that acupressure is another effective alternative medicine in reducing low back pain, although the standard operating procedures involved with acupressure treatment should be carefully assessed in the future	Good sample size, powered using a pilot study. Sample was convenience, over specified time period. Random assignment and control and intervention groups are homogenous (no significant differences in demographics). Validity of SF PQ assessed for the translated version. Although not possible to blind: – Practitioners blind to pre-test scores – Follow up staff blind to treatment – Patients blind to pre-test scores No non-response bias. Intention to treat analysis used, which is debatable but protects against attrition (dropout) bias. Only assessed pain, not functional status etc, which reduces comparability with other studies. Results very highly significant. Generalisability quite good as a wide range of age and types of LBP, and age/gender did

				not affect results. Acupressure treatment was individualised rather than standardised like other studies. Only one therapist was used though, which increases internal validity but decreases external.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Hsieh,L.L., Kuo,C.H., Lee,L.H., Yen,A.M., Chien,K.L., and Chen,T.H. (2006). Treatment of low back pain by acupressure and physical therapy: randomised controlled trial. **Note this is not the same as** Hsieh,L.L., Kuo,C.H., Yen,M.F., and Chen,T.H. (2004). A randomized controlled clinical trial for low back pain treated by acupressure and physical therapy.	**Design**: Randomised controlled trial **Setting**: Orthopaedic outpatient clinic in Kaohsiung, Taiwan. **Sample**: 129 patients with chronic low back pain **Health issue**: low back pain **Intervention**: Acupressure or physical therapy for one month, six sessions. Physical therapy was routine at the clinic and included traction, spinal manipulation, thermotherapy, infrared, electrical stimulation and exercise. Self administered Chinese versions of standard outcome measures for low back pain (primary outcome: Roland and Morris disability questionnaire) at baseline, after treatment, and at six month follow-up. Analysis was t-test, chi-squared, Wilcoxon rank and logistic regression and was Intention to Treat.	The mean total Roland and Morris disability questionnaire score after treatment was significantly lower in the acupressure group than in the physical therapy group regardless of the difference in absolute score (-3.8, 95% confidence interval -5.7 to -1.9) or mean change from the baseline (-4.64, -6.39 to -2.89). Acupressure conferred an 89% (95% confidence interval 61% to 97%) reduction in significant disability compared with physical therapy. The improvement in disability score in the acupressure group compared with the physical group remained at six month follow-up. Statistically significant differences also occurred between the two groups for all six domains of the core outcome, pain visual scale, and modified Oswestry disability questionnaire after treatment and at six month follow-up.	Acupressure was effective in reducing low back pain in terms of disability, pain scores, and functional status. The benefit was sustained for six months	Random group assignment. Sample size powered from pilot study. 15.5% loss to follow up (20 of 129) but intention to treat analysis assumed those lost had no changes from baseline. Control and intervention groups are homogenous (no significant differences in demographics). Outcome measures were not validated for use in Chinese language. Placebo effect not assessed. Blinding not possible but therapists blind to pre-test scores and data collectors blind to treatment as far as possible. Used one therapist rather than a standardised procedure, which increases internal but decreases external validity.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Jun,E.M., Chang,S., Kang,D.H., and Kim,S. (2006). Effects of acupressure on dysmenorrhea and skin temperature changes in college students: A non-randomized controlled trial.	**Design**: A non-equivalent control group pre and post-test design **Setting**: Classrooms at two universities in Korea **Sample**: 58 Young (18-28) female nursing students with primary dysmenorrhea. **Health issue**: Primary dysmenorrhea **Intervention**: Participants were allotted to either a SP6 acupressure group or placebo group that received light touch on the SP6 acupoint. Group allocation was sequential, so those recruited May-June were in treatment groups and those recruited July-August in placebo group. The experimental group received acupressure treatment within the first 8h of menstruation, and severity of dysmenorrhea and skin temperature changes in the Zhongwan (CV2) and Qugu (CV12) acupoints were assessed prior to and 30min, 1, 2, and 3h following treatment.	There was a significant difference in severity of dysmenorrhea between the two groups immediately after ($F=18.50$, $p=0.000$) and for up to 2h ($F=8.04$, $p=0.032$) post treatment. Skin temperature was significantly elevated at 30min after acupressure at the suprapubic CV2 acupoint in the experimental group compared to the control group. Temperature elevation was also noted at the epigastric CV12 acupoint post treatment but group differences were not significant, indicating that SHP6 acupressure relieves dysmenorrhea primarily by temperature elevation in the CV2 pathway.	Acupressure to the SHP6 meridian can be an effective non-invasive nursing intervention for alleviation of primary dysmenorrhea, with effects lasting 2h post treatment	Participants may have been students of the researchers which could introduce Hawthorne bias. Sample size powered using pilot study. Groups not randomly assigned (assigned sequentially according to time period), so results may be affected by seasonal effects (which have been suggested as affecting dysmenorrhea). Groups were however homogenous for demographics and factors affecting dysmenorrhea Students and data collectors blinded. Placebo controlled. Validity of outcome measure translated not established. No clinical outcomes, only (subjective) VAS. Limited generalisability (young and nursing students)

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Kober,A., Scheck,T., Greher,M., Lieba,F., Fleischhackl,R., Fleischhackl,S., Randunsky,F., and Hoerauf,K. (2002). Prehospital analgesia with acupressure in victims of minor trauma: a prospective, randomized, double-blinded trial.	**Design**: Prospective, randomised, double-blinded trial **Setting**: Austria **Sample**: 60 trauma patients. **Health issue**: Untreated pain during the transportation of patients after minor trauma (simple fractures, small wounds, contusions). **Intervention**: Patients were randomly assigned into three groups; "true points," "sham-points," and "no acupressure". All were treated accordingly for 3 minutes. An independent observer, blinded to the treatment assignment, recorded vital variables and visual analog scales (VAS) for pain and anxiety before and after treatment. At the end of transport, we asked for ratings of overall satisfaction. For statistical evaluation, one-way analysis of variance and the Scheffe F test were used. $P < 0.05$ was considered statistically significant.	Morphometric and demographic data and potential confounding factors such as age, sex, pain, anxiety, blood pressure, and heart rate before treatment did not differ among the groups. At the end of transport we found significantly less pain, anxiety, and heart rate and a greater satisfaction in the "true points" groups ($P < 0.01$), both sham and no acupressure groups did not change significantly in any variable..	Our results show that acupressure is an effective and simple-to-learn treatment of pain in emergency trauma care and leads to an improvement of the quality of care in emergency transport. We suggest that this technique is easy to learn and risk free and may improve paramedic-based rescue systems.	Double-blind (paramedic A who was treating did not know which point was sham or real). Sampling not given, but acknowledgment section suggests that ambulance staff chose eligible patients to be recruited. Randomised and all groups homogenous. Treatment and data collection by different paramedics, who were not present together. Treatment and data collection were also independently audited. No dropouts. Intention to treat analysis used, which is debatable but protects against attrition (dropout) bias. Reliability of VAS not given. No discussion of limitations.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Lee,A. and Done,M.L. (2004). Stimulation of the wrist acupuncture point P6 for preventing postoperative nausea and vomiting .	**Design**: Systematic review **Setting**: N/A **Sample**: RCTs of techniques that stimulate the P6 acupoint compared with either sham treatment, or antiemetic drugs for prevention of PONV. **Health issue**: Postoperative nausea and vomiting (PONV) following surgery and anaesthesia. **Intervention:** We searched CENTRAL (The Cochrane Library, Issue 1, 2003), MEDLINE (January 1966 to January 2003), EMBASE (January 1988 to January 2003) and the National Library of Medicine publication list of acupuncture studies up to and including January 2003. Reference lists of retrieved papers and reviews were consulted for additional references SEARCH STRATEGY: SELECTION CRITERIA: All randomized trials of techniques that stimulated the P6 acupoint compared with: sham treatment or drug therapy for the prevention of PONV. Interventions used in these trials included	Twenty-six trials (n = 3347) were included, none of which reported adequate allocation concealment. There were significant reductions in the risks of nausea (RR 0.72, 95% CI 0.59 to 0.89), vomiting (RR 0.71, 95% CI 0.56 to 0.91) and the need for rescue antiemetics (RR 0.76, 95% CI 0.58 to 1.00) in the P6 acupoint stimulation group compared with the sham treatment, although many of the trials were heterogeneous. There was no evidence of difference in the risk of nausea and vomiting in the P6 acupoint stimulation group versus individual antiemetic groups. However, when different antiemetics were pooled, there was significant reduction in the risk of nausea but not vomiting in the P6 acupoint stimulation group compared with the antiemetic group (RR 0.70, 95% CI 0.50 to 0.98; RR 0.92, 95% CI 0.65 to 1.29 respectively). The side effects associated with P6 acupoint stimulation were minor. There was some evidence of asymmetry of the funnel plot.	This systematic review supports the use of P6 acupoint stimulation in patients without antiemetic prophylaxis. Compared with antiemetic prophylaxis, P6 acupoint stimulation seems to reduce the risk of nausea but not vomiting	Cochrane Review Included children Search terms seem comprehensive although not clear how P6 studies were identified. Combined data using a model for heterogenous studies.

	acupuncture, electro-acupuncture, transcutaneous nerve stimulation, laser stimulation, acustimulation device and acupressure. DATA COLLECTION AND ANALYSIS: Two reviewers independently assessed methodological quality and extracted the data. Primary outcomes were incidences of nausea and vomiting. Secondary outcomes were the need for rescue antiemetic therapy and adverse effects. A random effects model was used and relative risk (RR) with associated 95% confidence intervals (95% CI) are reported. Egger's test was used to measure the asymmetry of the funnel plot.			

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Lee,M.K., Chang,S.B., and Kang,D.H. (2004). Effects of SP6 acupressure on labor pain and length of delivery time in women during labor.	**Design**: Randomized clinical trial. **Setting**: Delivery room in a university hospital, Korea **Sample**: Seventy-five (75) women in labor, **Health issue**: Labor pain **Intervention**: 30-minute acupressure (n=36) or touch (n=39) on SP6 acupoint was performed. Labor pain was measured four times using a structured questionnaire, a subjective labor pain scale (visual-analogue scale [VAS]): before intervention, immediately after the intervention, and 30 and 60 minutes after the intervention. Length of delivery time was calculated in two stages: from 3 cm cervical dilation to full cervical dilatation, and full cervical dilatation to the delivery.	There were significant differences between the groups in subjective labor pain scores at all time points following the intervention: immediately after the intervention ($p = 0.012$); 30 minutes after the intervention ($p = 0.021$); and 60 minutes after the intervention ($p = 0.012$). The total labor time (3 cm dilatation to delivery) was significantly shorter in the SP6 acupressure intervention group than in the control group ($p = 0.006$) although length of second stage did not differ. Anxiety was significantly reduced in acupressure group ($p=0.03$) after intervention compared to control. No significant difference in analgesia use.	These findings showed that SP6 acupressure was effective for decreasing labor pain and shortening the length of delivery time. SP6 acupressure can be an effective nursing management for women in labor	Double-blind randomised trial Participants were blinded and data collectors were blinded (not treatment givers) N=75, quite small and volunteer sample could really bias the results. Groups were randomly assigned and matched (according to parity, cervical dilation, labor stage, rupture of amniotic membrane, and husband's presence during labor.). Control and intervention groups are homogenous (no significant differences in demographics). Use of touch group as control allows testing for meridian effects compared to 'emotional supportive effects'. Confounders controlled for; anxiety and use of analgesics. Anxiety was lower posttest in acupressure group. Very detailed control of reliability of procedure.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Litscher,G. (2004). Effects of acupressure, manual acupuncture and Laserneedle acupuncture on EEG bispectral index and spectral edge frequency in healthy volunteers.	**Design**: randomized, controlled and partly blinded cross-over trial **Setting**: Austria **Sample**: Twenty-five healthy volunteers (mean age +/- SD: 25.5 +/- 4.0yr) were investigated during the awake state. **Health issue**: None, investigating effects of EEG **Intervention**: The acupuncture point Yintang and a placebo control point were stimulated for 10mins. Each person received sensory (acupressure and acupuncture) and optical stimulation (Laserneedle acupuncture) or sham acupressure. The sequence was randomly decided for each patient. Outcomes were measured using electroencephalographic bispectral index, spectral edge frequency and a verbal sedation score.	Bispectral index and spectral edge frequency values both decreased significantly ($P < 0.001$) during acupressure on Yintang to values of 62.9 (minimum 35) +/- 13.9 bispectral index and to 13.3 (minimum 2.9) +/- 8.1 Hz (spectral edge frequency right) and 13.8 (minimum 2.7) +/- 7.3 Hz (spectral edge frequency left), respectively. Bispectral index was also significantly ($P < 0.05$) affected by Laserneedle acupuncture and acupressure on the control point but the changes were not clinically relevant, 95.4 +/- 4 and 94.2 +/- 4.8, respectively. All interventions significantly (Yintang: $P < 0.001$; control point: $P < 0.012$) reduced VSS. Heart rate and Blood pressure were reduced after acupressure.	Acupressure at Yintang gave statistically significant and clinically relevant reductions in BIS and EFV. The study highlights the electroencephalographic similarities of acupressure induced sedation and general anaesthesia as assessed by bispectral index and spectral edge frequency	Volunteer sample and quite small (25). They were paid for participation. Subjects and data collectors blinded. Within subject randomisation of order of treatments (crossover design) to reduce carryover effects. However no analysis of these effects. Also only 20mins between treatments which may not be enough time for effect to wear off, and effects not tested beyond 1min after intervention Controlled to reduce placebo effect.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Lu,D.P., Lu,G.P., and Reed,J.F., (2000). Acupuncture/acupressure to treat gagging dental patients: a clinical study of anti-gagging effects	**Design**: Double-blind RCT **Setting**: Dental treatment centre, USA **Sample**: 109 dental patients aged 17-76 years. **Health issue**: Severe gagging which prevented dental procedure. **Intervention**: Patients divided into three groups: 1. Acupuncture at P6 or sham point 2. Acupressure at P6 or sham, further divided into three subgroups using thumb, device or sea-band. 3. Conscious (pharmacological) sedation with either acupressure (3 types) or acupuncture. All for 5 mins (for impression taking) or 3 mins (all other procedures. Dental treatment was then given and the outcome evaluated by treatment team and patient on 4 point ranking scale.	There was a significant difference in outcome for acupuncture (team evaluation p=0.047, patient p=0.009) and for device acupressure (team p=0.002, patient p=0.001) at P6 versus sham point. No other significant differences for acupressure. No significant difference using acupressure with conscious sedation. Acupuncture had a better effect than acupressure. For acupressure, device was better than thumb which was better than Seaband.	Stimulation of P6 with acupuncture needle or acupressure device has an anti-gagging effect for dental procedures.	Double blind, although blinding of practitioners not described. Random group allocation. Small groups Outcome measures not clinical or validated. No details of sample, sampling, comparison of groups on baseline factors, response data, No inclusion criteria.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Maa,S.H., Gauthier,D., and Turner,M. (1997). Acupressure as an adjunct to a pulmonary rehabilitation program	**Design**: single-blind pretest-posttest, cross-over **Setting**: two private hospitals **Sample**: Thirty-one new patients beginning a 12-week PRP at two private hospitals were randomly assigned to one of two groups. **Health issue**: dyspnoea and other symptoms in patients with chronic obstructive pulmonary disease (COPD). **Intervention**: Patients in group 1 were taught acupressure and practiced it daily at home for 6 weeks, then sham acupressure for the following 6 weeks. In group 2, the order of acupressure and sham acupressure was reversed. During weeks 1, 6, and 12, patient dyspnoea, other symptoms associated with COPD, activity tolerance, lung function, and functional exercise capacity were assessed. Analysis was extension of a paired t test, regression and sensitivity analysis for a small sample to test for outliers.	Real acupressure was more effective than sham acupressure for reducing dyspnoea as measured by a visual analogue scale (P = .009, one-tailed), and was minimally effective for relieving decathexis (P = .044, one-tailed). Other dyspnoea and other measures showed no significant difference. Sham acupressure seemed to be more effective than real acupressure for reducing peripheral sensory symptoms (P = .002, two-tailed), but the presence of these symptoms may also be an indication that the acupressure is affecting the body.	Acupressure seems to be useful to patients with COPD as an adjunct to a PRP in reducing dyspnoea. Some persons who are not initially familiar with traditional Chinese medicine can learn and will accept self-administered acupressure as part of their self-care	Single-blind (and stated that many patients could identify sham vs real) with placebo treatments. Crossover – patients act as own controls. Gives sample details, reasons for dropout etc, but dropout was high (20 of 51), mostly due to medical reasons. Small sample, although sensitivity test did not identify any idiosyncratic individuals. Outcome measures validated for this group and reliability tested. Placebo controlled. Gender was determined to be a covariable (results significantly different for male/female)

