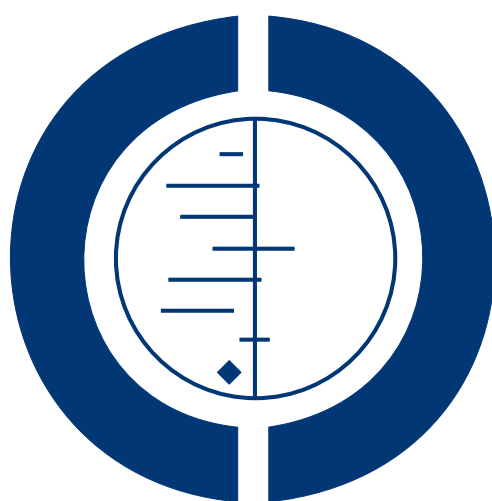


# Acupuncture for treatment of irritable bowel syndrome (Review)

Lim B, Manheimer E, Lao L, Ziea E, Wisniewski J, Liu J, Berman BM



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[Intervention Review]

# Acupuncture for treatment of irritable bowel syndrome

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## ABSTRACT

### Background

Irritable bowel syndrome (IBS), a disorder of altered bowel habits associated with abdominal pain or discomfort. The pain, discomfort, and impairment from IBS often lead to healthcare medical consultation (Talley 1997) and workplace absenteeism, and associated economic costs (Leong 2003). A recent randomized controlled trial shows variable results but no clear evidence in support of acupuncture as an effective treatment for IBS (Fireman 2001).

### Objectives

The objective of this systematic review is to determine whether acupuncture is more effective than no treatment, more effective than 'sham' (placebo) acupuncture, and as effective as other interventions used to treat irritable bowel syndrome. Adverse events associated with acupuncture were also assessed.

### Search strategy

The following electronic bibliographic databases were searched irrespective of language, date of publication, and publication status: MEDLINE, the Cochrane Central Register of Controlled Trials (CENTRAL) on The Cochrane Library, EMBASE, the Chinese Biomedical Database, the Cumulative Index to Nursing and Allied Health (CINAHL), and the Allied and Complementary Medicine Database (AMED). References in relevant reviews and RCTs were screened by hand. The last date for searching for studies was 7 February 2006.

### Selection criteria

Published reports of randomized controlled trials (RCTs) and quasi-randomised trials of acupuncture therapy for IBS.

### Data collection and analysis

All eligible records identified were dually evaluated for eligibility and dually abstracted. Methodological quality was assessed using the Jadad scale and the Linde Internal Validity Scale.

Data from individual trials were combined for meta-analysis when the interventions were sufficiently similar. Heterogeneity was assessed using the I squared statistic.

## Main results

Six trials were included. The proportion of responders, as assessed by either the global symptom score or the patient-determined treatment success rate, did not show a significant difference between the acupuncture and the sham acupuncture group with a pooled relative risk of 1.28 (95% CI 0.83 to 1.98;n=109). Acupuncture treatment was also not significantly more effective than sham acupuncture for overall general well-being, individual symptoms (e.g., abdominal pain, defecation difficulties, diarrhea, and bloating), the number of improved patients assessed by blinded clinician, or the EuroQol score. For two of the studies without a sham control, acupuncture was more effective than control treatment for the improvement of symptoms: acupuncture versus herbal medication with a RR of 1.14(95% CI 1.00 to 1.31;n=132); acupuncture plus psychotherapy versus psychotherapy alone with a RR of 1.20 (95% CI 1.03 to 1.39;n=100). When the effect of ear acupuncture treatment was compared to an unclearly specified combination of one or more of the drugs diazepam, perphenazine or domperidone, the difference was not statistically significant with a RR of 1.49(95% CI 0.94 to 2.34;n=48).

## Authors' conclusions

Most of the trials included in this review were of poor quality and were heterogeneous in terms of interventions, controls, and outcomes measured. With the exception of one outcome in common between two trials, data were not combined. Therefore, it is still inconclusive whether acupuncture is more effective than sham acupuncture or other interventions for treating IBS.

