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Acupuncture for overweight or obese people (Protocol)

Li J, Lu Y, Shi YM, Lenon G, Shi Y

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http://www.thecochranelibrary.com

Acupuncture for overweight or obese people (Protocol)
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Acupuncture for overweight or obese people

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Editorial group: Cochrane Metabolic and Endocrine Disorders Group.


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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To assess the effects of acupuncture for overweight or obese people.
**BACKGROUND**

**Description of the condition**

Overweight and obesity are defined as abnormal or excessive fat accumulation that presents a risk to health (WHO 2010). The fundamental cause of obesity and overweight is an energy imbalance between calories consumed and calories expended. Global increases in overweight and obesity are attributable to a number of factors including: a global shift in diet towards increased intake of energy-dense foods that are high in fat and sugars and a trend towards decreased physical activity due to the increasingly sedentary nature of many forms of work, changing modes of transportation, and increasing urbanization. The WHO recommends using the body mass index (BMI), which is defined as the weight in kilograms divided by the square of the height in meters (kg/m²), to assess the level of overweight and obesity. At present, the WHO defines overweight as a BMI equal to or more than 25, and obesity as a BMI equal to or more than 30. The range of 18.50 to 24.99 is considered as normal. For Asia-Pacific region, the WHO recommend different ranges (WHO 2000). BMI cut-points provide a benchmark for individual assessment, but must be regarded as a rough guide for adults (WHO 2006). The BMI criteria used for children and teens are different from those used for adults. In addition to the BMI, there are other measurements, such as waist circumference and waist-to-hip ratio (WHR), in identifying individuals at increased risk from obesity-related illness.

The problem of overweight and obesity was labelled as a global epidemic in the World Health Organization (WHO) report ten years ago. Evidence is now emerging to suggest that the prevalence of the global epidemic - “globesity” - is increasing at an alarming rate in both high-income and middle- and low-income countries (WHO 2010).

In the European region, prevalence has tripled in many countries since the 1980s (WHO 2008). The African region has seen an alarming increase since the early 1990s (WHO 2010). Prevalence of obesity in the Western Pacific region is well above 20% in most communities (WHO 2002). In the USA, Colorado is the only state having a prevalence less than 20% in 2008 while 32 states had a prevalence equal to or greater than 25% (CDC 2009a). In the South-East Asia region, data suggest that obesity is growing rapidly in affluent urban populations (WHO 2004). WHO further projects that by 2015, approximately 2.3 billion adults will be overweight and more than 700 million will be obese (WHO 2006).

This is not only happening in the adult population but also in children and adolescents. According to the latest estimates from the International Obesity Task Force (IOTF), at least 155 million school-age children worldwide are overweight. Around 30 to 45 million within that population are classified as obese - accounting for 2% to 3% of the world’s children aged 5 to 17. A further 22 million children are also affected according to previous IOTF global estimates based on WHO data for under five years of age (IOTF 2002). More than 75% of overweight and obese children live in low- and middle-income countries (WHO 2010).

Obesity has physical, psychological, and social consequences in adults and children (CDC 2009b). It increases risk of premature death and debilitating complaints which have an adverse effect on quality of life. It is also a major risk factor for non communicable diseases (NCDs) such as non-insulin-dependent diabetes mellitus (NIDDM), cardiovascular diseases (CVD) and cancer (WHO 2004). It may also result in many psychological disorders. Besides, overweight and obesity and their associated health problems lead to economic burdens to many societies. Obesity has already accounted for 2% to 8% of health costs in several parts of the European region (WHO 2008); the medical costs of obesity reached an estimated $147 billion (123 billion EUR, June 2010 estimate) in the U.S in 2008 (CDC 2009c).