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Maa,S.H., Sun,M.F., Hsu,K.H., Hung,T.J., Chen,H.C., Yu,C.T., Wang,C.H., and Lin,H.C. (2003). Effect of acupuncture or acupressure on quality of life of patients with chronic obstructive asthma: a pilot study	**Design**: prospective, randomized study **Setting**: Outpatients department of Thoracic medicine, Chang Gung Memorial Hospital (Tao-Yuan, Taiwan) between March 1997 and September 1998. **Sample**: Forty-one (n = 41) patients with chronic obstructive asthma **Health issue**: chronic obstructive asthma **Intervention**: Patients were randomly assigned to receive acupuncture in addition to standard care (n = 11), acupressure and standard care (n = 17), or standard care alone (n = 13). Twenty (20) acupuncture treatments were administered, and self-administered acupressure was performed daily for 8 weeks. Six-minute walking, the Dyspnea Visual Analogue Scale, the modified Borg scale, St. George's Respiratory Questionnaire (SGRQ), and the Bronchitis Emphysema Symptom Checklist (BESC) were used at the beginning and end of the 8 weeks of treatment. Analysis was ANOVA, Kruskal-Wallis, chi-squared, odds ratio and multiple logistic regression.	The total SGRQ score of acupuncture subjects showed an average 18.5-fold improvement (95% confidence interval [CI] 1.54-211.48, p = 0.02); the improvement for the acupressure subjects was 6.57-fold (95% C.I. 0.98-44.00, p = 0.05). Additionally, for patients who received acupressure, the irritability domain score determined by the BESC exhibited an 11.8-fold improvement (95% C.I. 0.88-158.64, p = 0.06) after adjustment for covariables. The other variables did not differ from those of the controls	Patients with clinically stable, chronic obstructive asthma experienced clinically significant improvements in quality of life when their standard care was supplemented with acupuncture or acupressure	Pilot study. Small sample, although sensitivity test did not identify any idiosyncratic individuals Non-probability, purposive sampling. High attrition rate (29 out of 70), mostly due to non-medical reasons, plus greater from acupuncture group & not intention to treat analysis -> final sample may have had different views/beliefs of treatment. Not blinded as control group received no intervention. Control and intervention groups are homogenous (no significant differences in demographics). Outcome measures were valid.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Markose,M.T., Ramanathan,K., and Vijayakumar,J. (2004). Reduction of nausea, vomiting, and dry retches with P6 acupressure during pregnancy	**Design**: Uncontrolled, one group pre post test design. **Setting**: India? **Sample**: 35 women pregnant less than 12 weeks with nausea with/without vomiting **Health issue**: nausea with/without vomiting during early pregnancy **Intervention**: Acupressure on P6 from the 4th day of study, 10 mins on each hand four times a day for four days. Rhodes Inventory of Nausea, Vomiting and Retching used to record symptoms. McNemar non parametric tests to compare scores before and after treatment.	After treatment (day 7) there was a significant reduction from day 3 of frequency of nausea (p=0.008), vomiting (p=0.000), retching (p=0.004 and distress due to nausea (p=0.002), vomiting (p=0.008) and retching (p=0.016). There was no further decrease from day 8 to 10.	This study found P6 acupressure useful for the reduction of nausea, vomiting and retching.	Article is a 'brief communication' so comments are limited. Very small sample. Poor response rate of 17 out of 35. Not RCT – not randomised or controlled. Sample was homogenous for baseline symptoms. Sampling not given.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Ming,J.L., Kuo,B.I., Lin,J.G., and Lin,L.C. (2002). The efficacy of acupressure to prevent nausea and vomiting in post-operative patients	**Design**: Randomized block experimental **Setting**: Medical centre, Taipei **Sample**: 150 subjects scheduled for functional endoscopic sinus surgery (FESS) under general anaesthesia. Each group consisted of 50 subjects. **Health issue**: Post-operative nausea and vomiting **Intervention**: Patients were matched for motion sickness then randomly assigned to a finger-pressing group, a wrist-band group, and a control group. The acupoints (P6 and H7) and treatment times were similar in the finger-pressing group and wrist-band pressing group, whereas only conversation was employed in the control group. Treatment was for 20mins on three occasions; 1 hour before, directly before and 10 hours after operation. The Rhodes Index of Nausea, Vomiting and Retching (INVR) questionnaire was used as a tool to measure incidence and the State Anxiety Inventory was used.. Data was collected the day before and at random points during 24 hours postoperation.	Significant differences in the incidence of the post-operative nausea ($p=0.001$) and vomiting ($p<0.001$)were found between the acupressure, wrist-band, and control groups, with a reduction in the incidence rate of nausea from 73.0% to 43.2% and vomiting incidence rate from 90.5% to 42.9% in the former. Retching did not differ. Nausea and vomiting were significantly different between groups ($p<0.05$). The amount of vomitus and the degree of discomfort were, respectively, less and lower in the former group ($p<0.01$ and $p<0.001$ respectively). Anxiety decreased in the wrist band ($p<0.05$) and control ($p<0.01$) groups but not for acupressure or overall.	In view of the total absence of side-effects in acupressure, its application is worthy of use. This study confirmed the effectiveness of acupressure in preventing post-operative nausea and vomiting	Good sample size (150) and low attrition rate (98.7%). Block design matched for motion sickness – not sure why. Not blinded. Internal validity controlled by inter rater reliability and independent verification of acupressure points. Limited generalisability (only for FESS patients). Control and intervention groups are homogenous (no significant differences in a wide range of variables).

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Pouresmail,Z. and Ibrahimzadeh,R. (2002). Effects of acupressure and ibuprofen on the severity of primary dysmenorrhea	**Design**: 3-armed RCT **Setting**: 3 High Schools, Iran. **Sample**: 216 female high school students, aged between 14 to 18 years, were randomly selected and divided into three groups **Health issue**: Primary dysmenorrhea (PD) **Intervention**: Each group underwent different treatment techniques: acupressure, Ibuprofen and sham acupressure as a placebo. Acupressure was on Li4, SP15, ST36,Sp6 and LR3 for 2mins each, sham was four sham points ,not acupoints, and Ibuprofen was 9 tablets (400ml), all for 3 days starting 24 hours before onset of period. Acupressure and sham also had a relaxation session. 2 checklists were used to assess the severity of dysmenorrhea before and after treatment.	The results indicated that the three therapeutic techniques were significantly effective in reducing the pain, with a before and after reduction ($p<0.01$) for all three. The score on the dysmenorrhea scale was 0 for 0% before, increasing to 50% after acupressure, 36% in Ibuprofen and 18% in placebo. However the therapeutic efficacies of acupressure and Ibuprofen were similar with no significant difference, and were significantly better than the placebo.	Acupressure, with no complications, is recommended as an alternative and also a better choice in the decrease of the severity of PD	Random sample. 3 armed RCT Selected from a range of socio-economic backgrounds. Followed up for 3 months prior to study to determine menstruation pattern. Outcome measure not clinical. Low attrition rate. Not clear if provider or patient blinded (in sham vs acupressure). Very strict inclusion criteria may reduce generalisability.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Shiao,S.Y. and Dune,L.S. (2006). Metaanalyses of acustimulations: effects on nausea and vomiting in postoperative adult patients Thirty-three quality randomized controlled trials (RCT) published over the past three decades were identified by evaluating the quality of randomization and treatment methods, and results were pooled using a fixed effects model.	**Design**:Meta analysis **Setting**: N/A **Sample**: RCTs on any acupoint stimulation for nausea and vomiting symptoms (NVS) in postoperative adult populations. **Health issue**: nausea and vomiting symptoms (NVS) in postoperative adult populations. **Intervention**: Metaanalyses of effects of various acupoints stimulations (AS) (including acupuncture, acupressure, and electrical stimulation) on NVS in postoperative adult populations were performed. Two reviewers independently reviewed and evaluated all relevant information and data was pooled.	Twenty-four trials were pooled for nausea, 29 trials for vomiting, and 19 trials for rescue antiemetics, with AS compared with placebo or controls. Two additional trials did not have control groups but compared AS to medication groups. Compared with the controls, AS (all modalities) reduced nausea (relative risk [RR] = 0.60, 95% confidence interval [CI]: 0.54-0.67, P < .0001), vomiting (RR = 0.51, 95% CI: 0.45-0.57, P < .0001), and use of rescue antiemetics (RR = 0.63, 95% CI: 0.54-0.74, P < 0001). All AS modalities were effective in reducing NVS. Korean hand acupressure stimulations (two trials) had the best impact on reducing vomiting. There were no significant differences on pooled RRs for nausea (five trials) and vomiting (eight trials) between medication and AS groups, but medication groups had increased use of rescue antiemetics (two trials, RR = 2.27, 95% CI: 1.48-3.49, P = .0002). There was a placebo effect when compared with controls in reducing nausea (four trials, RR = 0.67, 95% CI: 0.50-0.90, P = .0069) and vomiting (three trials, RR = 0.39, 95% CI: 0.19-0.80, P = .0106).	This metaanalysis demonstrated that AS is just as effective as medications in reducing NVS and that acupressure is just as effective as acupuncture or electrical stimulation in reducing NVS for postoperative adult populations	Some grey literature included. Only RCTs Good selection process. Studies used had quite similar procedures and outcomes allowing combinability. 18 acupressure trials identified.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Shin,Y.H., Kim,T.I., Shin,M.S., and Juon,H.S. (2004). Effect of acupressure on nausea and vomiting during chemotherapy cycle for Korean postoperative stomach cancer patients.	**Design**: Non-equivalent, control group trial. **Setting**: Oncology wards at University Medical Centres, South Korea. **Sample**: Forty postoperative gastric cancer patients receiving the first cycle of chemotherapy with cisplatin and 5-Fluorouracil **Health issue**: Nausea and vomiting associated with cancer chemotherapy **Intervention**: Both groups received regular antiemesis medication; however, the intervention group (n=20) received acupressure training and was instructed to perform the finger acupressure manoeuvre for 5 minutes on P6 (Nei-Guan) point located at 3-finger widths up from the first palmar crease, between palmaris longus and flexor carpi radialis tendons point, at least 3 times a day before chemotherapy and mealtimes or based on their needs. Both groups received equally frequent nursing visits and consultations. Nausea and vomiting measured by Rhode's Index of Nausea, Vomiting and Retching, side effects assessed by data from medical records. Groups compared for severity, duration and frequency of nausea and vomiting using t tests and two way ANOVA	Significant differences found between intervention and control groups in the severity of nausea and vomiting, the duration of nausea, and frequency of vomiting (all $p<0.01$). Repeated measures ANOVA showed significant time effects for all three aspects ($p<0.01$) and interaction effect (with time) was significant for duration ($p<0.01$) and frequency ($p<0.05$).	This study suggests that acupressure on P6 point appears to be an effective adjunct manoeuvre in the course of emesis control	Small sample and not randomised (convenience sampling and allocation; first 20 patients in control group, next 20 in intervention group). Although control and intervention groups are homogenous (no significant differences in demographics, disease or treatment variables) Not clear if all patients were from the same hospital. Limited to patients with stomach cancer and on specific drug regimen. Acupressure self/family administered. Tests acupressure as an adjunct to standard care (anti emetic drugs used in both groups). Intervention group had additional attention from research staff. Highly significant results Tested for interaction effects. Self-reported N&V may be subject to recall bias, although measure has high reliability.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Tsay,S.L. and Chen,M.L. (2003). Acupressure and quality of sleep in patients with end-stage renal disease--a randomized controlled trial **Note this is based on the same study as ref 90** (Tsay,S.L., Rong,J.R., and Lin,P.F. (2003). Acupoints massage in improving the quality of sleep and quality of life in patients with end-stage renal disease)	**Design**: randomized controlled trial **Setting**: Dialysis centers of four major hospitals **Sample**: 98 participants were randomly assigned into an acupressure group, a sham acupressure group, and a control group. **Health issue**: sleep quality of end-stage renal disease patients **Intervention**: Patients were randomly assigned into an acupressure group, a sham acupressure group, and a control group. Acupressure and sham acupressure group patients received acupoints (H17 & Ki1) or no acupoints massage (5mins relaxing massage, 9 mins acupoint massage) three times a week during haemodialysis treatment for a total of 4 weeks. Control group received no additional intervention (standard care). The main outcomes measured were the Pittsburgh sleep quality index (PSQI) and the daily sleep log. Data were collected at pre-treatment (before randomisation) and following treatment. Primary statistical analysis was by means of Analysis of Covariance, the Kruskal-Wallis Test and repeated measure ANOVA.	The results indicated that PSQI scores of the acupressure group have a significantly greater improvement ($p < 0.01$) than the control group. However, there were no differences between the acupressure group and the sham group or the sham group and the control group ($p > 0.05$). Subscales of PSQI were further analyzed. Results demonstrated significant differences between the acupressure group and the control group in subjective sleep quality ($p = 0.009$), sleep duration ($p = 0.004$), habitual sleep efficiency ($p = 0.001$), and sleep sufficiency ($p = 0.004$). Significant differences in the subscale of subjective sleep quality ($p = 0.003$) between the sham acupressure group and the control group were also observed. Sleep log data showed that the acupressure group significantly decreased awake time and improved quality of sleep over time more than the control group ($p < 0.01$). The improvement could be seen as soon as the acupoints massage was implemented, and it was maintained through the post intervention	This study supports the effectiveness of acupoints massage in improving the quality of sleep and life quality of end-stage renal disease patients, and offers a noninvasive therapy for sleep-disturbed patients	Blinded (interviewer/data collector, usual care provider, participant) but not researcher or acupressure nurse. Three armed. Outcome measures are reliable. Attrition was low (98 from 105) Reliability and validity of acupressure procedure established. Groups homogenous for demographics, sleep affecting behaviour and ESRD related factors. Bonferroni correction used to control for type 1 error. Limited generalisability (renal end stage and northern Taiwan)

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Tsay,S.L., Rong,J.R., and Lin,P.F. (2003). Acupoints massage in improving the quality of sleep and quality of life in patients with end-stage renal disease **Note this is based on the same study as ref 93** **(**Tsay,S.L. and Chen,M.L. (2003).Acupressure and quality of sleep in patients with end-stage renal disease--a randomized controlled trial)	**Design**: Randomized control trial **Setting**: Four outpatient dialysis centres in hospitals in Taipei. **Sample**: 98 end-stage renal disease patients with sleep disturbances **Health issue**: Sleep disturbance and diminished quality of life in patients with end-stage renal disease **Intervention**: Patients were randomly assigned into an acupressure group, a sham acupressure group, and a control group. Acupressure and sham acupressure group patients received acupoints or no acupoints massage (5mins relaxing massage, 9 mins acupoint massage) three times a week during haemodialysis treatment for a total of 4 weeks. Control group received no additional intervention (standard care). Data collected at baseline and one week after course, using Pittsburgh Sleep Quality Index, and the Medical Outcome Study - Short Form 36. Plus daily Sleep Log.	The results indicated significant differences between the acupressure group and the control group in Pittsburgh Sleep Quality Index subscale scores of subjective sleep quality (p=0.009), sleep duration (p=0.004), habitual sleep efficiency (p=0.001), sleep sufficiency (p=0.004), and global Pittsburgh Sleep Quality Index scores (p=0.003). No significant difference between acupressure and sham. Sleep log data revealed that the acupressure group significantly decreased wake time and experienced an improved quality of sleep at night over the control group. Medical Outcome Study - Short Form 36 data also documented that acupressure group patients experienced significantly improved quality of life on a number of subscales: physical role (p=0.01), body pain (p=0.001), vitality (p=0.001), social function (p=0.05), total physical (p=0.05) and total mental (p=0.05). These were greater for acupressure group.	This study supports the effectiveness of acupoints massage in improving the quality of sleep and life quality of end-stage renal disease patients, and offers a noninvasive therapy for sleep-disturbed patients	Blinded (interviewer, usual care provider, participant) but not researcher or acupressure nurse. Three armed. Outcome measures are reliable. Attrition was low (98 from 105) Reliability and validity of acupressure procedure established. Groups homogenous for demographics, sleep affecting behaviour and ESRD related factors. Limited generalisability (renal end stage)