## PLAIN LANGUAGE SUMMARY

### Acupuncture for treatment of irritable bowel syndrome

Irritable bowel syndrome (IBS) is a disorder of altered bowel habits associated with abdominal pain or discomfort. Therapies for irritable bowel syndrome are generally directed at gastrointestinal motor, gastrointestinal sensory, or central nervous system processing; however, the efficacy of such conventional therapies varies from study to study, and the possibility of placebo effects make short-term studies difficult to interpret. The lack of effective therapies for irritable bowel syndrome is accompanied by increased use of complementary and alternative therapies, such as acupuncture. Acupuncture is receiving increasing acceptance in Western medicine for treating certain gastrointestinal disorders. When randomized controlled trials of acupuncture for irritable bowel syndrome were evaluated, some trials showed no clear evidence in support of acupuncture as an effective treatment for IBS, although other poor quality trials showed beneficial effects of acupuncture. There is no evidence to support the use of acupuncture for the treatment of irritable bowel syndrome. Acupuncture for irritable bowel syndrome needs further investigation.

## BACKGROUND

Irritable bowel syndrome (IBS) is a functional gastrointestinal disorder characterized by chronic or recurrent abdominal pain or discomfort and disturbed bowel habits. The estimated prevalence of IBS is 14% to 25% of women and 5% to 19% of men in the United States and Great Britain (Drossman 1997). The pain, discomfort, and impairment from IBS contribute to significant healthcare resource consumption and workplace absenteeism (Talley 1997; Leong 2003). In 2002, total direct cost estimates per patient per year ranged from 348 to 8,750 US dollars and total absenteeism from work, attributed to IBS symptoms, averaged between 8.5 and 21.6 days per year (Maxion 2006).

The Manning (Manning 1978), Rome I (Drossman 1994), and Rome II criteria (Thompson 2000) are the most commonly used methods for diagnosing irritable bowel syndrome in the research setting. A firm diagnosis of IBS based on validated symptom criteria, the absence of alarming symptoms (fever, weight loss, blood in stools, anemia and family history of IBD or cancer), and a normal physical examination coupled with limited relevant diagnostic testing, is reassuring to patients (Mertz 2003). Further diagnostic studies depend on patient age and medical history.

Interplay between motor dysfunction and sensory dysfunction appears to explain the symptoms of irritable bowel syndrome, but

the cause of these symptoms remains to be elucidated. Effects of luminal factors (e.g. meals, gut distention, inflammation, bacteria) and provocative environmental factors (e.g. psychosocial stress) on gastrointestinal motility and visceral sensitivity appear to be exaggerated in patients with irritable bowel syndrome. The gastrointestinal sensory-motor dysfunction is consistent with an up-regulation in neural processing between the gut and the brain, termed “brain-gut-axis” (Mertz 2003).

Therapies for irritable bowel syndrome are generally directed at gastrointestinal motor, gastrointestinal sensory, or central nervous system processing. The efficacy of such conventional therapies varies from study to study. In each of two drug trials, 20 to 50 percent of subjects randomized to placebo reported remission of IBS symptoms for the duration of the three month trials (Camilleri 1999; Muller-Lissner 2001). This salutary placebo effect makes short-term effects of therapeutic trials, as well as the findings of any studies of therapy for irritable bowel syndrome that are not randomized, blinded, and placebo-controlled, difficult to interpret (Mertz 2003).

Conventional therapies for IBS include lactose restriction, fiber supplementation, smooth muscle relaxants/antispasmodics, tegaserod, loperamide, stimulant laxatives, psychological interventions, and antidepressants. Some conventional therapies are of proven benefit (e.g. smooth muscle relaxants/antispasmodics, tegaserod, loperamide, psychological interventions and antidepressants); others have not been well evaluated in RCTs (e.g. lactose restriction, and diphenoxylate); and finally, others have shown little benefit in RCTs but are commonly used (e.g. fiber supplementation, stimulant laxatives, and bulking agents) (Halpert 2004).

The lack of efficacious therapies for irritable bowel syndrome is accompanied by increased use of complementary and alternative therapies (Drossman 1997). Between 11% and 43% of patients with gastrointestinal disorders use alternative or complementary techniques, and many consider them beneficial (Spanier 2003).