Effective weight management is an important goal for every overweight and obese person. Presently, treatments for obesity suggested by the WHO are dietary management, physical activity, behavior modification, pharmacological treatment, surgery, traditional medicine and other treatments. Dietary restriction is the most conventional way for managing weight; adding physical activity and exercise to diet is more effective than either method alone in promoting fat loss; behavior treatment is regarded as an essential component of any adequate obesity-treatment program. But all these three treatments have a common limitation, that is showing short term effects only. The concept of long-term drug treatment has emerged as an adjunct to other weight-loss therapies and as a way of helping to maintain body weight over time, however, its long-term use has raised safety concerns in recent years. Weight management drugs do not cure obesity, so weight regain is expected when medication is discontinued. Furthermore, drugs for weight management have not yet been recommended for routine use but should be used under medical supervision. Bariatric surgery is considered to be the most effective way of reducing weight and may result in a sustained weight loss (WHO 2004). However, serious complications can occur, so patients should be selected carefully (Marielle 2008).

Currently, there is an increasing number of people who turn to complementary and alternative medicine (CAM). Although the use of acupuncture in the treatment of obesity is relatively new, it has become one of the most widely used therapies (Cho 2009).

**Description of the intervention**

Acupuncture originated in China thousands of years ago, constituting an integral part of Traditional Chinese Medicine (TCM). TCM, a traditional medical system, represents the wisdom of the Chinese people as well as a great treasure house of China. Its profound effect appears irreplaceable in maintaining good health of the Chinese. TCM holds a unique view of the world and the human body which is different from western medicine concepts. It has the ‘concept of holism’ and ‘treatment according to syndrome
Differentiation’. From the viewpoint of TCM, a sound body is considered as a delicate balance between the two opposing, complementary and inseparable forces, Yin and Yang. The concept of Yin and Yang is rooted in the ancient Chinese philosophy: Yin represents cold, slow, weak, dark, or passive aspects, while Yang represents hot, excited, strong, bright, or active aspects. A major theory is that health is achieved by maintaining a balance of Yin and Yang and disease is caused by an imbalance of Yin and Yang (NCCAM 2009). TCM practitioners make a comprehensive analysis of a patient’s condition by using four diagnostic methods: observing, hearing and smelling, asking and interviewing, and touching and palpating as well as applying individual or combined therapies. As a part of TCM, acupuncture has been practiced in China for more than 5000 years and gained popularity among Chinese people. Over the last few decades, its popularity has grown significantly in the world, spreading first throughout Asia and later to Europe and the Americas. After thousands of years improving and developing, today’s acupuncture techniques are quite different from ancient times. The term ‘acupuncture’, in modern times, describes the practice of stimulating the specific points on the human body by penetrating the skin with thin, solid, metallic needles that are manipulated by the hands, electrical stimulation and so on.

Adverse effects of the intervention
Acupuncture used for treating overweight and obesity is associated with local pain, inflammation, or occasional infection (Lacey 2003). Relatively few complications have been reported from the use of acupuncture in general (NCCAM 2009). However, adverse effects of using acupuncture need to be assessed systematically.

How the intervention might work
Up to now, the mechanism of acupuncture has not been clearly explained. According to Western medicine, the effects of acupuncture are probably the result of stimulating the nervous system to release chemicals which may in turn release other neurotransmitters or hormones producing the desired effects. This theory is supported by the basic research work which has shown acupuncture’s effect on adrenocorticotropin (ACTH), insulin, thyroid hormones, growth stimulating hormone, beta-endorphin, white blood cell production and plasma cholesterol levels. It is also believed that acupuncture may work on an electromagnetic bio-information system (AMFI 2007).

In TCM, acupuncture regulates the balance of Yin and Yang, remove blockages of Qi (vital force) and Blood as well as dredge the meridian to restore and maintain the healthy condition. Being different from the common western understandings, Qi and Blood are the fundamental substances that maintain the life activities of the human body. The meridian system is a distribution network for Qi and Blood, linking different areas of the body together and making the body an organic whole. Its pathways make up a comprehensive yet complex body map that supplies vital energy to every part of the body. Acupoints are the specific sites through which the Qi of the internal organs and meridians is transported to the body surface. They are classified into three categories: acupoints of the fourteen meridians, extraordinary points and Ashi points. Distributed on their related meridian pathways, acupoints are closely linked with the meridians. So acupoints should not be regarded as superficial points alone, but as special sites which connect with each other, and through which the internal tissues and organs are related (Li 1999). Using acupuncture to restore and maintain the internal balance of body is accomplished by acupoint prescription and acupuncture manipulation.