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Tsay,S.L. (2004). Acupressure and fatigue in patients with end-stage renal disease-a randomized controlled trial ***Note this is very similar to 90 and 93 (**Tsay,S.L., Rong,J.R., and Lin,P.F. (2003) and Tsay,S.L. and Chen,M.L. (2003)), **but the sample size is different (same as** Tsay,S.L., Cho,Y.C., and Chen,M.L. (2004).) **so not sure if this is an original study.**	**Design**: a randomized control trial **Setting**: not clear **Sample**: 106 participants **Health issue**: fatigue in patients with end-stage renal-disease (ESRD). **Intervention** Participants randomly assigned into acupressure group, sham group or control group. All received standard care. Acupressure was 3mins of relaxing massage then 3mins per acupoint on K1, St36, GB34 and Sp6. Sham group was acupressure on sham points. Acupressure was three times a week for a total of 4 weeks Patients in the control group only received routine unit care. All instructed not to massage any acupoints. The measures included the revised Piper Fatigue Scale (PFS), VAS of Fatigue, the Pittsburgh Sleep Quality Index and the Beck Depression Inventory. Data of fatigue measures were collected at pretreatment and a week following treatment. Sleep quality and depression were collected during post-test only. The statistical methods included the descriptive statistics, one-way ANOVA, ANCOVA, and repeated-measures ANOVA.:	ANCOVA that adjusted for differences in baseline fatigue scores (PFS), post-test of depression and sleep quality, result was significant, $F(2,100)=3.99$, $p=0.02$. Post-hoc tests revealed that patients in the acupressure group were significantly having lower scores of fatigue than patients in the control group. ANCOVA results also significant for VAS of Fatigue among groups, $F(2,100)=5.63$, $p=0.003$. Comparisons indicated that there were significant differences between the acupressure group and the control group ($p=0.01$) and between the sham group and control group ($p=0.003$). Predialysis fatigue was assessed routinely by using a rating of 0-10. Repeated-measures ANOVA results demonstrate the group main effect was significant in the perceived fatigue ($F(2,88)=19.46$, $p<0.001$). Follow-up tests indicated there were significant differences between the acupressure group and the control group ($p<0.001$) and between the sham group and control group ($p<0.001$).	The study provided an alternative method for health care providers to managing ESRD patients with fatigue	Random group assignment. Three armed (treatment, placebo and control) BUT NOT blinded (in conclusion – "*obviously patients are aware that they are receiving acupoints or nonacupoints treatments*") Control and intervention groups are homogenous (no significant differences in demographic and clinical factors) and baseline factors were controlled for. Reliability and validity of procedure evaluated (expert validation). Internal consistency of outcome measures good.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Tsay,S.L., Cho,Y.C., and Chen,M.L. (2004). Acupressure and Transcutaneous Electrical Acupoint Stimulation in improving fatigue, sleep quality and depression in hemodialysis patients	**Design**: Prospective, randomized controlled trial **Setting**: 4 dialysis centres in major hospitals in Northern Taiwan. **Sample**: 106 patients randomly assigned to acupressure, Transcutaneous Electrical Acupoint Stimulation (TEAS) or control groups. **Health issue**: Fatigue, sleep quality and depression in patients who were receiving routine hemodialysis treatment **Intervention**: Patients in the acupressure and TEAS groups received 15 minutes of treatment 3 times a week for 1 month, instructed not to massage any acupoints. Acupressure was 3mins of relaxing massage then 3mins per acupoint on K1, St36, GB34 and Sp6. Acupressure was three times a week for a total of 4 weeks Patients in the control group only received routine unit care. Methods of measurement included the revised Piper Fatigue Scale (PFS), the Pittsburgh Sleep Quality Index and the Beck Depression Inventory. Data were collected at baseline, during the intervention and post-treatment.	The results indicated that patients in the acupressure ($p=0.006$) and TEAS groups ($p=0.02$) had significantly lower levels of fatigue, a better sleep quality ($p=0.05$ and $p=0.016$ respectively) and less depressed moods ($p=0.009$ and $p=0.008$ respectively) compared with patients in the control group based upon the adjusted baseline differences (group main effect was significant $p<0.001$). However, there were no differences between acupressure and TEAS groups in outcome measures ($p>0.05$).	This study provides an alternative method for health care providers in managing dialysis patients with symptoms of fatigue, poor sleep or depression	Random group assignment. Three armed. Sample size was powered. Reliability and validity of procedure evaluated (expert validation). Internal consistency of outcome measures good. Very low attrition rate (2 out of 108). Groups homogenous. ANCOVA to test for baseline differences to establish group effect as main effect. No details of blinding. Low generalisability (haemodialysis patients in northern Taiwan).

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Tsay,S.L., Wang,J.C., Lin,K.C., and Chung,U.L. (2005). Effects of acupressure therapy for patients having prolonged mechanical ventilation support	**Design**: Two group experimental blocking design. **Setting**: Two intermediate respiratory intensive care units. The study was carried out in 2003. **Sample**: 52 patients with chronic obstructive pulmonary disease in northern Taiwan. **Health issue**: dyspnoea, anxiety and physiological indicators of heart rate and respiratory rate in patients with chronic obstructive pulmonary disease having mechanical ventilation support. **Intervention**: After matching for sex, age and length of ventilation use, patients were randomly assigned to an acupressure group and a comparison group. In the experimental group received daily acupressure therapy and massage treatment for 10 days, on L14, PC6, HT7 for 4mins each and 3mins relaxing massage. Patients in the comparison group received massage treatment and handholding. The primary outcome measures were the visual analogue scales for dyspnoea and anxiety, and physiological indicators of heart rate and respiratory rate. Data were collected every day from baseline (day 1), during the treatment (days 2-10) and follow-up (days 11-17). Data were analysed using generalized estimation equations.	Patients with chronic obstructive pulmonary disease who were using prolonged mechanical ventilatory support experienced high levels of dyspnoea and anxiety. Dyspnoea ($P = 0.009$), anxiety ($P = 0.011$) Heart rate ($p=0.005$) and respiratory rate ($P < 0.0001$) in the acupressure group improved statistically significantly over time when compared with those of the comparison group.	This results support the suggestion that acupressure therapy could decrease sympathetic stimulation and improve perceived symptoms of dyspnoea and anxiety in patients with chronic obstructive pulmonary disease who are using prolonged mechanical ventilation	Sample size powered. Procedure reliable and valid (expert validation). Clinical outcome measures (HR and RR) as well as self-reported (VAS) Single blinded (patients, data collectors and caregivers) but not researchers, nurses giving acupressure. Groups homogenous for baseline demographics and clinical factors. Used GEE to control for confounding variables. No information on dropout/compliance rates.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Waters,B.L. and Raisler,J. (2003). Ice massage for the reduction of labor pain	**Design**: A one-group, pretest, posttest design **Setting**: Hospital in New Mexico **Sample**: Hispanic and white Medicaid recipients who received prenatal care at a women's clinic staffed by certified nurse-midwives and obstetricians **Health issue**: labor pain during contractions **Intervention**: Ice bag was applied to Li4 during contractions for 20mins each hand. A family member was then taught the procedure so could continue. The study used 100-mm Visual Analog Scales (VAS) and the McGill Pain Questionnaire (MPQ) ranked numerically and verbally to measure pain levels; the pretest served as the control. Analysis was standard analysis of variance.	Participants noted a pain reduction mean on the VAS of 28.22 mm on the left hand and 11.93 mm on the right hand. The postdelivery ranked MPQ dropped from number 3 (distressing) to number 2 (discomforting).	The study results suggest that ice massage is a safe, noninvasive, nonpharmacological method of reducing labor pain	No control or randomisation or blinding. Convenience sample, no sample size calculated. Low dropout rate (4 from 53). Only early labour stages investigated due to difficulties completing VAS later on. Limited generalisability. No monitoring of extra use of ice (by family member) which was an option. Statistical analysis was limited.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Wu,H.S., Wu,S.C., Lin,J.G., and Lin,L.C. (2004). Effectiveness of acupressure in improving dyspnoea in chronic obstructive pulmonary disease.	**Design**: A randomized block experimental design. **Setting**: Outpatients department at a medical centre and three regional hospitals in Taipei. **Sample**: 44 patients diagnosed with COPD and living at home. **Health issue**: Dyspnoea in patients with chronic obstructive pulmonary disease (COPD) **Intervention**: Using age, sex, pulmonary function, smoking, and steroid use as matching factors, were randomly assigned either to a true acupoint acupressure or a sham group. The true acupoint acupressure group received a programme to decrease dyspnoea. Those in the sham group received acupressure using sham pressure points. Both acupressure programmes consisted of five sessions per week lasting 16 minutes per session, extending over 4 weeks for a total of 20 sessions. Before and after outcome measures: Pulmonary Status and Dyspnoea Questionnaire-modified scale (PFSDQ-M); Spielberger State Anxiety scale; 6-minute walking distance test. Physiological indicators of oxygen saturation	Scores from the PFSDQ-M improved significantly more in true acupoint group than sham group for all three subscales; dyspnoea ($p<0.05$), fatigue ($p<0.01$) and activity ($p<0.001$). Tolerance for activity (walking distance measurement) was improved significantly in true acupoint group ($p<0.001$). Pulmonary function (respiratory rate and oxygen saturation) and state anxiety scores also improved significantly more in true acupoint group than sham group (both $p<0.001$)	The findings suggest that acupressure can be used as a nursing intervention to improve dyspnoea in patients with COPD	Small sample (n=44) Sampling method not given in detail. Randomised block design, this will give more powerful treatment effects, but only if the blocks are more homogenous than the whole sample, and no discussion of how block factors were decided/justified is given here. Controlled design with sham treatment should isolate meridian effects. Sham points especially good as on different meridians and ganglionic sections. However effects may be due to location of points (on the back) promoting relaxation. Acupressure protocol highly reliable and valid as subject to many tests: - independently rated for validity and amended to give 100% score - accuracy of points observed by TCM practitioner - True and sham treatments compared on video for homogeneity in timing

	and respiratory rate were measured before and after every session. Results analysed using descriptive statistics, chi-squared and Mann-Whitney U tests.			Outcome measures are reliable and valid. Results highly significant (most $p<0.001$) for *all* variables. Generalisability limited as majority of sample male and average age = 73

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Yip,Y.B. and Tse,S.H. (2004). The effectiveness of relaxation acupoint stimulation and acupressure with aromatic lavender essential oil for non-specific low back pain in Hong Kong: a randomised controlled trial	**Design**: Randomised controlled trial **Setting**: The community centre, Old-Aged Home and Women Workers Association, Hong Kong. **Sample**: adults with sub-acute or chronic non-specific low back pain. **Health issue**: sub-acute or chronic non-specific low back pain. **Intervention**: 8-session (35-40mins each relaxation acupoint stimulation followed by acupressure with lavender oil over a 3-week period. Acupoint stimulation was with digital Electronic Muscle Simulator on Li10, Li11, Si10, TW15 and BL10, acupressure on UB22,23,25,40. The control group received usual care only. Changes from baseline to the end of treatment were assessed in pain intensity (by Visual Analogue Scale) and duration; lateral fingertip-to-ground distance in centimetres; walking time and interference on daily activities.	The baseline VAS scores for the intervention and control groups were 6.38 (S.E.M. = 0.22) and 5.70 (S.E.M. = 0.37) out of 10, respectively (P=0.24). One week after the end of treatment, the intervention group had 39% greater reduction in VAS pain intensity than the control group (P=0.0001), improved walking time (P=0.05) and greater lateral spine flexion range (P=0.01). Groups were similar for pain duration (p=0.08). Interference in daily activities was unaffected. 78% were satisfied and 15% strongly satisfied with treatment.	Our results show that 8-sessions of acupoint stimulation followed by acupressure with aromatic lavender oil were an effective method for short-term LBP relief. No adverse effects were reported. To complement mainstream medical treatment for sub-acute LBP, the combined therapy of acupoint stimulation followed by acupressure with aromatic lavender oil may be one of the choices as an add-on therapy for short-term reduction of LBP	Co-interventions of electrodes and lavender oil, also performed on different acupoints to acupressure. Hard to isolate the acupressure effect. Random group assignment. Acupoints validated by expert. Sample size powered although volunteer sample, may introduce bias. 84% follow up and dropout not for medical reasons. However, dropout group were older and had greater interference on daily activities which may cause bias. Outcome measures content validated Groups homogenous for socio-demographic and clinical variables Not blinded and no placebo – placebo effect may be present Intervention group had much more frequent measurements – may cause bias.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Yip,Y.B. and Tse,S.H. (2006). An experimental study on the effectiveness of acupressure with aromatic lavender essential oil for sub-acute, non-specific neck pain in Hong Kong	**Design**: Experimental study design **Setting**: The Telehealth clinic and the community centre, Hong Kong. **Sample**: adults with sub-acute non-specific neck pain. **Health issue**: sub-acute non-specific neck pain **Intervention**: A course of 8-session manual acupressure with lavender oil over a 3 week period. 30min neck pain acupuncture massage on 20 points for 2 mins each. Changes from baseline to the end of treatment were assessed on neck pain intensity [by Visual Analogue Scale (VAS)]; stiffness level; stress level; neck lateral flexion, forward flexion and extension in cm, and interference with daily activities.	The baseline VAS score for the intervention and control groups were 5.12 and 4.91 out of 10, respectively (P = 0.72). One month after the end of treatment, compared to the control group, the manual acupressure group had 23% reduced pain intensity (P = 0.02), 23% reduced neck stiffness (P = 0.001), 39% reduced stress level (P = 0.0001), improved neck flexion (P = 0.02), neck lateral flexion (P = 0.02), and neck extension (P = 0.01). However, improvements in functional disability level were found in both the manual acupressure group (P = 0.001) and control group (P = 0.02). Interference with daily life improved in both groups at 1 month follow up (p=0.001 treatment and p=0.02 control). 76% were satisfied and 16% strongly satisfied with treatment.	Our results show that eight sessions of acupressure with aromatic lavender oil were an effective method for short-term neck pain relief	Small sample (28 completed) Follow-up good 88% Co-intervention of lavender oil, Hard to isolate the acupressure effect. Random group assignment. Points validated by expert. Outcome measures content validated Groups homogenous for socio-demographic and clinical variables Not blinded and no placebo – placebo effect may be present Improvement in both groups at 1month indicates maybe need to test for time effect Intervention group had much more frequent measurements – may cause bias.

Author, date and title	Study methodology, design, setting, sample, condition and intervention	Results	Study Conclusions	Comments on quality
Yuksek,M.S., Erdem,A.F., Atalay,C., and Demirel,A. (2003). Acupressure versus oxybutinin in the treatment of enuresis	**Design**: RCT **Setting**: Unclear, may be Turkey **Sample**: 24 patients **Health issue**: nocturnal enuresis **Intervention** Acupressure was administered to 12 patients by their parents, who had been taught the technique. Pressure was applied by the parent for 5sec per point per day at acupuncture points Gv4, Gv15, Gv20, B23, B28, B32, H7, H9, St36, Sp4, Sp6, Sp12, Ren2, Ren3, Ren6, K3 and K5. Twelve control patients received 0.4 mg/kg oxybutinin. Parents were asked to record incidences of bed-wetting and patients and/or parents completed a questionnaire 15 days and 1, 3 and 6 months after the start of treatment. Analysis was independent samples t test, chi-squared/Fishers exact test.	NO significant difference between groups. Complete (no bed-wetting) and partial responses (reduction in bed-wetting) after 6 months of treatment were seen in 83.3% and 16.7%, respectively, of patients treated with acupressure, and in 58.3% and 33.3%, respectively, of children who received oxybutinin	In conclusion, nocturnal enuresis can be partially treated by oxybutinin but acupressure could be an alternative non-drug therapy. Acupressure has the advantages of being non-invasive, painless and cost-effective	Very small sample (12 in each group). 3 patients who had previously unsuccessful pharmacological treatment moved to group A (acupressure) -> selection bias. Significance values not given. 6 month follow up period Ethical approval was NOT sought. Very brief report, no details of sampling, randomisation, comparison of groups at baseline… Intro states study investigated acupressure "*especially for those not wanting drug or acupuncture*"… Acupressure compared to drug not placebo/sham.

Appendix 10 - Excluded from review

Full text publications excluded at Stage 3 screening

Exclusion criteria:
Foreign language papers
Use of Korean points/meridians
Use of plasters, devices, wristbands
Auricular acupressure
Anecdotal evidence
Personal experience
Shiatsu / acupressure are mentioned as treatments in general complementary medicine publications but are not the main subject area of the publication.
Guidelines for treatment
Reports of possible adverse events
Surveys
Conference abstracts / posters

Of the 146 publications that remained for screening and review, 44 were reviewed as evidence and assessed for quality. 41 publications were considered useful as background information but not evidence on Shiatsu / acupressure. The remaining 61 publications were excluded at this stage, 13 Shiatsu and 48 acupressure.