Acupuncture, a 3000-year old traditional Chinese medical practice, is receiving increasing acceptance in Western medicine for treating certain medical conditions. In accordance with the visceral hyperalgesia theory of the central nervous system, acupuncture is believed to affect the visceral system by stimulating the somatic system (Fireman 2001). The belief that acupuncture has beneficial effects on various gastrointestinal disturbances has spurred increasing efforts to review such literature objectively. The first objective assessment of the effects of acupuncture for treatment of IBS showed relief of bloating and improved well-being (Chan 1997). A recent randomized controlled trial (RCT) shows variable results but no clear evidence in support of acupuncture as an effective treatment for IBS (Fireman 2001). Therefore, this review focused on evaluating the evidence to assess the efficacy of acupuncture for IBS.

## OBJECTIVES

The objective of this systematic review is to determine whether acupuncture is more effective than: no treatment, ‘sham’ (placebo) acupuncture, and other interventions used to treat irritable bowel syndrome. Adverse events of acupuncture were also assessed.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

Randomized controlled trials (RCTs) and quasi-randomised trials (i.e., allocation on the basis of medical record number, social security number or date of birth) of acupuncture therapy for IBS. Studies were included, regardless of language, blinding, or report type. Unpublished studies were excluded. In randomized cross-over trials, only data from the first period were included because of the risk of carry-over effects. Studies reporting only non-clinical outcomes were excluded.

#### Types of participants

Trials involving adult subjects with irritable bowel syndrome, as diagnosed by any defined or specified diagnostic criteria, were included. Studies in which patients were reported as having irritable bowel syndrome but for which the diagnostic criteria was not described were included. Examples of diagnostic criteria include but are not limited to Rome II (Thompson 2000), Rome I (Drossman 1994), and Manning criteria (Manning 1978). RCTs that included subjects with irritable bowel symptoms found to be caused by primary organic bowel disease were excluded.

#### Types of interventions

Acupuncture is defined as the stimulation of acupuncture points or trigger points by needles that pierce the skin. For the present purposes, three styles of acupuncture are defined: Chinese acupuncture: needles inserted into traditional meridian points, usually with the intention of influencing energy flow in the meridian. Additional tender points may also be used; Western acupuncture: the use of tender or trigger points only with no named acupuncture points; and Japanese acupuncture: superficial needling in the area of the pain. Methods of stimulating acupuncture points that do not involve needle insertion (e.g., laser, acupressure) were excluded. Articles comparing acupuncture to the following control interventions were included: sham acupuncture (either penetrating or non-penetrating), another sham intervention, no treatment, or any other active interventions. Adjunctive treatments (e.g., herbs)

were allowed as long as they had been given to both the acupuncture and control groups. Studies in which one form of acupuncture was compared with another were excluded. Studies in which only a single treatment of acupuncture was administered were excluded.

### Types of outcome measures

The primary outcome measure is the patient's overall assessment of general well-being. Secondary outcomes include the effects of treatment on the following specific items:

1. GI symptoms: abdominal pain, bloating, gas, distension, diarrhea, constipation;
2. quality of life, including the IBS\_QoL which is a specific quality of life instrument used for IBS patients; and
3. adverse events.

### Search methods for identification of studies

Relevant RCTs meeting the inclusion criteria for this review were identified in the following steps:

#### A. Electronic searches

The following databases were searched irrespective of language, date of publication, and publication status: PubMed, the Cochrane Central Register of Controlled Trials (CENTRAL) on *The Cochrane Library*, EMBASE, the Chinese Biomedical Database, the Cumulative Index to Nursing and Allied Health (CINAHL), and the Allied and Complementary Medicine Database (AMED).