Why it is important to do this review
Due to the high prevalence of obesity worldwide and increasing popularity of acupuncture, this review aims to assess the effects of acupuncture for overweight or obese people. Acupuncture appears to be effective, safe and convenient in overweight or obese patients, but scientific evidence of its efficacy and safety is still lacking. Lacey et al evaluated descriptive and controlled trials of acupuncture for enhancing weight loss (Lacey 2003). This publication provided a brief overview of the methods and mechanisms of acupuncture, a summary of descriptive and controlled studies of acupuncture in the treatment of obesity and an agenda for future research. Pittler et al aimed to assess the evidence from RCTs and systematic reviews of complementary therapies for reducing body weight (Pittler 2005). The evidence related to acupuncture and acupressure (one systematic review and three RCTs) were also included and reviewed. The authors found that acupuncture or acupressure for reducing body weight was not convincing. Currently, there are three systematic reviews and meta-analyses of the evidence on the effects of acupuncture for overweight or obese people (Cho 2009; Lin 2009; Yu 2010):
The aim of the first systematic review by Cho et al was to assess the effects on body weight reduction after acupuncture and to evaluate adverse events of this therapy based on the results of RCTs that evaluated various types of acupuncture therapies (Cho 2009). It suggested that acupuncture is an effective treatment for obesity. However, the amount of evidence was not fully convincing because of the poor methodological quality of trials reviewed.

The aim of the second systematic review was to evaluate the effects of acupuncture for treating obesity and to analyze the current situation of clinical studies (Lin 2009). The review concluded that besides reasonable diet and exercise, acupuncture was safe and effective for treating obesity. It may be more effective than pharmacological treatment. Because the quantity of literature was limited and the quality of some publications was low, more high-quality and large-scale RCTs are needed.

The aim of the third systematic review was to investigate the effects of acupuncture in treating obesity (Yu 2010). Results suggested that acupuncture may have certain advantages over routine medical treatment. As the quality of some studies was low, definite conclusions could not be obtained.

However, the previous systematic reviews have some limitations. For example, firstly, search strategies have not been documented clearly and most of the search strategies were not conducted up-to-date, therefore it is possible that relevant studies were overlooked and recent trials were not included. Secondly, the methodological quality of reviews appeared not to be rigorously controlled by a methodology panel and editorial team. Moreover, these publications can not be updated easily and reviewers can not change or adapt searches, methods, outcomes, conclusions and so on.

O B J E C T I V E S
To assess the effects of acupuncture for overweight or obese people.

M E T H O D S

Criteria for considering studies for this review

Types of studies
Randomized controlled trials, quasi-randomized trials and controlled clinical trials.

Types of participants
Male or female patients of any age or ethnic origin who are overweight or obese will be eligible. The diagnosis of overweight and obese should preferably be consistent with the WHO definition. However, Studies used other general accepted standard will be also included.

Diagnostic criteria
The WHO defines overweight in adult Europeans as a body mass index (BMI) equal to or more than 25 (kg/m²), and obesity as a BMI equal to or more than 30; in Asians, overweight is defined as a BMI equal to or more than 23 and obesity as a BMI equal to or more than 25.

Diagnostic criteria will be potentially subjected to a sensitivity analysis.

Types of interventions

Intervention
Acupuncture. Acupuncture involves the act of needle insertion, although there are many other non-invasive techniques for acupuncture point stimulation. Points may be selected according to traditional medical systems, symptoms, point selection based on the scientific relationships of point function and point prescription. Methods of stimulating acupoints which are quite different from traditional acupuncture, such as laser acupuncture and surface electrodes, will be excluded.