Excluded publications and reasons for exclusion

10.1 Shiatsu

1.Atchison,J.W., Taub,N.S., Cotter,A.C., and Tellis,A. (1999). Complementary and alternative medicine treatments for low back pain. *Physical Medicine and Rehabilitation: State of the Art Reviews* 13:561-586.
This is a review of information and efficacy of treatments for low back pain which include manipulation, massage therapy, mind-body therapy and acupuncture
Reason for exclusion: Shiatsu and acupressure are described as therapies in the 'Massage' section and briefly mentioned in a paragraph discussing efficacy studies

2. Booth,B. (1993). Shiatsu. *Nurs Times* 89:38-40.
This is a part of a series on complementary medicine
Reason for exclusion: This is a very general article is not a study and does not add to the knowledge base for Shiatsu.

3. Centre for Reviews and Dissemination (2006). Is massage useful in the management of diabetes: a systematic review (Structured abstract)
***Database of Abstracts of Reviews of Effectiveness*.**
This is a summary of a systematic review.
Reason for exclusion: Shiatsu and acupressure were included in the search terms but not in any of the studies reviewed.

4. Daniels,J.M., Ishmael,T., and Wesley,R.M. (2003). Managing Myofascial Pain Syndrome: sorting through the diagnosis and honing treatment
***Physician and Sports Medicine* 31:39-45.**
This paper discusses treatment options and guidelines
Reason for exclusion: There is one paragraph describing Shiatsu as a technique with one reference dating back to 1975

5. Elliott,M.A. and Taylor,L.P. (2002). "Shiatsu sympathectomy": ICA dissection associated with a Shiatsu massager. *Neurology* 58:1302-1304.
These are two case reports of internal carotid artery (ICA) dissection that occurred after use of a 'Shiatsu' massage machine.
Reason for exclusion: This is not related to the practice of Shiatsu.

6. Fields,N. (1995). Teaching the gentle way to labour... midwifery, yoga, Shiatsu. *Nursing Times* 1995 Feb 8-14; 91:44-45.
This short article explains the benefits of practising yoga and Shiatsu during pregnancy.
Reason for exclusion: This is a personal viewpoint and discusses courses available at a centre where the author teaches yoga.

7. Inagaki,J., Yoneda,J., Ito,M., and Nogaki,H. (2002). Psychophysiological effect of massage and Shiatsu while in the prone position with face down. *Nurs Health Sci* 4:A5-A6.
This study examined the effect of Shiatsu and massage on 24 healthy women.
Reason for exclusion: This is an abstract for a symposium on healthy care for the elderly. There are no references and the study has not been published.

8. Omura,Y. and Beckman,S.L. (1995). Application of intensified (+) Qi Gong energy, (-) electrical field, (S) magnetic field, electrical pulses (1-2 pulses/sec), strong Shiatsu massage or acupuncture on the accurate organ representation areas of the hands to improve circulation and enhance drug uptake in pathological organs: clinical applications with special emphasis on the "Chlamydia-(Lyme)-uric acid syndrome" and "Chlamydia-(cytomegalovirus)-uric acid syndrome". *Acupunct.Electrother.Res* 20:21-72.
This study included 15 patients presenting with a variety of symptoms. It investigated a number of interventions used to improve circulation by stimulation of organ points on the hands.
Reason for exclusion: Korean points were used and deep massage and / or Shiatsu was applied for 'about a minute on organ representation areas'.

9. Omura,Y., Shimotsura,Y., Ooki,M., and Noguchi,T. (1998). Estimation of the amount of telomere molecules in different human age groups and the telomere increasing effect of acupuncture and Shiatsu on St.36, using synthesized basic units of the human telomere molecules as reference control substances for the bi-digital O-ring test resonance phenomenon. *Acupunct.Electrother.Res* 23:185-206.
This study included approximately 30 subjects with ages ranging from infancy to 76 years of age. There was no indication on how these subjects were grouped to receive the interventions.
Reason for exclusion: This was a preliminary report to assess the effect of acupuncture and / or Shiatsu on telomere levels. There were some results reported for those who had received acupuncture but none given for Shiatsu, other than a comment that Shiatsu had less of an effect than acupuncture. It was unclear if subjects had received both acupuncture and Shiatsu.

10. Saito,H. (2000). Preventing and resolving post-laparotomy intestinal obstruction: an effective Shiatsu method. *Am J Chin Med* 28:141-145.
This describes the effect of Shiatsu from personal experience and from one case report.
Reason for exclusion: This is a personal viewpoint with references to the author's publications following his experience with cancer.

11. Toth,M., Kahn,J., Walton,T., Hrbek,A., Eisenberg,D.M., and Phillips,R.S. (2003). Therapeutic Massage Intervention for Hospitalized Patients with Cancer: A Pilot Study. *Alternative & Complementary Therapies* 9:117-124.
This pilot study investigated the effect of permitted massage techniques on seven consenting patients, four of whom died during hospitalisation
Reason for exclusion: Shiatsu and acupressure were both mentioned as permitted techniques, but there is no indication that either was used.

12. Viggo Hansen,N., Jorgensen,T., and rtenblad,L. (2004). Massage and Touch for dementia [Protocol]. *Cochrane Database of Systematic Reviews*.
Comment: This is the protocol for the systematic review which was subsequently published on 18th October 2006:
Viggo Hansen N, Jørgensen T, Ørtenblad L. Massage and touch for dementia. *Cochrane Database of Systematic Reviews* 2006, Issue 4. Art. No.: CD004989. DOI: 10.1002/14651858.CD004989.pub2.
Reason for exclusion: Shiatsu was included in the search term for trials. However, no Shiatsu trials were included and only two trials were found to meet the 'minimal methodological criteria'.

13. Zullino,D.F., Krenz,S., Fresard,E., Cancela,E., and Khazaal,Y. (2005). Local back massage with an automated massage chair: general muscle and psychophysiologic relaxing properties. *J Altern Complement Med* 11:1103-1106.
This studies the effect of three different Shiatsu massage programmes on ten healthy volunteers.
Reason for exclusion: Use of a massage chair.

10.2 Acupressure

A. Devices used

In the 14 studies listed in this section, acupressure was not applied manually but by using devices such as wristbands, particularly in studies investigating the effects of acupressure on nausea and vomiting. Those most commonly used were Sea-Band® which resemble sweat bands which have a plastic button attached. These bands were initially produced to relieve travel sickness but their use has been extended to include treatment of nausea and vomiting associated with pregnancy, chemotherapy and post operative effects of anaesthesia. (Bayreuther, Pickering, Lewith,1994)

1. Alkaissi,A., Stalnert,M., and Kalman,S. (1999). Effect and placebo effect of acupressure (P6) on nausea and vomiting after outpatient gynaecological surgery. *Acta Anaesthesiol.Scand.* 43:270-274.
Reason for exclusion: Wristbands (Sea-Band®) used

2. Alkaissi,A., Ledin,T., Odkvist,L.M., and Kalman,S. (2005). P6 acupressure increases tolerance to nauseogenic motion stimulation in women at high risk for PONV. *Can.J Anaesth.* 52:703-709.
Reason for exclusion: Wristbands (Sea-Band®) used

3. Bayreuther,J., Pickering,R., and Lewith,G.T. (1994). A double-blind cross-over study to evaluate the effectiveness of acupressure at pericardium 6 (P6) in the treatment of early morning sickness (EMS). *Complementary Therapies in Medicine* 2:70-76.
Reason for exclusion: Wristbands (Sea-Band®) used

4. Felhendler,D. and Lisander,B. (1996). Pressure on acupoints decreases postoperative pain. *Clin J Pain* 12:326-329.
Reason for exclusion: Dentist's tool used

5. Felhendler,D. and Lisander,B. (1999). Effects of non-invasive stimulation of acupoints on the cardiovascular system. *Complement Ther Med* 7:231-234.
Reason for exclusion: Dentist's tool used

6. Harmon,D., Gardiner,J., Harrison,R., and Kelly,A. (1999). Acupressure and the prevention of nausea and vomiting after laparoscopy. *Br J Anaesth.* 82:387-390.
Reason for exclusion: Wristbands (Sea-Band®) used

7. Harmon,D., Ryan,M., Kelly,A., and Bowen,M. (2000). Acupressure and prevention of nausea and vomiting during and after spinal anaesthesia for caesarean section. *Br J Anaesth.* 84:463-467.
Reason for exclusion: Wristbands (Sea-Band®) used

8. Heazell,A., Thorneycroft,J., Walton,V., and Etherington,I. (2006). Acupressure for the in-patient treatment of nausea and vomiting in early pregnancy: a randomized control trial *Am J Obstet.Gynecol.* 194:815-820.
Reason for exclusion: Wristbands (Sea-Band®) used

9. Melchart,D., Ihbe-Heffinger,A., Leps,B., von,S.C., and Linde,K. (2006). Acupuncture and acupressure for the prevention of chemotherapy-induced nausea-a randomised cross-over pilot study. *Support.Care Cancer* 14(8):878- 882.
Reason for exclusion: Acupressure wrist bands used, brand not specified.

10. Neri,I., Allais,G., Schiapparelli,P., Blasi,I., Benedetto,C., and Facchinetti,F. (2005). Acupuncture versus pharmacological approach to reduce Hyperemesis gravidarum discomfort. *Minerva Ginecol.* 57:471-475.
Reason for exclusion: Wristbands (Sea-Band®) used.

11. Tokumaru,O. and Chen,J.D. (2005). Effects of acupressure on gastric myoelectrical activity in healthy humans. *Scand.J Gastroenterol* 40:319-325.
Reason for exclusion: Pressure applied using a 3 pound dumb-bell.

12. Wang,S.M., Gaal,D., Maranets,I., Caldwell-Andrews,A., and Kain,Z.N. (2005). Acupressure and preoperative parental anxiety: a pilot study. *Anesth.Analg.* 101:666-9.
Reason for exclusion: Acupressure bead "manufactured with an occlusive tape covering".

13. Werntoft,E. and Dykes,A.K. (2001). Effect of acupressure on nausea and vomiting during pregnancy. A randomized, placebo-controlled, pilot study. *J Reprod.Med* 46:835-839.
Reason for exclusion: Acupressure wrist bands used, brand not specified.

14. Wollaston,D.E., Xu,X., Tokumaru,O., Chen,J.D., and McNearney,T.A. (2005). Patients with systemic sclerosis have unique and persistent alterations in gastric myoelectrical activity with acupressure to Neiguan point PC6. *J Rheumatol.* 32:494-501.
Reason for exclusion: Pressure applied using a 3 pound dumb-bell.

B. Application to other points and / or treatment guidelines

Acupressure was included in the MeSH terms of the MEDLINE citations of the following papers, but this was not the main therapeutic intervention or subject area in the majority of them. It should also be noted that the references in papers from the Journal of Traditional Chinese Medicine are in Chinese and therefore cannot be checked or verified.

1. Bei,Y., Fang,X., and Yao,Z. (2004). Sixty-two cases of simple obesity treated by acupuncture combined with massage. *J Tradit.Chin Med* 24:36-39.
This study compared 32 cases treated with auricular seed embedding and massage with 30 cases treated with auricular seed embedding and acupuncture
Reason for exclusion: Treatment did not include acupressure or acupoints. Massage included spinal pinching and manipulation.

2. Chen,R. (1997). Treatment of apoplectic hemiplegia by digital acupoint pressure--a report of 42 cases. *J Tradit.Chin Med* 17:198-202.

This paper describes 3 methods of digital acupoint pressure (DAP) – one, three and five digits – which the author has used to treat 42 cases with differing diagnoses.
Reason for exclusion: This paper focuses on how to apply a therapeutic procedure and briefly summarises the author's analysis of the therapeutic effect on 42 unrelated cases.

3. Cui,M. (1996). Advanced in studies on acupuncture abstinence. *J Tradit.Chin Med* 16:65-69.
This paper reviews methods for treating addiction (smoking and alcohol). These include auricular acupuncture, electro acupuncture, auricular plasters with seeds embedded and laser radiation.
Reason for exclusion: Acupressure was not a considered method

4. Cummings,M. (2001). Hand acupressure reduces postoperative vomiting after strabismus surgery (n=50). *Acupunct.Med* 19:53-54.
This is a review of a study which is included in a section of research reviews. The study investigated the effects of placing an acupressure device (small disc) on a Korean hand acupuncture point.
Reason for exclusion: A Korean point and a device were used.

5. Dai,G. (1997). Advances in the acupuncture treatment of acne. *J Tradit.Chin Med* 17:65-72.
This paper reviews 38 studies on the treatment of acne. The interventions include body acupuncture in combination with either moxibustion, electric stimulation, herbs, cupping, pricking or drawing blood and auricular acupuncture. There is one study which refers to "digital facial acupoint pressure".
Reason for exclusion: Acupressure is only mentioned briefly and the reference to the study is in Chinese.

6. Li,Y. and Peng,C. (2000). Treatment of 86 cases of facial spasm by acupuncture and pressure on otopoints. *J Tradit.Chin Med* 20:33-35.
This study compared 86 cases treated with a combination of acupuncture on facial acupoints and pressure with *Vaccaria segetalis* seeds on selected otopoints with 38 cases treated with facial acupuncture only and 40 cases treated with pressure on otopoints only.
Reason for exclusion: Treatment did not include acupressure on acupoints.

7. Ma,J. (1995). Periomarthritis treated with pain point pressure in combination with local exercises. *J Tradit.Chin Med* 15:289.
This paper describes the application of pressure to pain points and quotes one case study.
Reason for exclusion: Treatment did not involve acupoints

8. Shen,P. (2004). Two hundred cases of insomnia treated by otopoint pressure plus acupuncture. *J Tradit.Chin Med* 24:168-169.
This paper describes a treatment protocol using self applied pressure with *Vaccaria segetalis* seeds on selected otopoints combined with acupuncture at selected points for different levels and types of insomnia.
Reason for exclusion: Treatment did not include acupressure on acupoints.

9. Vachiramon,A. and Wang,W.C. (2002). Acupressure technique to control gag reflex during maxillary impression procedures. *J Prosthet.Dent.* 88:236.
This is a letter which describes the authors' use of acupressure to manage the gag reflex. The authors refer to a study that has been included for review :
Lu,D.P., Lu,G.P., and Reed,J.F., III (2000). Acupuncture/acupressure to treat gagging dental patients: a clinical study of anti-gagging effects. *Gen Dent.* 48:446-452.
Reason for exclusion: This is based on the authors' personal experience.

10. Vachiramon,A. and Wang,W.C. (2005). Acupuncture and acupressure techniques for reducing orthodontic post-adjustment pain. *J Contemp.Dent.Pract* 6:163-167.
This paper introduces techniques that the may reduce dental pain. As in **9** above, the authors refer to a study that has been included for review:
Lu,D.P., Lu,G.P., and Reed,J.F., III (2000). Acupuncture/acupressure to treat gagging dental patients: a clinical study of anti-gagging effects. *Gen Dent.* 48:446-452.

Reason for exclusion: This introduced a technique to fellow dentists and their patients. It cannot be considered as evidence.

C. Comments referring to papers included for review

1. Bledsoe,B.E. and Myers,J. (2003). Future trends in prehospital pain management. *JEMS.* 28:68-71.
This focuses on various drug options and briefly mentions one study that is included in the evidence review:
Kober,A., Scheck,T., Greher,M., Lieba,F., Fleischhackl,R., Fleischhackl,S., Randunsky,F., and Hoerauf,K. (2002). Prehospital analgesia with acupressure in victims of minor trauma: a prospective, randomized, double-blinded trial. *Anesth.Analg.* 95:723-

2. Golembiewski,J.A. and O'Brien,D. (2002). A systematic approach to the management of postoperative nausea and vomiting. *Journal of PeriAnesthesia Nursing* 17:364-376.
Although this is an extensive review, only three out of 59 references refer to acupoint stimulation and only one of these is included in this evidence review:
Ming,J.L., Kuo,B.I., Lin,J.G., and Lin,L.C. (2002). The efficacy of acupressure to prevent nausea and vomiting in post-operative patients. *J Adv Nurs* 39:343-351

D. Systematic and other reviews where 'acupressure' is included in the MeSH terms of MEDLINE citations

1. Allaire,A.D. (2001). Complementary and alternative medicine in the labor and delivery suite. *Clin Obstet.Gynecol.* 44:681-691.
This is a literature review with a limited methodology. Acupressure is included with acupuncture and related modalities.
Reason for exclusion: Acupressure is described as a form of acupuncture, there are no references to any acupressure studies.

2. Dune,L.S. and Shiao,S.Y. (2006). Metaanalysis of acustimulation effects on postoperative nausea and vomiting in children *Explore (NY)* 2:314-320.
This metaanlysis investigated the effects of a number of acupuncture and acupressure techniques. These included the use of electrodes, lasers, bands and plasters. 12 RCTs were reviewed, five of these referred to acupressure or acupressure in conjunction with acupuncture.
Reason for exclusion: None of the five studies used manual acupressure. The interventions were acuplasters, bands, pressure on Korean points, electrode acupressure.