1. MEDLINE was searched using the following search strategy: (exp colonic diseases, functional OR irritable bowel syndrome [text word] OR ((irritable[tw] OR functional[tw] OR spastic[tw]) AND (bowel[tw] OR colon[tw]))) AND (Exp acupuncture therapy OR Acupunctur\* [tw] OR (electroacupuncture[tw] OR electro-acupuncture[tw]) OR acupoints [text word] OR percutaneous electrical nerve stimulation [text word] OR auriculoacupuncture[tw]) AND (randomized controlled trial [pt] OR controlled clinical trial [pt] OR randomized controlled trials [mh] OR random allocation [mh] OR double-blind method [mh] OR single-blind method [mh] OR clinical trial [pt] OR clinical trials [mh] OR ("clinical trial" [tw]) OR ((singl\* [tw] OR doubl\* [tw] OR trebl\* [tw] OR tripl\* [tw]) AND (mask\* [tw] OR blind\* [tw])) OR (placebos [mh] OR placebo\* [tw] OR random\* [tw] OR research design [mh:noexp] OR comparative study [mh] OR evaluation studies [mh] OR follow-up studies [mh] OR prospective studies [mh] OR control\* [tw] OR prospectiv\* [tw] OR volunteer\* [tw]) NOT (animals [mh] NOT human [mh]))

A modification of this strategy was used to search the other electronic bibliographic databases.

#### B. Additional searches

References in relevant reviews and RCTs identified in step A were screened by hand. The Science Citation Index was used to check the reference lists of identified randomized clinical trials and review

articles (except the Chinese language articles) from A and B in order to find randomized trials not identified by the electronic or hand searches.

### Data collection and analysis

#### Study selection

One reviewer (EM) executed the PubMed search strategy described above using PubMed. The syntax and MeSH terms of the PubMed strategy were modified for searching other databases. Citation information of all identified studies from each database searched were downloaded into separate ProCite databases. EM and JW independently reviewed the English language citations. EZ and LL independently reviewed the Chinese language citations to identify potentially relevant articles, for which the full reports were obtained and reviewed dually for eligibility. Where necessary, translations of essential details were obtained. Any disagreements between reviewers were resolved by discussion. Where agreements could not be reached, BL, a third reviewer was consulted. Unpublished reports were not included.

#### Assessment of methodological quality

The methodological quality of each RCT was assessed independently by EM and JW for English language citations, and EZ and LL for the Chinese language citations. Any disagreements between reviewers were assessed by BL, a third reviewer. BL and EM in consultation arrived at the final decision for each of these items. The methodological quality of the RCTs was assessed using the Jadad scale (Jadad 1996) and the Linde Internal Validity Scale, which has been used in several systematic reviews of complementary medicine (Linde 1996a; Linde 1996b; Linde 1997). The Linde Internal Validity Scale has the following six items: method of allocation to groups, concealment of allocation, baseline comparability, blinding of patients, blinding of evaluators, and likelihood of selection bias after allocation to groups by dropouts. Each item is scored as 0 (criterion not met or insufficient information provided), 0.5 (criterion partially met), or 1 (criterion met).

#### Data extraction

Two reviewers, EM and JW for English language citations, and EZ and LL for the Chinese language citations, independently extracted data relevant to the primary outcome measure of the patient's overall assessment of general well-being, as well as secondary outcome measures related to specific GI symptoms (abdominal pain, bloating, gas, distension, constipation, and diarrhea), quality of life, and adverse events. Data were extracted on the characteristics of the study population, such as mean age and gender; patient inclusion and exclusion criteria; diagnostic method; and duration of irritable bowel syndrome. Data were also extracted on the acupuncture and control interventions, such as type, administration, duration of acupuncture therapy, regimen of the controlled intervention, follow-up duration, numbers lost to follow-

up. BL and EM assessed all discrepancies in the extracted data from primary reviewers and together made the final decision.

#### Data analysis

Data from individual trials were to be combined for meta-analysis when the interventions and controls were sufficiently similar. For pooled data, summary test statistics were derived using the relative risk and 95% confidence intervals. For continuous data, summary test statistics were derived using the standardized mean difference and 95% confidence intervals. A fixed effects model was used for pooling of data. Trials of Chinese style acupuncture and Western style acupuncture were analyzed separately. Also trials using sham, no treatment, and active treatment controls were analyzed separately. Among the subsets of trials, the I squared statistic was used to describe the percentage of variability in the effect estimates that were due to heterogeneity. Intention to treat analysis was to be used if it would not involve imputing study results. However, an available case analysis was used because complete data were not available for intention to treat analysis. The analyses were carried out using the Cochrane Review Manager software.