Control
No intervention, placebo acupuncture, sham acupuncture, pharmacological treatments, or other non-acupuncture interventions. Trials comparing acupuncture plus non-acupuncture treatment with the same non-acupuncture treatment will be also included. Trials that only compare different forms of acupuncture or different acupoints will be excluded.

Types of outcome measures

Primary outcomes
- measures of weight or obesity, fat content or fat distribution (such as kg, body mass index, waist-to-hip ratio and fat free mass);
- morbidity (such as hypertension, coronary heart disease, diabetes mellitus and insulin resistance).

Secondary outcomes
- change in risk factors (such as blood pressure, lipid profile and glycosylated haemoglobin A1c (HbA1c));
- recurrence rate;
- adverse effects (such as local pain, inflammation and infection);
• physical activity;
• quality of life measures;
• costs.

Possible covariates, effect modifiers and confounders
• compliance with the treatment;
• co-morbidities such as cancer, diabetes mellitus and respiratory disease that may cause weight loss or increase.

Timing of outcome measurement
• short-term: more than two weeks to twelve weeks;
• medium-term: more than twelve weeks to six months;
• long-term: more than six months.

Search methods for identification of studies

Electronic searches
We will use the following sources for the identification of trials:
• The Cochrane Library (until recent);
• MEDLINE (until recent);
• EMBASE (until recent);
• AMED (until recent);
• CBM (Chinese Biomedical Medicine Database) (until recent);
• CNKI (China National Knowledge Infrastructure) (until recent);
• VIP (VIP Database for Chinese Technical Periodicals) (until recent);
• Digital Journal of Wanfang Data (until recent).

We will also search databases of ongoing trials: 'Current Controlled Trials' (www.controlled-trials.com - with links to other databases of ongoing trials).
For detailed search strategies see under Appendix 1.
Additional key words of relevance may be detected during any of the electronic or other searches. If this is the case, electronic search strategies will be modified to incorporate these terms. Studies published in any language will be included.
Publications not in English or Chinese will be translated with the help of the Cochrane Metabolic and Endocrine Disorders Group.

Data collection and analysis

Selection of studies
To determine the studies to be assessed further, two authors (YL, GL) will independently scan the abstract, title or both sections of every record retrieved. All potentially relevant articles will be investigated as full text. Interrater agreement for selection of potentially relevant studies will be measured using the kappa statistic (Cohen 1960). Differences will be marked and if these studies are later on included, the influence of the primary choice will be subjected to a sensitivity analysis. Where differences in opinion exist, they will be resolved by a third party. If resolving disagreement is not possible, the article will be added to those 'awaiting assessment' and authors will be contacted for clarification. We will attach an adapted PRISMA (preferred reporting items for systematic reviews and meta-analyses) flow-chart of study selection (Liberati 2009).

Data extraction and management
For studies that fulfil inclusion criteria, two authors (YL, GL) will independently abstract relevant population and intervention characteristics using standard data extraction templates (for details see ‘Characteristics of included studies, Table 1, Appendix 2, Appendix 3, Appendix 4, Appendix 5) with any disagreements to be resolved by discussion, or if required by a third party. Any relevant missing information on the trial will be sought from the original author(s) of the article, if required.
Interventions will be reported according to the standards for reporting clinical trials of acupuncture (STRICTA) (STRICTA 2010).

Dealing with duplicate publications
In the case of duplicate publications and companion papers of a primary study, we will try to maximise yield of information by simultaneous evaluation of all available data. In cases of doubt, the original publication (usually the oldest version) will obtain priority.

Assessment of risk of bias in included studies
Two authors (YL, GL) will assess each trial independently. Possible disagreements will be resolved by consensus, or with consultation of a third party. Interrater agreement for key bias indicators (e.g. allocation concealment, incomplete outcome data) will be calculated using the kappa statistic (Cohen 1960). In cases of disagreement, the rest of the group will be consulted and a judgement will be made based on consensus.
We will assess risk of bias using the Cochrane Collaboration’s tool (Higgins 2009). We will use the following criteria:
• was the allocation sequence adequately generated?
• was the allocation adequately concealed?
• was knowledge of the allocated intervention adequately prevented during the study?
• were incomplete outcome data adequately addressed?
• were reports of the study free of suggestion of selective outcome reporting?
• was the study apparently free of other problems that could put it at a high risk of bias?