3. Ernst,E. (1997). Acupuncture/acupressure for weight reduction? A systematic review. *Wien.Klin.Wochenschr.* 109:60-62.
Four clinical trials fulfilled the inclusion criteria for this review. One of these studies used acupressure as the intervention.
Reason for exclusion: Acupressure devices, one in the ear and one on the wrist, were used

4. Fugh-Berman,A., Kronenberg,F. (2003). Complementary and alternative medicine (CAM) in reproductive-age women: a review of randomized controlled trials. *Reproductive Toxicology* 17:137-152.
This systematic review investigated complementary and alternative medicine trials relevant to obstetrics and gynaecology. Ten trials where acupressure was used for nausea and vomiting associated with pregnancy were included.
Reason for exclusion: Nine of these trials used acupressure wrist bands. One trial where acupressure was self applied, dated from 1988 and therefore not considered for inclusion.

5. Keller,V.E. (1995). Management of nausea and vomiting in children. *Journal of Pediatric Nursing* 10:280-286.
This reviewed available pharmacological and nonpharmacological interventions including acupuncture and acupressure.
Reason for exclusion: The use of acupressure bands was mentioned as a possible intervention.

6. Thompson,H.J. (1999). The management of post-operative nausea and vomiting. *J Adv Nurs* 29:1130-1136.
This reviewed pharmacological, dietary and behavioural interventions. Acupressure was considered as a behavioural intervention.
Reason for exclusion: The use of acupressure bands was mentioned as a possible intervention.

7. White,A., Rampes,H., and Campbell,J. (2006). Acupuncture and related interventions for smoking cessation. *Cochrane Database Syst Rev* (1): CD000009.
Acupressure was considered as a related intervention and investigated for its effectiveness for smoking cessation. 24 studies were included in the review, three of these referred to the use of acupressure either alone or in conjunction with acupuncture or electro acupuncture.
Reason for exclusion: Auricular acupressure with seeds was the intervention used in all three studies.

E. Application of substances to acupressure points

All four papers discuss the possible therapeutic effects of applying flower essences and essential oils to acupressure points. These papers may be of general interest but they do not add to the evidence base.

1. Balinski,A.A. (1998). Use of Western Australian flower essences in the management of pain and stress in the hospital setting. *Complementary Therapies in Nursing and Midwifery* 4:111-117.
Abstract: This article explores the use of the unique flora from Western Australia. These wildflower essences are collected from across the state and are made into flower essences. These essences are made in a form similar to homoeopathy. The essences can be given internally, or applied to the external body and acupressure points. Angela and Craig Balinski have used the Western Australian flower essences in their complementary therapy practice where patients are treated for stress and pain management. This programme is currently being utilized at nine of Perth's hospitals. The Western Australian flower essences and their specific application techniques are compatible within the hospital environment because they are safe, produce consistent results, and take little time to apply to the patient. One of the other outstanding features of these essences is that they can be used without any interference to medical procedures. The Western Australian flower essences and the techniques for their use are unique and have, over the last two years, been presented at all of the major nursing conferences in Australia. At present, across Australia there are over 16 hospitals which are currently offering these treatments to their patients

2. Mojay,G. (1998). Aromatic acupressure: The therapeutic application of specific essential oils for the organ meridians and acupressure points of oriental medicine. *International Journal of Aromatherapy* 9:105-114.
No abstract available

3. Mojay,G. (2002). Healing the jade pool--the phyto-aromatic and acupressure treatment of dysmenorrhoea and menopausal syndrome: an East-West approach. *International Journal of Aromatherapy* 12:131-141.
Abstract: Contrary to orthodox scientific medicine, gynaecological therapeutics in traditional Chinese medicine (TCM) is inseparable from the treatment of the woman as a whole—primarily because, from the perspective of TCM, the precise nature of her symptomatology, carefully analyzed and assessed, implicates imbalances that have their root in her energetic-constitutional physiology. Thus, in the language of TCM, it is only by addressing the problem in the 'root' *(Ben)* that one is able to begin healing the manifestation or 'branch' *(Biao).*

While pharmacological drugs, through their refined or synthesized single compound structure, are necessarily designed to address only the branch of a disease, essential oils have a dynamic, complex structure and thus a synergistic activity which is fundamentally in keeping with the body's own functional–biochemical homeostatic intricacy. However, the full potential of the whole-system properties of essential oils can only be achieved through a therapeutic system that can describe and match these, through thorough diagnosis and accurate application, to the true clinical needs of the client-patient.
Through affording such a system, Oriental medicine allows the clinical aromatherapist to approach the treatment of common gynaecological conditions such as dysmenorrhoea and menopausal syndrome with the diagnostic differentiation that a truly individualized natural therapy demands. In such a context, the practitioner's scientific, evidence-based knowledge of essential oil therapeutics need not be disregarded—and indeed is often provided with a broadened significance and a more precise application.
In this paper, Gabriel Mojay draws from his 15 years' experience of treating dysmenorrhoea and menopausal syndrome with the aid of essential oils and aromatic acupressure according to the diagnostic wisdom of Oriental medicine.

4. Mojay,G. (2004). The aromatic and acupressure treatment of common musculoskeletal disorders: an Oriental medicine approach *International Journal of Aromatherapy* 14:81-88.
Abstract: Although research evidence does exist for many of the most common essential oils used in the relief of joint pain, stiffness and inflammation, the purpose of this paper is to outline a terrain-based approach to the aromatic treatment of rheumatic conditions - an approach that is defined by the principles of Oriental medicine. The purpose behind this is not to offer an alternative therapeutic methodology, but one that is complementary to that of science

F. <u>Conference abstracts and posters</u>

These publications have been excluded as they are very brief reports of studies, there are no references and no subsequent publications have been found.

1. Hoffman,T.S., Hu,S., Stritzel,R., and Chandler,A. (1995). P6 acupressure reduces nausea and gastric tachyarrhythmia provoked by optokinetic rotation. *Gastroenterology* 108:A615.
This study, with 64 subjects, investigated the effectiveness of P6 acupressure on reducing nausea induced by viewing an "optokinetic rotating drum". The abstract did not state how acupressure was applied, but as the subjects sat in the drum, it is probable that wristbands were used. From the results, it was concluded that P6 acupressure reduced nausea.

2. Lu,B., Ren,S., Hu,X., and Lichstein,E. (2000). A randomized controlled trial of acupuncture and acupressure treatment for essential hypertension
***American Journal of Hypertension* 13:S185.**
This study, with 12 patients, investigated the effect of acupuncture and self-administered acupressure on high blood pressure. Although not clearly stated, it would appear that auricular acupressure was self administered. The results suggested that the interventions "may be efficacious in decreasing arterial BP in hypertensive patients".

3. Park,Y., Cho,J., Kwon,J., Ahn,E., Lim,J., and Chang,S. (2003). The effect of San-Yin-Jiao (SP-6) acupressure on labor progression. *American Journal of Obstetrics and Gynecology* 189:S209.
This study, with 62 pregnant women, evaluated the effect of acupressure on pain relief, labour time and frequency and intensity of uterine contractions. It was not stated how the acupressure was applied. From the results it was concluded that pain was reduced and "effective and adequate" uterine contractions induced in the group receiving acupressure.

G. <u>Miscellaneous</u>

1. Hoo,J.J. (1997). Acupressure for hyperemesis gravidarum. *Am J Obstet.Gynecol.* 176:1395-1397.
<u>Reason for exclusion:</u> This letter discusses the location of the correct acupoint and refers to a review of 33 controlled trials – Vickers A.J (1996) Can acupuncture have specific effects on health? A systematic review

of acupuncture antiemesis trials. J R Soc Med 89:303-311. This review was not included in the results of any of the Shiatsu searches.

2. Simkin,P. and Bolding,A. (2004). Update on nonpharmacologic approaches to relieve labor pain and prevent suffering *Journal of Midwifery & Women's Health* 49:489-504.
Reason for exclusion: This is an update to previous reviews which found no acupressure trials for labour pain and therefore has no relevance to this review.

3. Youngs,P.J. (2000). Acupressure and prevention of nausea and vomiting. *Br J Anaesth.* 85:807-808.
Reason for exclusion: This is a comment on the drugs used in a study that investigated the use of wristbands.

H. Duplicate publications from Science Direct searches

1. Markose,M.T., Ramanathan,K., and Vijayakumar,J. (2004). Reduction of nausea, vomiting, and dry retches with P6 acupressure during pregnancy *International Journal of Gynecology & Obstetrics* 85:168-169.
Reason for exclusion: This is a duplicate reference from a Science Direct search. The result from the MEDLINE search has been included for review.

2. McDougall G J,J. (2005). Research review: The effect of acupressure with massage on fatigue and depression in patients with end-stage renal disease *Geriatric Nursing* 26:164-165.
Reason for exclusion: This is a duplicate reference from a Science Direct search. The result from the MEDLINE search has been included in the background information section..

3. Murphy,P.A. (1998). Alternative therapies for nausea and vomiting of pregnancy *Obstetrics & Gynecology* 91:149-155.
Reason for exclusion: This is a duplicate reference from a Science Direct search. The result from the MEDLINE search, where the author details appreared as Aikins M.P has been included in the background information section.

I. Publications in German

Foreign language papers were part of the exclusion criteria. It was hoped that the following two papers could be translated and therefore included; however, this was not possible.

1. Litscher,G. (2004). Effects of acupressure, manual acupuncture and Laserneedle acupuncture on EEG bispectral index and spectral edge frequency in healthy volunteers. *Eur J Anaesthesiol.* 21:13-19.
Abstract: BACKGROUND AND OBJECTIVE: The main purpose of this study was to investigate the effects of sensory (acupressure and acupuncture) and optical stimulation (Laserneedle acupuncture) on electroencephalographic bispectral index, spectral edge frequency and a verbal sedation score. METHODS: Twenty-five healthy volunteers (mean age +/- SD: 25.5 +/- 4.0yr) were investigated during the awake state. The acupuncture point Yintang and a placebo control point were stimulated. The study was performed as a randomized, controlled and partly blinded cross-over trial. RESULTS: Bispectral index and spectral edge frequency values both decreased significantly ($P < 0.001$) during acupressure on Yintang to values of 62.9 (minimum 35) +/- 13.9 bispectral index and to 13.3 (minimum 2.9) +/- 8.1 Hz (spectral edge frequency right) and 13.8 (minimum 2.7) +/- 7.3 Hz (spectral edge frequency left), respectively. Bispectral index was also significantly ($P < 0.05$) affected by Laserneedle acupuncture and acupressure on the control point but the changes were not clinically relevant, 95.4 +/- 4 and 94.2 +/- 4.8, respectively. All interventions significantly (Yintang: $P < 0.001$; control point: $P < 0.012$) reduced verbal sedation score.

CONCLUSIONS: The study highlights the electroencephalographic similarities of acupressure induced sedation and general anaesthesia as assessed by bispectral index and spectral edge frequency

2. Schlager,A. (1998). [Acupuncture in prevention of postoperative nausea and vomiting]. *Wien.Med Wochenschr.* 148:454-456.
Abstract: In this review the effectiveness of the acupuncture point Pericard 6 (P 6) on postoperative nausea and vomiting (PONV) is described. Use of the acupuncture, acupressure as well as the laser stimulation of P6 proved as efficient prophylaxis of PONV in numerous studies. These methods are free of side effects and represent therefore a good alternative to the pharmacological prophylaxis and treatment of PONV.

J. Publications from second MeSH term seach
(see Appendix 4 for search details)

1. Matsumura,W.M. (1993). Use of acupressure techniques and concepts for nonsurgical management of TMJ disorders. *J Gen Orthod.* 4:5-16.
There was no abstract available for this publication and it was not possible to obtain a full text copy, it was therefore excluded.

2. Vickers,A.J. (1996). Can acupuncture have specific effects on health? A systematic review of acupuncture antiemesis trials. *J R Soc Med* 89:303-311.
This was referred to in an excluded letter :
Hoo,J.J. (1997). Acupressure for hyperemesis gravidarum. *Am J Obstet.Gynecol.* 176:1395-1397.
It was found to be indexed under 'acupuncture therapy ' and did not appear in any searches, original or those carried out on 24th August as the key words included 'acupuncture'. 34 studies were reviewed, seven of which referred to manual acupressure, three were before 1990, three were excluded from this evidence review and one was subsequently included from the MEDLINE 'acupressure' search of 24th August. (Belluomini,J., Litt,R.C., Lee,K.A., and Katz,M. (1994). Acupressure for nausea and vomiting of pregnancy: a randomized, blinded study. *Obstet Gynecol* 84:245-248.)

Appendix 11 - Background review

Background information on Shiatsu and acupressure

Of the 146 publications that remained for screening and review, 44 were reviewed as evidence and assessed for quality and 61 were excluded from any further assessment. 41 publications were considered useful as background information but did not provide specific evidence on effectiveness of either Shiatsu or acupressure. 22 of these publications referred to Shiatsu and 19 to acupressure. Abstracts, where available are shown below, together with any applicable comments on the publications.

11.1 Shiatsu

Four papers were single case reports of adverse events that occurred following Shiatsu massage.

1. Herskovitz,S., Strauch,B., and Gordon,M.J. (1992). Shiatsu massage-induced injury of the median recurrent motor branch. *Muscle Nerve* 15:1215.
Comment: This letter expressed the concern that the popularity of massage techniques, particularly vigourous ones, may result in this type of injury. The case for concern was that of a 61 year old physician who underwent a professional Shiatsu massage which included ' the application of strong digital pressure in the region of the base of the palm and thenar muscles.' The day after Shiatsu, the recipient noticed 'painless weakness of the left thumb, without sensory symptoms'. Medical examination suggested 'isolated dysfunction of the recurrent thenar motor branch of the median nerve, apparently the result of focal trauma from the massage.' The symptoms improved after three weeks and normalised over the next few months. While it could be considered that that there is no direct evidence that the massage caused the injury, practitioners should be aware of this possible adverse event occurring.

2. Mumm,A.H., Morens,D.M., Elm,J.L., and Diwan,A.R. (1993). Zoster after Shiatsu massage. *Lancet* 341:447.
Comment: This letter referred to a case of varicella zoster virus diagnosed in a 64-year old woman seven days after receiving an 'overly vigorous Shiatsu massage'. The authors speculate that in this case 'zoster resulted from either direct trauma to the nerve or nerve root during the massage, or to subsequent inflammation causing swelling or immunological injury to the nerve'. They also state that varicella zoster virus is rarely diagnosed today, this patient having suffered a previous episode at the age of 11, and that much of the evidence for the existence of this condition is anecdotal. Although a causal link cannot be scientifically proven, this case raises awareness of possible adverse events.

3. Tsuboi,K. (2001). Retinal and cerebral artery embolism after "Shiatsu" on the neck. *Stroke* 32:2441.
Comment: This letter referred to the case of an 80-year old man who had been hospitalised for seven days following a transient ischemic attack. On the evening he was discharged, he received a Shiatsu massage on his neck for 10 minutes and 'immediately after rising, he was aware that the nasal half of his right visual field was impaired.' He was hospitalised for a further seven days and examinations revealed 'diffuse retinal edema with multiple emboli in many branches of the central retinal artery'. Although the author could not find 'any medical reports of cerebral or retinal artery embolisms directly caused by Shiatsu', he stressed that 'complications can be avoided if patients at high risk are properly informed beforehand of the potential association between embolic stroke and manipulation on the neck.'
This letter highlights a potential risk of 'embolic accidents' and 'serious neurological symptoms in patients with atherosclerotic extracranial carotid artery disorders'.

4. Wada,Y., Yanagihara,C., and Nishimura,Y. (2005). Internal jugular vein thrombosis associated with Shiatsu massage of the neck. *J Neurol Neurosurg Psychiatry* 76:142-143.
Comment: This letter suggested, that although possibly coincidental, a causal link between Shiatsu massage and IJV thrombosis 'supported by patient's claim of a massage induced swelling and pain in his neck, and by the temporal relation between the massage and the onset of symptoms that progressed to IJV

and cerebral venous sinus thrombosis'. Although the exact mechanism of the thrombosis in this case could not be determined, the authors state two possibilities. 'One possibility is that direct trauma or pressure may have induced both venous stasis and vascular injury during the Shiatsu massage. The other possibility is that extrinsic compression of the IJV by tissue swelling subsequent to trauma during the Shiatsu massage may have induced venous stasis, resulting in thrombosis at this unusual site'.
The authors refer to the previous case (Tsuboi,K. 2001) as a further incidence of 'vascular complications following Shiatsu massage' and 'would therefore like to draw attention to the possibility that Shiatsu massage of the neck may cause serious neurological complications'.