#### Sensitivity analysis

Sensitivity analyses could not be conducted due to the lack of available studies.

## RESULTS

### Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#); [Characteristics of ongoing studies](#).

Twelve potentially eligible studies were identified by the searches and considered for inclusion. Six studies were excluded for the following reasons: one study was not a randomized controlled trial ([Chan 1997](#)); for two potentially eligible studies, data could not be abstracted from the full reports because of language barriers, one written in Russian ([Gabuzian 1994](#)) and the other in German ([Kunze 1990](#)); two studies evaluated test treatments that combined acupuncture with another intervention, either vitamin injection ([Wang 2002](#)) or herbal enema ([Yang 2000](#)); one study did not use acupuncture, but instead used transcutaneous electrical nerve stimulation ([Xiao 2004](#)).

The six included studies were randomized controlled trials. Five of them were parallel design ([Forbes 2005](#); [Liao 2000](#); [Liu 1995](#); [Liu 1997](#); [Lowe 2000](#)), and one was a cross-over design ([Fireman 2001](#)). Five studies are reported as fully published papers ([Fireman 2001](#); [Forbes 2005](#); [Liao 2000](#); [Liu 1995](#); [Liu 1997](#)), while one study was reported only in abstract form ([Lowe 2000](#)). Three studies were written in English language ([Fireman 2001](#); [Forbes 2005](#); [Lowe 2000](#)), and three were in Chinese ([Liao 2000](#); [Liu 1995](#); [Liu 1997](#)).

The six trials included a total of 464 patients (221 males and 244 females) with irritable bowel syndrome. The reported age of patients in the included studies ranged from 16 years ([Liao 2000](#)) to 79 years ([Forbes 2005](#)). The durations of IBS symptoms before enrollment varied between studies, ranging from 3 months ([Liu 1997](#)) to 32 years ([Liao 2000](#)).

The Rome criteria were used for diagnosis of IBS in three studies ([Fireman 2001](#); [Forbes 2005](#); [Lowe 2000](#)). [Fireman 2001](#) used the 'Rome I', and [Forbes 2005](#) used the 'Rome II', but [Lowe 2000](#) did not state which version of the Rome criteria was used. Three Chinese studies ([Liao 2000](#); [Liu 1995](#); [Liu 1997](#)) classified patients as having IBS based on relevant symptoms, for example, belching, abdominal pain, bloating, and diarrhea. It is uncertain whether all of these patients would be considered IBS patients based on the Rome criteria. The patients were required to have had symptoms for at least three months in the [Forbes 2005](#) study, and for at least one year (with symptoms at least three times a week) to be included in the [Fireman 2001](#) study. The other studies ([Liao 2000](#); [Liu 1995](#); [Liu 1997](#); [Lowe 2000](#)) did not consider the duration or the frequency of symptoms as inclusion criteria.

The five studies published as full reports stated that patients who had organic bowel diseases were excluded, and three of these studies presented detailed diagnostic methods for diagnosing organic diseases ([Forbes 2005](#); [Fireman 2001](#); [Liu 1995](#)). There were no other exclusion criteria in any of the studies with the exception of [Forbes 2005](#) where patients who had psychiatric disease were excluded.

Two studies had a short treatment duration, each with a treatment period of 4 weeks ([Lowe 2000](#); [Fireman 2001](#)); one study had a moderate treatment duration of 12 weeks ([Forbes 2005](#)); the 3 Chinese studies did not clearly report the total treatment duration. Of all included studies, only [Liu 1997](#) presented longer term follow-up, which was at 6 months.