A judgement of ‘Yes’ indicates low risk of bias, ‘No’ indicates high risk of bias and ‘Unclear’ indicates unclear or unknown risk of bias. We will use these criteria for a judgement of ‘Yes’, ‘No’ and ‘Unclear’ for individual bias items as described in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2009). A ‘risk of bias graph’ figure and ‘risk of bias summary’ figure will be attached.

We will assess the impact of individual bias domains on study results at endpoint and study levels.

**Measures of treatment effect**

Dichotomous data will be expressed as odds ratio (OR) or risk ratio (RR) with 95% confidence intervals (CI). Continuous data will be expressed as weighted differences in means (WMD) with 95% CI.

**Unit of analysis issues**

We will take into account the level at which randomisation occurred, such as cross-over trials, cluster-randomised trials and multiple observations for the same outcome.

**Dealing with missing data**

We will obtain relevant missing data from authors, if feasible and carefully perform evaluation of important numerical data such as screened, randomised patients as well as intention-to-treat (ITT), as-treated and per-protocol (PP) populations. We will investigate attrition rates, for example drop-outs, losses to follow up and withdrawals and critically appraise issues of missing data and imputation methods (for example last-observation-carried-forward (LOCF)).

**Assessment of heterogeneity**

In the event of substantial clinical or methodological or statistical heterogeneity we will not report study results as meta-analytically pooled effect estimates. We will identify heterogeneity by visual inspection of the forest plots and by using a standard Chi² test with a significance level of $\alpha = 0.1$, in view of the low power of this test. We specifically will examine heterogeneity employing the $I^2$ statistic which quantifies inconsistency across studies to assess the impact of heterogeneity on the meta-analysis (Higgins 2002; Higgins 2003), where an $I^2$ statistic of 75% and more indicates a considerable level of inconsistency (Higgins 2009). When heterogeneity is found, we will attempt to determine potential reasons for it by examining individual study and subgroup characteristics.

**Assessment of reporting biases**

Funnel plots will be used to assess for the potential existence of small study bias. There are a number of explanations for the asymmetry of a funnel plot (Sterne 2001). Therefore, we will carefully interpret results (Lau 2006).

**Data synthesis**

Data will be summarised statistically if they are available, sufficiently similar and of sufficient quality. We will perform statistical analyses according to the statistical guidelines referenced in the newest version of the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2009).

**Subgroup analysis and investigation of heterogeneity**

We will mainly carry out subgroup analyses if one of the primary outcome parameters demonstrates statistically significant differences between intervention groups. In any other case subgroup analyses will be clearly marked as a hypothesis generating exercise.

The following subgroup analyses are planned:

- degree of overweight or obesity (depending on data);
- age (depending on data);
- gender.

**Sensitivity analysis**

We will perform sensitivity analyses in order to explore the influence of the following factors on effect size:

- repeating the analysis excluding unpublished studies;
- repeating the analysis taking account risk of bias, as specified above;
- repeating the analysis excluding very long or large studies to establish how much they dominate the results;
- repeating the analysis excluding studies using the following filters: diagnostic criteria, language of publication, source of funding (industry versus other), country.