General information, surveys, uses of Shiatsu

1. Adams,G. (2002). Shiatsu in Britain and Japan: personhood, holism and embodied aesthetics. *Anthropology & Medicine* 9:245-265.
Abstract: In this paper, globalisation processes are examined through the prism of Shiatsu, an originally Japanese, touch-based therapy, now practised in Europe, Japan, North America, and many other places. Examining this emergent plane of therapeutic practice provides an opportunity to reflect on categories of personhood, notably that of the individual, and its place within processes of globalisation. The article is divided into two parts. In the first part the holisms inherent to East Asian medical practice and underlying notions of personhood in Japan and Britain are critically examined. The seemingly reductionistic practice of 'bodily holism' in Japan is shown to reflect socio-centred notions of the person. The concept of holism animating Shiatsu in a British school in London, far from being Japanese, 'ancient', or 'timeless', is shown to reflect individualism characteristic of the New Age movement. In the second part of the paper, using an auto-phenomenological approach, a description of practitioner and client's lived experience of Shiatsu is given in case study form. This illustrates how 'holism' is felt within the context of a Shiatsu treatment. The aesthetic form of the Shiatsu touch described is shown to be implicitly individualising. This has, it is argued, profound implications for understanding the embodied dimensions of practitioner-patient encounters, the potential efficacy of treatment, and more generally the practice of globalised East Asian 'holistic' therapies in Britain and other settings.

2. Cheesman,S., Christian,R., and Cresswell,J. (2001). Exploring the value of Shiatsu in palliative care day services. *Int J Palliat.Nurs* 7:234-239.
Abstract: This qualitative study sought to evaluate the effects of Shiatsu therapy on clients attending hospice day services. Eleven clients with advanced progressive disease received five therapy sessions each at weekly intervals. Data about the effects was collected through five unstructured interviews with each client. Four of these were conducted before, during, and shortly after the therapy regime, and the fifth was undertaken four weeks after treatment ended. All the interviews were tape-recorded, transcribed and subject to content analysis. The results of the analysis revealed significant improvements in energy levels, relaxation, confidence, symptom control, clarity of thought and mobility. These benefits were of variable duration - in some instances lasting a few hours but in others extending beyond the 5-week treatment regime. Action to ensure research trustworthiness included keeping research journals to provide an audit trail, conducting member checks and using peer debriefing. The study involved three overlapping cohorts of participants in a data collection period that took approximately 6 months.
Comment: This is a purely qualitative study with no quantifiable or statistical analysis and therefore cannot be assessed as evidence. It does however, offer an insight into the possible benefits of the use of Shiatsu for palliative care patients.

3. Ferguson,P. (1995). Empowerment through self-healing. Shiatsu for nurses. *Revolution: The Journal of Nurse Empowerment* 1995 Winter; 5:44-46.
Comment: This introduces the practice of Shiatsu to nurses for patients and for themselves.

4. Fujisaki,N. and Fujisaki,M. (2004). The three principles of Shiatsu therapy and their effects. *Shiatsu Society News* 91:10-11.
Comment: This article has been included as requested by the Shiatsu Society UK to provide some background information.

5. Furlan,A.D., Brosseau,L., Imamura,M., and Irvin,E. (2002). Massage for low-back pain [Systematic Review]. *Cochrane Database of Systematic Reviews*.

Abstract: Background:, Low-back pain is one of the most common and costly musculoskeletal problems in modern society. Proponents of massage therapy claim it can minimize pain and disability, and speed return to normal function., Objectives:, To assess the effects of massage therapy for non-specific low-back pain., Search strategy:, We searched Medline, Embase, Cochrane Controlled Trials Register, HealthSTAR, CINAHL and Dissertation abstracts from their beginning to May 2001 with no language restrictions. References in the included studies and in reviews of the literature were screened. Contact with content experts and massage associations was also made., Selection criteria:, The studies had to be randomized or quasi-randomized trials investigating the use of any type of massage (using the hands or a mechanical device) as a treatment for non-specific low-back pain., Data collection and analysis:, Two authors blinded to authors, journal and institutions selected the studies, assessed the methodological quality using the criteria recommended by the Cochrane Back Review Group, and extracted the data using standardised forms. The studies were analysed in a qualitative way due to heterogeneity of population, massage technique, comparison groups, timing and type of outcome measured., Main results:, Nine publications reporting on eight randomized trials were included. Three had low and five had high methodological quality scores. One study was published in German and the rest in English. Massage was compared to an inert treatment (sham laser) in one study that showed that massage was superior, especially if given in combination with exercises and education. In the other seven studies, massage was compared to different active treatments. They showed that massage was inferior to manipulation and TENS; massage was equal to corsets and exercises; and massage was superior to relaxation therapy, acupuncture and self-care education. The beneficial effects of massage in patients with chronic low-back pain lasted at least one year after the end of the treatment. One study comparing two different techniques of massage concluded in favour of acupuncture massage over classic (Swedish) massage., Conclusions:, Massage might be beneficial for patients with subacute and chronic non-specific low-back pain, especially when combined with exercises and education. The evidence suggests that acupuncture massage is more effective than classic massage, but this need confirmation. More studies are needed to confirm these conclusions and to assess the impact of massage on return-to-work, and to measure longer term effects to determine cost-effectiveness of massage as an intervention for low-back pain

Comment: This review referred to a conference abstract for an on going trial from 1998 investigating the 'Effectiveness of back school or Shiatsu massage reflex therapy on chronic low back pain: a prospective randomised controlled blind trial – Mandala 2001' No further publications for this trial have been found.

6. Galantino,M.L., Boothroyd,C., and Lucci,S. (2003). Complementary and alternative medicine interventions for the orthopedic patient: A review of the literature. *Seminars in Integrative Medicine.Vol.1 (2):* 65-79.

Abstract: New branches of established disciplines are continually being developed to help patients with chronic orthopedic ailments. What is thought to be conventional treatment varies between countries and changes over time. Therefore the boundary between complementary and conventional medicine remains blurred and constantly shifting. This article reviews the most frequently used CAM interventions for the orthopedic population and will include the use of massage, acupuncture, herbal medication, nutrition, chiropractic, osteopathy, Shiatsu, prayer/spirituality, visualization, hypnosis, relaxation, biofeedback, and various forms of exercise (e.g., Feldenkrais method, tai chi, and yoga).

Comment: This review includes a two page section on Shiatsu and spinal manipulation as therapies for low back pain and refers to one of the studies that have been reviewed as evidence:

Brady,L.H., Henry,K., Luth,J.F., and Casper-Bruett,K.K. (2001). The effects of Shiatsu on lower back pain. *J Holist Nurs* 19:57-70.

7. Harris,P.E. and Pooley,N. (1998). What do Shiatsu practitioners treat? A nationwide survey. *Complementary Therapies in Medicine*. 6(1):30-35.

Abstract: Objective: The study aimed to survey the illness-conditions presenting for Shiatsu treatment. Design: A nation-wide questionnaire survey was conducted of all qualified Shiatsu practitioners registered with the Shiatsu Society UK. Methods: Client and practitioner questionnaires were piloted during a

preliminary stage. In the main survey, all registered Shiatsu practitioners in the UK (n = 397) were asked to complete structured questionnaires about themselves and three of their clients. Results: in the nation-wide survey 288 practitioners (73%) completed at least one client questionnaire, giving a total of 792 client questionnaires for analysis. It was evident from both the preliminary stage and the main survey that musculoskeletal and psychological problems were the most common conditions presenting for Shiatsu treatment. Conclusion: It was concluded that efficacy research in Shiatsu should focus on musculoskeletal and psychological problems particularly neck/shoulder and lower back problems, arthritis, depression, stress and anxiety
Comment: This survey was funded by the Research Council for Complementary Medicine (RCCM) and supported by the Shiatsu Society UK to ascertain the direction of future research into the efficacy of Shiatsu.

8. Pooley,N. (1998). The pinning down of Shiatsu, or what I learned from my research experience. *Complementary Therapies in Medicine* 6:45-46.
Comment: This provides a background, by one of the authors of the paper on the survey conducted on what Shiatsu practitioners treat (Harris and Pooley 1998).

9. Long,A.F. and Mackay,H.C. (2003). The effects of Shiatsu: findings from a two-country exploratory study. *J Altern Complement Med* 9:539-547.
Abstract: OBJECTIVES: To provide insight into client and practitioner perceptions of the effects of Shiatsu, in the short and longer term, and positive and negative in nature. DESIGN: A two-country, exploratory study was undertaken in the United Kingdom and Germany. In-depth interviews were undertaken with a purposive sample of 14 Shiatsu practitioners and 15 clients. Client interviews focused on the experience of Shiatsu and perceptions of its effects, both positive and negative. Practitioners were also asked about factors that enhanced or inhibited successful treatment. The taped and transcribed data were analyzed using grounded theory, assisted by NVivo (QSR, Markham, Ontario, Canada) software. To enhance generalizability, the findings from the alternative country data set were presented to a further set of practitioners in each country and as a whole to an international meeting of practitioners from seven European countries. RESULTS: There was similarity in the perspectives of the clients and practitioners and participants from the United Kingdom and Germany. Both described a wide range of common, immediate and longer term effects. These included effects on initial symptoms, relaxation, sleeping, posture, and experiences of the body. A category of transitional effect arose, describing an effect that was not particularly positive and did not last long. Practitioners characterized this as being part of the healing response. Only a few negative effects were described by clients. One mentioned a negative physical reaction and two indicated difficulties coping with emotional reactions. While most practitioners conceived negative effects to be possible, these were more likely to be described as negative reactions. CONCLUSION: This exploratory study has shed greater light on the effects of Shiatsu. The sample findings provide a user and practitioner grounded base for the design of appropriate questions for exploration in a larger and more generalizable study of the effects of Shiatsu.
Comment: The full report, which was commissioned by the European Shiatsu Federation, provides more details of the study and its results:
Mackay H, Long AF. (2003) The Experience and Effects of Shiatsu: A Two Country Exploratory Study. Salford: Health Care Practice R&D Unit, University of Salford, Report No. 9, 2003.

10. Long,A.F. (2005). The effects and experiences of Shiatsu: a cross-European study. *Shiatsu Society News* 95:14-15.
Comment: This provides an overview of the above mentioned study.

11. Palanjian,K. (2004). Shiatsu. *Seminars in Integrative Medicine*. 2(3):107-115.
Comment: This provides the history, principles and philosophy, diagnosis, practices, techniques and treatments of Shiatsu. There is also a short section on RCTs that have been recently published, the majority of which refer to acupressure, including the use of acupressure bands.

12. Peace,G. and Manasse,A. (2002). The Cavendish Centre for integrated cancer care: assessment of patients' needs and responses. *Complement Ther Med* 10:33-41.

Abstract: The use of complementary therapies in combination with conventional medicine is increasing. In cancer care, as at the Cavendish Centre for Cancer Care in Sheffield, the range of therapies offered can include aromatherapy, massage, reflexology, Shiatsu, acupuncture, homeopathy, counselling, visualization, hypnotherapy, relaxation, healing and art therapy. Before offering any therapy careful assessment of patients' needs is important as patients seeking complementary therapies may present with unrealistic hopes and expectations of benefit. There are wide variations in provision of services offering complementary cancer care throughout the United Kingdom but few offer a comprehensive assessment which is used as a baseline for both planning treatment and evaluating its outcome and which is conducted by a trained and objective practitioner who has no investment in any specific therapy. We describe the model of care developed at the Cavendish Centre with particular emphasis on the assessment process. Our model of assessment provides an opportunity for patients to tell their story, make sense of the illness experience, construct meaning from it and set realistic expectations for the chosen intervention. It also offers patients involvement and choice in decisions about their care. In addition we present evaluative data from a case series of 157 patients, 138 of whom (88%) reported improvement in their main concern on MYMOP (Measure Your Medical Outcome Profile)
Comment: There is no specific reference to the use of Shiatsu in this particular centre, but this paper provides an example of a model of care for cancer patients.

13. Sommers,E., Porter,K., and DeGurski,S. (2002). Providers of complementary and alternative health services in Boston respond to September 11. *American Journal of Public Health* 92:-1598.
Abstract: Examined the use of complementary and alternative medical (CAM) treatments by those who responded to the September 11, 2001, attacks on the World Trade Center. 47 firefighters, police, emergency medical technicians, and other rescue personnel (aged 6-60 yrs) who responded to the September 11 attack attended clinics and received services from acupuncturists, reiki practitioners, massage therapists, Shiatsu providers, and polarity therapists. Results show that 81 treatments were provided during the clinic sessions. Of these, 51% were acupuncture treatments, 15% were reiki sessions, 12% were Shiatsu, and 9% were massage. 51% of subjects (Ss) received a single treatment, 34% received 2 treatments, and 15% received 3-6 treatments. At least 8 Ss indicated that their treatment was their 1st use of CAM therapy. 12 Ss who received 1+ treatment reported improved relaxation and sleep, reduced pain and stress, and increased energy.
Comment: This describes the evaluation of stress reduction clinics that were set up. Twenty-five CAM practitioners, including one Shiatsu practitioner, provided the treatments.

14. Weintraub, M. I. (1996) Shiatsu massage therapy: a remarkable healing technique in spine pain. Journal of Back and Musculoskeletal Rehabilitation 7(3): 195-197.
Comment: This is the author's discussion and analysis of a study which he conducted in 1992. This study was an open and uncontrolled trial of a medically supervised programme created by the author. This programme consisted of 'Shiatsu, Swedish muscle massage and trigger point suppression (SSMMTPS) as a hands-on attempt to interrupt the pain cycle'. The publication of the study did not appear in any of the search results and a copy could not be obtained from the British Library and therefore could not be reviewed:
Weintraub M.I. (1992) Shiatsu, Swedish Muscle Massage, and Trigger Point Suppression in Spinal Pain Syndrome *American Journal of Pain Management (AJPM)* 2(2), 74-78.

15. White,A. (2002). The case for uncontrolled clinical trials. *Shiatsu Society News* 62:10-13.
Comment: This provides a trial protocol for undertaking uncontrolled trials to establish whether there is a 'clinical effect worth investigating'.

16.Yates,S. (2005). Shiatsu and acupressure in practice. *MIDIRS Midwifery Digest.*
Abstract: An Insight into the Use of Complementary Therapies in Maternity Care supplement. Use of Shiatsu in midwifery practice, including a summary of its benefits for the mother, baby, midwives and maternity units. A case study on setting up a Shiatsu service in the Borders Hospital, Scotland and comments from midwives who have attended Shiatsu courses are included.

Comment: In addition to detailing the process of setting up a service, the author lists a number of benefits of the use of Shiatsu from anecdotal evidence.

Water Shiatsu (Watsu)

Two publications referred to the aquatic use of Shiatsu.

1. Davies,L. (2003). Water and Shiatsu: water therapy and wombs. (Benefits of Watsu, water-based massage, for pregnant women and fetuses. *MIDIRS Midwifery Digest*.
Comment: This personal account provides an introduction into water Shiatsu (Watsu) which was developed in the early 1980s.

2. Vogtle,L.K., Morris,D.M., and Denton,B.G. (1998). An aquatic program for adults with cerebral palsy living in group homes. *Phys Ther Case Rep* 1:250-259.
Comment: This included individual case reports therefore was not included in the review of evidence.
Abstract: Six adults with cerebral palsy participated in aquatic therapy 2 days a week for 7 weeks. Activities included approximately 35 minutes of water Shiatsu (WATSU) using a modified head cradle sequence and approximately 15 minutes of Halliwick method activities focused on head, trunk, and extremity movement control. Activities were conducted by entry level occupational and physical therapy students who were trained in the specific techniques used. Outcome measures included passive range of motion (PROM) of the shoulder, elbow, hip, and knee joints, resting heart rate, blood pressure, pain rating, caretaker reports, and social skill measures. Caretaker reports of ease of care substituted for functional measures owing to clients' limited functional ability and potential for functional improvement. Outcomes suggest that the program was effective for improving PROM, decreasing pain, and providing a pleasureable social experience. Benefits were also realised by the students participating in the swim program, including skill development and appreciation of patients with disability with individuals

11.2 Acupressure

These publications provide further information on acupressure and may inform the direction of future research. Several of them are reviews that refer to the effects of acupressure on nausea and vomiting. The references lists of the reviews were checked to ensure that all acupressure studies had been included in the search results for screening. The majority of these acupressure references were for studies that were published prior to 1990 or included the use of devices such as wristbands.

Reviews of research on acupressure

1. Collins,K.B. and Thomas,D.J. (2004). Acupuncture and acupressure for the management of chemotherapy-induced nausea and vomiting. *J Am Acad Nurse Pract* 16:76-80.
Abstract: PURPOSE: To review existing research, the National Institutes of Health (NIH) consensus statement, and federal regulations regarding the use of acupuncture and acupressure in the management of chemotherapy-induced nausea and vomiting in order to give nurse practitioners (NPs) the information they need to provide the best care for patients undergoing chemotherapy treatment for cancer. DATA SOURCES: Selected scientific literature and Internet sources. CONCLUSIONS: Research supports the effectiveness of acupuncture and acupressure for the treatment of chemotherapy-induced nausea and vomiting. Used in conjunction with current antiemetic drugs, acupuncture and acupressure have been shown to be safe and effective for relief of the nausea and vomiting resulting from chemotherapy. IMPLICATIONS FOR PRACTICE: Even with the best antiemetic pharmacological agents, 60% of cancer patients continue to experience nausea and vomiting when undergoing chemotherapy treatments. Because the NIH supports the use of acupuncture for nausea and vomiting, the NP is obligated to be knowledgeable about the use of these and other effective complementary treatments in order to provide the best care

2. Harris, P.E. (1997). Acupressure: a review of the literature *Complementary Therapies in Medicine* 5:156-161.
Abstract: Acupressure is a means of manipulating the same acupoints that are used in acupuncture, but without the needles. A literature review was conducted in two parts. The first part examines Western research regarding the prophylactic use of single-point acupressure. The second reviews a sample of mainly Chinese clinical research concerning the restorative use of multipoint acupressure. The primary literature search was conducted using the Research Council for Complementary Medicine database (CISCOM). The most convincing finding supporting the effectiveness of acupressure comes from methodologically rigorous studies of the use of PC6 as an antiemetic. A number of studies have shown that PC6 is more effective than placebo in reducing feelings of nausea during pregnancy, after surgery and in cancer chemotherapy. The scientific quality of most of the published studies examining the effectiveness of multipoint acupressure, predominantly auriculotherapy, has been poor, without adequate control groups, randomization, placebos, blinding and statistical analyses. There seems to be a cultural divide between theory and methodological rigour. The scientifically rigorous studies have tended to be atheoretical in selecting the acupoint for treatment and in explaining how the point may work

3. Hickman,A.G., Bell,D.M., and Preston,J.C. (2005). Acupressure and postoperative nausea and vomiting. *AANA.J* 73:379-385.
Abstract: Despite great strides during the preceding 3 decades, the ability to consistently eliminate postoperative nausea and vomiting (PONV) continues to elude anesthesia practitioners. The occurrence of PONV related to anesthesia and surgery prolongs hospital stays and increases healthcare costs. Protracted recovery times place constraints on patients, healthcare systems, and healthcare financiers. Many pharmacological antiemetics have been developed and are in use in the attempt to alleviate PONV. Side effects and cost profiles of many of these interventions, however, reinforce the broadly held belief that there remains opportunity for improvement. Because the Western culture almost exclusively favors evidence-based scientific practice and interventions, the search continues for an ideal, cost-effective, safe, and efficacious pharmacological agent to prevent PONV. Eastern culture, on the other hand, relies heavily on naturopathic remedies whose successful use has spanned thousands of years. Increasing attention has been given to the potential benefits of nonpharmacological intervention for the prevention of PONV in association with anesthesia care. Therefore, the purpose of this AANA Journal course will be to focus attention on what is known and what is unknown in the literature regarding use of the nonallopathic remedy of acupressure as a nonpharmacological alternative to commonly utilized antiemetic prophylaxis

Clinical Evidence reviews

This BMJ resource is a database of evidence for the effects of treatment for numerous conditions. '*Clinical Evidence* summarises the current state of knowledge and uncertainty about the prevention and treatment of clinical conditions, based on thorough searches and appraisal of the literature. It is neither a textbook of medicine nor a set of guidelines. It describes the best available evidence from systematic reviews, RCTs and observational studies where appropriate, and if there is no good evidence it says so.' (http://www.clinicalevidence.com/ceweb/about/index.jsp)

Three reviews included the effect of P6 acupressure, amongst other treatments, for nausea and vomiting. The most up to date review (2004) stated that it is likely to have a beneficial effect:
1. Oates-Whitehead,R. (2004). Nausea and vomiting in early pregnancy. *Clin Evid.*1840-1852.
2. Oates-Whitehead,R. (2003). Nausea and vomiting in early pregnancy. *Clin Evid.*1671-1682.
3. Jewell,D. (2003). Nausea and vomiting in early pregnancy. *Clin Evid.*1561-1570.

Reviews of non pharmacological interventions, including complementary and alternative treatments, for nausea and vomiting

Five reviews, where acupressure was included as an intervention, assessed the available evidence for the treatment of nausea and vomiting.

1. Aikins,M.P. (1998). Alternative therapies for nausea and vomiting of pregnancy. *Obstet.Gynecol.* 91:149-155.
Abstract: OBJECTIVE: To review available evidence about the effectiveness of alternative therapies for nausea and vomiting of pregnancy. DATA SOURCES: MEDLINE and 13 additional US and international data bases were searched in 1996-1997 for papers that described use of alternative medicine in the treatment of pregnancy and pregnancy complications, specifically those addressing nausea, vomiting, and hyperemesis. Bibliographies of retrieved papers were reviewed to identify additional sources. METHODS OF STUDY SELECTION: All relevant English language clinical research papers were reviewed. Randomized clinical trials addressing specifically the use of nonpharmaceutical and nondietary interventions were chosen for detailed review. TABULATION, INTEGRATION, AND RESULTS: Ten randomized trials studying the effects of acupressure, ginger, and pyridoxine on nausea and vomiting of pregnancy were reviewed. Evidence of beneficial effects was found for these three interventions, although the data on acupressure are equivocal. Insufficient evidence was found for the benefits of hypnosis. Other interventions have not been studied. CONCLUSION: There is a dearth of research to support or to refute the efficacy of a number of common remedies for nausea and vomiting of pregnancy. The best-studied alternative remedy is acupressure, which may afford relief to many women; ginger and vitamin B6 also may be beneficial

2. Anderson,F.W.J. and Johnson,C.T. (2005). Complementary and alternative medicine in obstetrics *International Journal of Gynecology & Obstetrics* 91:116-124.
Abstract: Objective: To identify, survey and review randomized controlled studies of the use of complementary and alternative medicine (CAM) for obstetric treatment or health promotion. Methods: The MEDLINE database was searched to identify randomized controlled trials of CAM treatment and therapies in obstetrics. Studies examining modalities for treatment or improvement of health status were reviewed. Results: Fifty-four articles assessing a variety of health modalities met the criteria for inclusion. Acupressure and ginger for prenatal nausea and vomiting, moxibustion for version of breech presentation, sterile water injections for back pain relief in labor, and perineal massage to prevent perineal trauma have three or more studies demonstrating beneficial effect. Other interventions have been studied less, and evidence for them is limited. Conclusions: Some CAM interventions have evidence of effectiveness for use in obstetric patients, while others require further investigation before they can be considered for use in practice

3. King,C.R. (1997). Nonpharmacologic management of chemotherapy-induced nausea and vomiting. *Oncol Nurs Forum* 24:41-48.

Abstract: PURPOSE/OBJECTIVES: To review the nonpharmacologic interventions indicated to prevent or control chemotherapy-induced nausea and vomiting. DATA SOURCES: Journal articles. DATA SYNTHESIS: Despite improvements in antiemetic drug therapy, as many as 60% of patients with cancer who are treated with antineoplastic agents experience nausea and vomiting. Anticipatory nausea and vomiting are thought to be caused by the behavioral process of classical conditioning. Most nonpharmacologic interventions that are used to prevent or control nausea and vomiting in patients with cancer are classified as behavioral interventions. Behavioral interventions involve the acquisition of adaptive behavioral skills to interrupt the conditioning cycle. CONCLUSIONS: Nonpharmacologic interventions appear to be effective in reducing anticipatory and post-treatment nausea and vomiting. IMPLICATIONS FOR NURSING PRACTICE: These behavioral interventions can be effective in reducing anticipatory and post-treatment nausea and vomiting. Oncology nurses must learn these nonpharmacologic techniques and teach their patients to use them in combination with their prescribed antiemetic therapy

4. Lee,A. and Done,M.L. (1999). The use of nonpharmacologic techniques to prevent postoperative nausea and vomiting: a meta-analysis. *Anesth.Analg.* 88:1362-1369.
Abstract: We assessed the efficacy of nonpharmacologic techniques to prevent postoperative nausea and vomiting (PONV) by systematic review. These studies included acupuncture, electroacupuncture, transcutaneous electrical nerve stimulation, acupoint stimulation, and acupressure. Of the 24 randomized trials retrieved by a search of articles indexed on the MEDLINE and EMBASE databases (1980-1997), 19

were eligible for meta-analysis. The primary outcomes were the incidence of nausea, vomiting, or both 0-6 h (early efficacy) or 0-48 h (late efficacy) after surgery. The pooled relative risk (RR) and numbers needed to treat (NNT) were calculated. In children, no benefit was found. Some results in adults were significant. Nonpharmacologic techniques were similar to antiemetics in preventing early vomiting (RR = 0.89 [95% confidence interval 0.47-1.67]; NNT = 63 [10-infinity]) and late vomiting (RR = 0.80 [0.35-1.81]; NNT = 25 [5-infinity]) in adults. Nonpharmacologic techniques were better than placebo at preventing early nausea (RR = 0.34 [0.20-0.58]; NNT = 4 [3-6]) and early vomiting in adults (RR = 0.47 [0.34-0.64]; NNT = 5 [4-8]). Nonpharmacologic techniques were similar to placebo in preventing late vomiting in adults (RR = 0.81 [0.46-1.42]; NNT = 14 [6-infinity]). Using nonpharmacologic techniques, 20%-25% of adults will not have early PONV compared with placebo. It may be an alternative to receiving no treatment or first-line antiemetics. IMPLICATIONS: This systematic review showed that nonpharmacologic techniques were equivalent to commonly used antiemetic drugs in preventing vomiting after surgery. Nonpharmacologic techniques were more effective than placebo in preventing nausea and vomiting within 6 h of surgery in adults, but there was no benefit in children

5. Pan,C.X., Morrison,R.S., Ness,J., Fugh-Berman,A., and Leipzig,R.M. (2000). Complementary and Alternative Medicine in the Management of Pain, Dyspnea, and Nausea and Vomiting Near the End of Life: A Systematic Review *Journal of Pain and Symptom Management* 20:374-387.
Abstract: To review the evidence for efficacy of complementary and alternative medicine (CAM) modalities in treating pain, dyspnea, and nausea and vomiting in patients near the end of life, original articles were evaluated following a search through MEDLINE, CancerLIT, AIDSLINE, PsycLIT, CINAHL, and Social Work Abstracts databases. Search terms included alternative medicine, palliative care, pain, dyspnea, and nausea. Two independent reviewers extracted data, including study design, subjects, sample size, age, response rate, CAM modality, and outcomes. The efficacy of a CAM modality was evaluated in 21 studies of symptomatic adult patients with incurable conditions. Of these, only 12 were directly accessed via literature searching. Eleven were randomized controlled trials, two were non-randomized controlled trials, and eight were case series. Acupuncture, transcutaneous electrical nerve stimulation, supportive group therapy, self-hypnosis, and massage therapy may provide pain relief in cancer pain or in dying patients. Relaxation/imagery can improve oral mucositis pain. Patients with severe chronic obstructive pulmonary disease may benefit from the use of acupuncture, acupressure, and muscle relaxation with breathing retraining to relieve dyspnea. Because of publication bias, trials on CAM modalities may not be found on routine literature searches. Despite the paucity of controlled trials, there are data to support the use of some CAM modalities in terminally ill patients. This review generated evidence-based recommendations and identified areas for future research.

Comments or letters referring to reviewed studies

1. Anon (2006). "Needling" away your (aching) back pain. Acupuncture and acupressure both can provide long-lasting relief for low back pain, new studies, say *Health News* 12:11-12.

2. Frost,H. and Stewart-Brown,S. (2006). Acupressure for low back pain. *BMJ* 332:680-681.

Comment: Both of the above refer to the following study:
Hsieh,L.L., Kuo,C.H., Lee,L.H., Yen,A.M., Chien,K.L., and Chen,T.H. (2006). Treatment of low back pain by acupressure and physical therapy: randomised controlled trial. *BMJ*.
Abstract: OBJECTIVE: To evaluate the effectiveness of acupressure in terms of disability, pain scores, and functional status. DESIGN: Randomised controlled trial. SETTING: Orthopaedic clinic in Kaohsiung, Taiwan. PARTICIPANTS: 129 patients with chronic low back pain. INTERVENTION: Acupressure or physical therapy for one month. MAIN OUTCOME MEASURES: Self administered Chinese versions of standard outcome measures for low back pain (primary outcome: Roland and Morris disability questionnaire) at baseline, after treatment, and at six month follow-up. RESULTS: The mean total Roland and Morris disability questionnaire score after treatment was significantly lower in the acupressure group than in the physical therapy group regardless of the difference in absolute score (-3.8, 95% confidence interval -5.7 to -1.9) or mean change from the baseline (-4.64, -6.39 to -2.89). Acupressure conferred an

89% (95% confidence interval 61% to 97%) reduction in significant disability compared with physical therapy. The improvement in disability score in the acupressure group compared with the physical group remained at six month follow-up. Statistically significant differences also occurred between the two groups for all six domains of the core outcome, pain visual scale, and modified Oswestry disability questionnaire after treatment and at six month follow-up. CONCLUSIONS: Acupressure was effective in reducing low back pain in terms of disability, pain scores, and functional status. The benefit was sustained for six months

3. Brill,J.R. (1995). Acupressure for nausea and vomiting of pregnancy: A randomized, blinded study *Obstetrics & Gynecology* 85:159-160.
This comments on a study that did not appear in the initial searches as the MeSH terms for the publication included 'acupuncture points' and 'acupuncture therapy / methods' not 'acupressure'. A copy was obtained and the study was subsequently reviewed:
Belluomini, J., Litt, R,C,, Lee, K.A., Katz, M. (1994) Acupressure for nausea and vomiting of pregnancy: a randomized, blinded study. *Obstet Gynecol*: 84(2):245-8.
OBJECTIVE: To evaluate the effectiveness of acupressure in reducing nausea and vomiting of pregnancy. METHODS: Symptomatic pregnant women were randomized to one of two acupressure groups: one treatment group using an acupressure point (PC-6) and one sham control group using a placebo point. Subjects were blind to the group assignment. Each evening for 10 consecutive days, the subjects completed an assessment scale describing the severity and frequency of symptoms that occurred. Data from the first 3 days were used as pre-treatment scores. Beginning on the morning of the fourth day, each subject used acupressure at her assigned point for 10 minutes four times a day. Data from day 4 were discarded to allow 24 hours for the treatment to take effect. Data from days 5-7 were used to measure treatment effect. RESULTS: Sixty women completed the study. There were no differences between groups in attrition, parity, fetal number, maternal age, gestational age at entry, or pre-treatment nausea and emesis scores. Analysis of variance indicated that both groups improved significantly over time, but that nausea improved significantly more in the treatment group than in the sham control group ($F_{1,58} = 10.4$, $P = .0021$). There were no differences in the severity or frequency of emesis between the groups. There was a significant positive correlation ($r = 0.261$, $P = .044$) between maternal age and severity of nausea. CONCLUSIONS: Our results indicate that acupressure at the PC-6 anatomical site is effective in reducing symptoms of nausea but not frequency of vomiting in pregnant women.

4. Chernyak,G. (2003). Tender active acupoint is not an ideal control for acupressure study. *Anesth.Analg.* 97:925-926.

5. Usichenko,T.I. and Pavlovic,D. (2003). Suggesting the optimal control procedure for acupressure studies. *Anesth.Analg.* 97:1196-1197.