We will also test the robustness of the results by repeating the analysis using different measures of effect size (relative risk, odds ratio etc.) and different statistical models (fixed-effect and random-effects models).
Additional references

AMFI 2007

CDC 2009a

CDC 2009b

CDC 2009c

Cho 2009

Cohen 1960

Higgins 2002

Higgins 2003

Higgins 2009

IOTF 2002

Lacey 2003

Lau 2006


### ADDITIONAL TABLES

Table 1. Overview of study populations

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Table 1. Overview of study populations  (Continued)

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C: control; I: intervention; ITT: intention-to-treat
### Appendix 1. Search strategies

**Search terms**

Unless otherwise stated, search terms are free text terms; MeSH = Medical subject heading (MEDLINE medical index term); exp = exploded MeSH; the dollar sign ($) stands for any character(s); the question mark (?) substitutes one or no characters; tw = text word; pt = publication type; sh = MeSH; adj = adjacent

#### The Cochrane Library

1. MeSH descriptor Obesity explode all trees
2. MeSH descriptor Weight Gain explode all trees
3. MeSH descriptor Weight Loss explode all trees
4. MeSH descriptor Body Mass Index explode all trees
5. (overweight in All Text or (over in All Text and weight in All Text) )
6. (adipos* in All Text or (fat in All Text and overload in All Text and syndrom* in All Text)
7. (overeat* in All Text or (over in All Text and eat* in All Text) )
8. (overfeed* in All Text or (over in All Text and feed* in All Text) )
9. (weight in All Text and (cycl* in All Text or reduc* in All Text or los* in All Text or maint* in All Text or (decreas*or in All Text and watch* in All Text) or control* in All Text) )
10. (weight in All Text and (gain in All Text or chang* in All Text) )
11. (body in All Text and mass in All Text and ind* in All Text)
12. MeSH descriptor Skinfold thickness explode all trees
13. MeSH descriptor Waist-Hip Ratio explode all trees
14. MeSH descriptor Abdominal fat explode all trees
15. MeSH descriptor Overweight explode all trees
16. (adipos* in All Text or obes* in All Text)
17. (waist-hip in All Text and ratio* in All Text)
18. ( (skinfold in All Text and thickness* in All Text) or (abdominal in All Text and fat* in All Text)
19. (#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18)
20. MeSH descriptor Acupuncture explode all trees
21. MeSH descriptor Acupuncture therapy explode all trees
22. MeSH descriptor Acupressure explode all trees
23. (acupuncture in All Text or acupressure in All Text or acupoint in All Text)
24. MeSH descriptor Electroacupuncture explode all trees
25. (electro-acupuncture in All Text or electroacupuncture in All Text)
26. (#20 or #21 or #22 or #23 or #24 or #25)
27. (#19 and #26)

#### Ovid MEDLINE

1. exp Acupuncture/
2. exp Acupuncture Therapy/
3. exp Acupressure/
4. (acupuncture or acupressure or acupoint).tw,ot.
5. exp Electroacupuncture/
6. (electro-acupuncture or electroacupuncture).tw,ot.
7. ot/1-6
8. exp Obesity/
9. exp weight gain/ or exp weight loss/
10. exp body mass index/ or exp skinfold thickness/ or exp waist-hip ratio/
(Continued)

11. exp Abdominal Fat/
12. exp Overweight/
13. (overweight$ or over weight$).tw,ot.
14. fat overload syndrom$.tw,ot.
15. (overeat$ or over eat$).tw,ot.
16. (overfeed$ or over feed$).tw,ot.
17. (adipos$ or obes$).tw,ot.
18. (weight adj3 (cyc$ or reduc$ or los$ or maint$ or decreas$ or watch$ or control$ or gain$ or chang$)).tw,ot.
19. (body mass ind$ or waist-hip ratio$).tw,ot.
20. skinfold thickness$.tw,ot.
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37. hta.tw,ot.
38. (health technology adj6 assessment$).tw,ot.
39. (meta analy$ or metaanaly$ or meta?analy$).tw,ot.
40. ((review$ or search$) adj10 (literature$ or medical database$ or medline or pubmed or embase or cochrane or cinhal or psychinfo
or psychlit or healthstar or biosis or current content$ or systemat$)).tw,ot.
41. or/33-40
42. (comment or editorial or historical-article).pt.
43. 41 not 42
44. 32 or 43
45. 23 and 44
46. (animals not (animals and humans)).sh.
47. 45 not 46