Comment: Both of the above refer to the following study:
Fassoulaki,A., Paraskeva,A., Patris,K., Pourgiezi,T., and Kostopanagiotou,G. (2003). Pressure applied on the extra 1 acupuncture point reduces bispectral index values and stress in volunteers. *Anesth.Analg.* 96:885-90.
Abstract: We investigated the effect of pressure application on the acupuncture point "extra 1" and on a control point on the bispectral index (BIS) values and on stress in 25 volunteers. In each volunteer, pressure was applied on the extra 1 point for 10 min and on a control point for 5 min on different days and in a randomized manner. The BIS value was recorded before applying pressure on the extra 1 point, during pressure application every 30 s for 10 min, and after pressure release. Regarding the control point, BIS values were recorded for 5 instead of 10 min during pressure application because acupressure on that point was associated with an unpleasant feeling. Each volunteer was asked to score stress before and after pressure application from 0 to 10. The BIS values were significantly reduced 2.5, 5, 7.5, and 10 min during pressure application on the extra 1 point ($P < 0.001$ for each comparison, respectively) and returned to the baseline values after pressure release. Pressure application on the control point decreased BIS values ($P < 0.01$ and $P < 0.05$ at 2.5 and 5 min, respectively). However, these values were maintained close to 90% and were significantly higher than those obtained during pressure on the extra 1 point ($P < 0.001$ and $P < 0.001$ for the 2.5- and 5-min comparisons). The verbal sedation score values obtained after

pressure application on the extra 1 point were also lower when compared with the values obtained after pressure application on the control point (P < 0.001). IMPLICATIONS: This crossover study investigated the effect of pressure application on the acupuncture "extra 1" point in healthy volunteers. Acupressure applied for 10 min on the extra 1 point significantly reduced the BIS values and the verbal stress score when compared with acupressure applied on a control point

6. McDougall,G.J. (2005). Research review: the effect of acupressure with massage on fatigue and depression in patients with end-stage renal disease. *Geriatr.Nurs* 26:164-165.
This refers to the following study:
Cho,Y.C. and Tsay,S.L. (2004). The effect of acupressure with massage on fatigue and depression in patients with end-stage renal disease. *J Nurs Res* 12:51-59.
Abstract: Fatigue and depressive mood are the most significant symptoms experienced by patients with end-stage renal disease. The purpose of this study was to examine the effectiveness of acupressure with massage in fatigue and depression in patients with end-stage renal disease (ESRD) receiving hemodialysis treatment. The study applied an experimental pretest and posttest design. Sixty-two hemodialysis patients participated in the study. Data were collected from two hemodialysis clinics in major hospitals in southern Taiwan. Following consent to the study, subjects were randomly assigned to an acupressure group or a control group. Patients in the acupressure group received acupoint massage for 12 minutes per day, three days per week, for four weeks. Subjects in the control group only received routine unit care. The measures included the Revised Piper Fatigue Scale, and Beck ' s Depression Inventory. Descriptive statistics, chi 2 tests, t-test and analyses of covariance were used for data analysis. The results indicate that subjects experienced a moderate level of fatigue. Nearly 65 % of hemodialysis patients had a depressed mood. ANCOVA results indicated that fatigue (F((1.54)) = 9.05, p =.004) and depression (F((1.54)) = 4.20, p =.045) among patients in the acupressure group showed significantly greater improvement than patients in the control group. The findings of this study provide an interventional model for nurses taking care of ESRD patients

Miscellaneous

1. Ostberg,O., Horie,Y., and Feng,Y. (1992). On the merits of ancient Chinese eye acupressure practices. *Appl Ergon.* 23:343-348.
Abstract: Chinese schoolchildren and adults with strenuous visual tasks routinely perform massage-and-pressure exercises on selected acupressure points around the eyes. This practice, taught by the Jing-Luo school of acupuncture for more than 4000 years, is claimed to prevent and cure myopia and other afflictions thought to result from visual close work. A four-week pilot experiment was carried out with the aim of designing a proper study on the possible short-term benefits of eye acupressure programmes. Questionnaire data revealed that the subjects did experience various eye/vision symptoms as a result of the 90 min experimental task. This could not be verified by the measurements of accommodation precision and critical flicker fusion, nor could any beneficial effects of acupressure be seen over the four experimental weeks
Comment: The aim of this vision exercise programme was to enable the design of a study on the possible short – term benefits of eye acupuncture.

2. Wu,X., Bai,G., Wen,J., and Yang,J. (2005). Evaluation on the therapeutic effects of digital acupoint pressure for obstetric spastic cerebral palsy. *J Tradit.Chin Med* 25:247-251.
Abstract: To probe the evaluation methods for effects of TCM treatment of cerebral palsy through clinical observation on the digital acupoint pressure in treating obstetric spastic cerebral palsy. From 1998-2003, 40 cases of spastic cerebral palsy were treated with digital acupoint pressure therapy. Ten indexes including intelligence, language, salivation, hand-grasping, thumb-adduction, turnover, sitting, standing, walking, and scissors-gait were divided into the 4 grades of normal, mild abnormal, moderate abnormal, and severe abnormal (dysfunction), respectively marked as 6, 4, 2, and 0 point, with 2 points increased for improving each grade of each item after the treatment. Meanwhile, the ranges were recorded and evaluated before and after the treatment on shoulder-abduction, elbow-extension, wrist-extension, forearm-backward-rotation, hip-abduction, straight-leg-lifting, knee-extension, and ankle-dorsiflexion. Those with the improvement of 10 degrees, 15 degrees, 20 degrees, 25 degrees, and 30 degrees in the range of

movement of their contractured joints would obtain respectively 1, 2, 3, 4, and 5 points. There were significant differences before and after the treatment in the 18 items under observation except for intelligence, with obvious improvement shown after the treatment ($P<0.01$), the effective rate being 92.5%. The therapeutic criteria set in this research are well established in reflecting the functional improvements of the patient

Comment: This was an observational study to 'probe the evaluation criteria for the TCM therapeutic effects on cerebral palsy'.

Appendix 12 - Evidence tables references

12.1 Shiatsu

Ballegaard,S., Norrelund,S., and Smith,D.F. (1996). Cost-benefit of combined use of acupuncture, Shiatsu and lifestyle adjustment for treatment of patients with severe angina pectoris. *Acupunct.Electrother.Res* 21:187-197.

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Ingram,J., Domagala,C., and Yates,S. (2005). The effects of Shiatsu on post-term pregnancy. *Complement Ther Med* 13:11-15.

12.2 Acupressure

Agarwal,A., Ranjan,R., Dhiraaj,S., Lakra,A., Kumar,M., and Singh,U. (2005). Acupressure for prevention of pre-operative anxiety: a prospective, randomised, placebo controlled study. *Anaesthesia* 60:978-981.

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Appendix 15 - Results from Index to Theses and ZETOC searches.

None of the results from either of these searches were included for review as they did not meet the inclusion criteria.

Index to Theses

http://www.theses.com/

This website provides a 'comprehensive listing of theses with abstracts accepted for higher degrees by universities in Great Britain and Ireland since 1716.'

Two searches were carried out in February 2006, one for 'Shiatsu' and one for 'acupressure'.
There were two results from both searches and one loan copy was ordered as one thesis referred specifically to Shiatsu. The abstracts as they appear on the website are shown below together with the reasons for exclusion.

15.1 Shiatsu search results

1. Pirie, Z. The impact of delivering Shiatsu in general practice.
2003, G5f
Ph.D., Sheffield, 53-13808
This thesis presents a PhD research study on the integration of a complementary medicine clinic in a general practice. It describes the impact of delivering Shiatsu on an inner-city general practice, its GPs, patients and the Shiatsu practitioner. Practitioner research was conducted utilising a postpositivist, constructivist epistemology and predominantly qualitative methods. These methods were integrated using Cunningham's (1998) Interactive Holistic Research (IHR) which includes action research. The qualitative findings were evaluated with Interpretive Phenomenological Analysis (Smith, 1995) and the quantitative data was assessed with a statistics package for the social services (SPSS).

The main impact of the Shiatsu clinic on the general practice was that GP consultations with referred patients significantly reduced in terms of duration and frequency and involved fewer prescriptions for medication. GPs claimed that the clinic saved practice resources, offered greater options for care, increased their confidence in referrals to Shiatsu, enhanced the reputation of the practice and encouraged a more holistic approach to health.

The referred patients presented a complex mix of chronic physical and psychological/emotional symptoms. After having Shiatsu, they claimed they experienced less pain, digestive disorders, stress, depression, anger and anxiety and more energy, immunity, relaxation and support. A cycle of improvement emerged that suggested how this was partly due to patients reassessing their health and adopting new behaviours to prevent and treat symptoms.

In this study, the researcher was both the researcher and the complementary practitioner. The main impact of the Shiatsu clinic on was on the role as practitioner and the challenge of working with a new patient group in a new setting and receiving detailed evaluation from the patients and GPs.
Reason for exclusion:
A loan copy of this thesis was obtained form the University of Sheffield for review. This was a predominantly qualitative research project with a sample of 10 patients who presented with a variety of health problems. Apart from a published abstract from a presentation at the 7th Annual Symposium on Complementary Health Care 7th–9th December 2000, Exeter, UK, which is shown below, no further publications were found for this author:

***Focus Altern Complement Ther* 2001; 6: 89**
Delivering Shiatsu in general practice

Pirie Z
Institute of General Practice and Primary Care, ScHARR, The University of Sheffield, Northern General Hospital, Sheffield, S5 7AU, UK
Objective
To assess the impact of delivering a Shiatsu clinic in an inner-city general practice.
Materials and methods
The impact of a Shiatsu clinic was measured by: analysing recruitment of patients (*n* = 10) via referral from four GPs; comparing GP and patient perceptions of patients' health; measuring changes in patients' health; length/content of consultations with their GPs; and the experiences and satisfaction of all involved. Qualitative data came from 30 semi-structured interviews with patients, six interviews with the GPs and the CPs' reflective journal. Quantitative data was gathered from two validated health questionnaires, the MYMOP and SF-12.
Results
Ten female patients aged between 27 and 63 years attended the Shiatsu clinic, receiving a total of 56 treatments. The most common symptom was clinical depression, reported by five (50%) of the 10 patients. Muscular pain and digestive symptoms were also common, and symptoms were mainly chronic, persisting over 10 years. However, during the study, patients and GPs reported many changes in these potentially very resistant symptoms and an improvement in health and well-being, including a dramatic reduction in medication and consultations.
Conclusion
Complementary medicine can be delivered effectively in general practice, increasing its equity of access to a range of patients in primary care. Several positive benefits can be associated with receiving Shiatsu and further research on clinical and cost effectiveness is warranted.

2. Burrows, R. Holistic approaches to health and well-being in Northern Ireland.
1993, B4
Ph.D., Queen's University Belfast, 45-3572
The thesis is an anthropological study of holistic approaches to health and well-being in Northern Ireland, which places these 'alternative' therapies within a wider new age movement. Definitions of holistic approaches to health-care are examined and a critique of conventional medicine is offered from a holistic perspective. Theories of social movements are analyzed and the new age movement is represented as an innovative form of the production of knowledge, with specific attention given to holistic practitioners and new age leaders who operate as 'movement intellectuals'. Central metaphors within the movement are identified and discussed, principally, 'nature', 'emotion', and 'the body'.
The researcher used participant observation to provide an in-depth analysis of specific therapies, including Shiatsu, aromatherapy, tai chi, and gestalt psychotherapy. As well as identifying the commonalities and divergences within movement discourses, the thesis seeks to contextualize what can be seen as a transcultural movement within a local, Northern Irish framework. New age communities and spirituality are understood as an aspect of a broad holistic movement which attempts to transform the world by transforming the self.
Reason for exclusion: Shiatsu was not the main subject area

15.2 Acupressure search results

1. Dent, H.E. Development of a research base and management position protocol for the use of nurses caring for patients with nausea and vomiting following acute myocardial infarction
1999, G5f
Ph.D., Exeter, 49-6544
To develop a knowledge base and management protocol for the use of nurses caring for patients experiencing nausea and/or vomiting occurring after acute myocardial infarction.
Study 1, an observational study with data collected on admission and at two hourly intervals for 24 hours, to determine: 1) Incidence of post-myocardial infarction nausea and/or vomiting occurring after commencement of medical treatment (PMINV), 2) Severity of PMINV measured by the number of episodes

and a severity score, 3) Association of PMINV with site, size and thickness of infarction, previous infarction, left ventricular failure, opiate administration, thrombolysis/reperfusion, cardiac pain, autonomic disturbances, age and gender, 4) Effectiveness of antiemetic treatment, and whether some PMINV is severe, persistent and intractable to treatment, 5) Whether the results of previous studies into the incidence of, and factors associated with, nausea and/or vomiting at onset of infarction prior to commencement of medical treatment could be confirmed.
The incidence of nausea and/or vomiting at onset of infarction was not associated with site, size or thickness of infarction, previous myocardial infarction, gender, age, or autonomic disturbance. These results dispute the results of previous studies which have suggested variously that nausea and vomiting were associated with inferior, transmural and large infarctions, and vagal over-excitation. The results of studies which indicated the symptoms were not associated with site of infarction were confirmed.
Study 2 was a partially randomised, placebo-controlled clinical trial, carried out concomitantly with the observational study, to determine whether P6 acupressure, applied continuously by wristband to both wrists, was effective as an adjunct to standard antiemetic therapy during the 24 hours after admission to the coronary care unit.
P6 acupressure reduced the incidence ($p < 0.05$) but not severity of PMINV compared with placebo during the latter 20 hours of treatment, but no benefit was demonstrated during the first four hours.
Reason for exclusion: Acupressure bands were used in this research project.

2. Yang, J. Cancer chemotherapy and anti-emetics
1989, G5c
M.Med.Sci., Queen's University Belfast, 40-4058
In recent years significant advances have been made in the treatment of malignant disease with cytotoxic drugs, but nausea and vomiting remains a severe side effect of many regimens. In a 204 patient survey, looking at which factors predisposed to chemotherapy sickness, women were more prone than men. Women who have post-operative sickness were particularly prone with moderately emetic drugs. Men who suffer from travel sickness are more prone to chemotherapy sickness than those who do not. Fear of the effects of chemotherapy predisposes to sickness, as does expectation of sickness. This research explored the clinical use of antiemetic drugs and acupunture at p6 point or other means of stimulating p6. Using up to data methodology it involved the following: (1) Assessing the efficacy of invasive and non-invasive methods. (2) Prolonging the effect of p6 acupuncture by acupressure. (3) Comparing the efficacy of small and large electrodes. P6 acupuncture is an effective adjuvant to conventional antiemetic therapy for patients having cytotoxic drugs. Its efficacy is limited to about 8 hours, but the benefit can be prolonged by use of a Sea Band, pressed for 5 minutes every two hours. Best results are obtained with invasive acupuncture. Surface electrodes are not good as needing but are still very effective. The larger size is slightly better than the smaller one. Acupressure by Sea Bands is not very effective as a primary treatment in these patients. P6 acupuncture has no side effects.
Reason for exclusion: This research was conducted prior to 1990 and acupressure bands were used.

15.3 ZETOC (British Library Electronic Table of Contents) search

'Zetoc provides access to the British Library's Electronic Table of Contents of around 20,000 current journals and around 16,000 conference proceedings published per year. The database covers 1993 to date, and is updated on a daily basis. It includes an email alerting service, to enable you to keep up-to-date with relevant new articles and papers.
Zetoc is free to use for members of JISC-sponsored UK higher and further education institutions. It is also available to NHS Scotland and Northern Ireland.'

It is not clear what the level of access is for the general public or non academic institutions. The database can be accessed at:

http://zetoc.mimas.ac.uk/

Two searches, one for Shiatsu and one for acupressure, were carried out in April 2006, both searches included conference proceedings. It was not possible to download references to Reference Manager®, copies of results were available via email from the site.

There were 57 results for Shiatsu and 220 for acupressure. There were a number of duplicates within the searches where the same result appeared twice with different identification numbers. In the acupressure search there were 45 results from 'Townsend Letter for Doctors and Patients', an online forum for complementary and alternative medicine, which referred to G-Jo acupressure 'a westernized version of the so-called "ah-shi" or "tender point" style of acupuncture without needles (acupressure)'. http://www.g-jo.com/faq.html

There were no abstracts available for a preliminary screening. All of the acupressure results were excluded according to the exclusion criteria. Copies of two publications from the Shiatsu results were obtained for further screening. These were collections of posters from a conference held in Japan in 2002 and therefore were not included for review.

Akira Fukuoka, Eriko Ueda, Hiroshi Fukuoka & Yuko Koyama (2002)
Comparison of the effectiveness that Shiatsu massage of cervico brachial area has on psychosomatic relaxation where Qi is applied and where it is not.
Journal of international Society of Life information Science: 20 (2) S 400 - 405.

Eriko Ueda, Hiroshi Fukuoka, Yuko Koyama & Akira Fukuoka (2002)
Usefulness of Shiatsu massage on cervico-brachial area and Transcutaneous Electrical Acupunkture-point Stimulation (TEAS) in dental treatment.
Journal of International Society of Life Information Science: 20 (2) S. 412 – 416

" The heart of shiatsu is like a mother' s love"
"Pressing the human body stimulates the fountains of life".

Tokujiro Namikoshi