**EMBASE**
1. exp acupuncture/
2. exp acupressure/
3. exp electroacupuncture/
4. (acupuncture or acupressure or acupoint).tw,ot.
5. (electro-acupuncture or electroacupuncture).tw,ot.
6. or/1-5
7. exp Obesity/
8. exp weight change/ or exp weight control/ or exp weight gain/ or exp weight reduction/
9. exp body mass/ or exp waist circumference/ or exp waist hip ratio/
10. (obes$ or overweight or over weight).ab,ti.
11. (overeat or over eat or overfeed or over feed or fat overload syndrom$).ab,ti.
12. (weight adj6 (cyc$ or reduc$ or los$ or maint$ or decreas$ or watch$ or control or chang$ or gain$)).ab,ti.
13. (body mass ind$ or waist hip ratio or waist circumferenc$).ab,ti.
14. adipos$.ab,ti.
15. exp skinfold thickness/
16. (abdominal fat or skinfold thickness).ab,ti.
17. exp skinfold thickness/
18. exp abdominal fat/
19. or/7-18
20. 6 and 19
21. exp Randomized Controlled Trial/
22. exp Controlled Clinical Trial/
23. exp Clinical Trial/
24. exp Comparative Study/
25. exp Drug comparison/
26. exp Randomization/
27. exp Crossover procedure/
28. exp Double blind procedure/
29. exp Single blind procedure/
30. exp Placebo/
31. exp Prospective Study/
32. ((clinical or control$ or comparativ$ or placebo$ or prospectiv$ or randomi?ed) adj3 (trial$ or stud$)).ab,ti.
33. (random$ adj6 (allocat$ or assign$ or basis or order$)).ab,ti.
34. ((singl$ or doubl$ or trebl$ or tripl$) adj6 (blind$ or mask$)).ab,ti.
35. (cross over or crossover).ab,ti.
36. or/21-35
37. exp meta analysis/
38. (metaanaly$ or meta analy$ or meta?analy$).ab,ti.ot.
39. ((review$ or search$) adj10 (literature$ or medical database$ or medline or pubmed or embase or cochrane or cinhal or psychinfo or psychlit or healthstar or biosis or current con$ or systematic$)).ab,ti.ot.
40. exp Literature/
41. exp Biomedical Technology Assessment/
42. hta.tw.ot.
43. (health technology adj6 assessment$).tw.ot.
44. or/37-43
45. (comment or editorial or historical-article).pt.
46. 44 not 45
47. 36 or 46
48. 20 and 46
### Appendix 2. Description of interventions

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<th>study ID2</th>
<th>study ID3</th>
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<th>study ID5</th>
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<td>Control(s) [route, frequency, total dose/day]</td>
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*Footnotes*

C: control; I: intervention

### Appendix 3. Baseline characteristics

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<td>Sex [female% / male%]</td>
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<td>Age [mean years (SD)]</td>
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<td>Duration of disease [mean years (SD)]</td>
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*Appendix 2. Description of interventions*
Appendix 4. Matrix of study endpoints

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Footnotes
1, 2 as stated in the publication; 3 not stated as primary or secondary endpoint(s) in the publication
C: control; I: intervention
## Appendix 5. Adverse events

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<td>Deceased participants [n]</td>
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<td>Serious adverse events [n / %]</td>
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<td>Dropouts due to adverse events [n / %]</td>
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**HISTORY**
Protocol first published: Issue 7, 2010

**CONTRIBUTIONS OF AUTHORS**
JIE LI: protocol draft, search strategy development, acquirement of trial copies, data interpretation, review draft, update draft.
YING LU: protocol draft, search strategy development, trial selection, data extraction, data interpretation, review draft, update draft.
YU MEI SHI: protocol draft, acquirement of trial copies, data analysis, data interpretation, review draft.
GEORGE LENON: protocol draft, trial selection, data extraction, review draft.
YIN SHI: protocol draft, acquirement of trial copies, review draft.

**DECLARATIONS OF INTEREST**
None known.

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**Internal sources**
- Shanghai University of Traditional Chinese Medicine, China.

**External sources**
- No sources of support supplied.