The included studies used heterogeneous acupuncture protocols, as well as heterogeneous active and inactive controls or comparators. [Fireman 2001](#) compared 2 sessions of acupuncture treatment using LI-4 acupoint with similar sessions of inserting sham acupuncture needles on a different acupoint (BL-60). [Forbes 2005](#) compared 10 sessions of acupuncture treatment on 4 to 8 acupoints with similar intervention on sham acupoints which were chosen from three different areas on the body (the anterior thigh distally, the posterior thigh, and the lateral aspect of the lower back). [Lowe 2000](#) compared 8 sessions of acupuncture treatment on 9 acupoints during 4 weeks with non-penetrating sham acupuncture needles placed at the same points as the needles used in the true acupuncture group. [Liu 1995](#) compared 30 sessions of ear acupuncture on 5 ear acupoints with a control group who received oral drugs including diazepam, perphenazine or domperidone. Based on the text, the [Liu 1995](#) study was a two-arm trial, but it is unclear whether control patients took all three drugs, or only one or two of the drugs, or other drugs in addition to these three drugs. [Liu 1997](#) compared acupuncture using 3 to 4 acu-

points plus psychotherapy with acupuncture and psychotherapy respectively. Liao 2000 compared acupuncture using 4 to 5 acupoints with Chinese herbal medication 'Tong Xie Yao Fang'. Chinese acupuncture was used in all studies except for Liu 1995 in which ear acupuncture was used. Methods of stimulating acupuncture points were stated in the trials to be electrical (Liu 1995), or manual (Forbes 2005; Liao 2000; Liu 1997), but not stated in the rest of the trials.

Although acupuncture protocols were heterogeneous, the overall acupuncture style was similar for five of the included studies: these studies used Chinese style acupuncture with flexible formulae (Fireman 2001; Forbes 2005; Liao 2000; Liu 1997; Lowe 2000), and one study used ear acupuncture (Liu 1995).

For the outcome measures, Fireman 2001 described the use of a Visual Analogue Scale (VAS) in which the patients were scored on a scale of 1 to 5 points (where 1 = significant deterioration and 5 = significant improvement) to assess their general well-being and changes in 7 symptoms. The seven symptoms were abdominal pain, defecation difficulties, diarrhea, alternating diarrhea and constipation, bloating, abdominal discomfort relieved by defecation, and stool with mucus. Forbes 2005 assessed changes in global 'symptom score' as a primary outcome measure. This score ranged from 0 to 30 and was numerically compiled from symptom diaries based on the Bristol scale. A reduction of four points was considered indicative of a clinically meaningful response. Secondary outcome measures included the assessment of patients status (improved, unchanged, or worse) by one of the blinded investigators, the Hospital Anxiety and Depression (HAD) scale, and the EuroQol. Lowe 2000 assessed 'patient-determined treatment success rate', dichotomized as greater than or less than a 40% overall improvement in response rate. Lowe 2000 also measured 'the proportion of patients with increased Barostat rectal sensory thresholds',

'McGill pain score' and 'IBS-36'.

Three Chinese studies (Liao 2000; Liu 1995; Liu 1997) presented outcome data using an ordinal scale that classified change in symptoms from baseline. Two of these studies (Liao 2000; Liu 1997) used the categories 'cured', 'improved', and 'no effect'. For these studies, we created a dichotomous measure, combining 'cured' and 'improved' into 'positive'. One of the studies (Liu 1995) used the categories 'marked effective', 'effective', 'improved', and 'no effect'. For this study, we created the category 'positive' combining 'marked effective', 'effective', and 'improved'.

Outcomes were measured at the end of the treatment period in all studies. Two studies (Liu 1997; Lowe 2000) also measured outcomes 6 months (Liu 1997) and 3 months (Lowe 2000) after the treatment period had ended.

### Risk of bias in included studies

Methodological quality was assessed using the Jadad scale and the Linde Internal Validity Scale (Table 1; Table 2; Table 3; Table 4). In most of the studies, the number of participants was small and the methodological quality was very low. All studies in this review reported patient randomization. However, only Forbes 2005 described the randomization process and allocation concealment in detail. There was no detailed description for allocation method or concealment in the other studies. Only in the Fireman 2001 and Forbes 2005 studies, patients signed informed consent, patients and evaluators were regarded to be blinded, and the handling of withdrawals was described carefully. In all studies except Forbes 2005 and Lowe 2000, there was no reporting of baseline characteristics of the acupuncture and control groups. Thus, it is impossible to know whether the groups were comparable at baseline.

**Table 1. Linde Internal Validity Scale (LIVS): items**

LIVS items	scoring of items
1. Treatment allocation	1
a) randomized stated	0
b) not randomized	0
c) no or unclear information	
2. Randomized concealment	1
a) adequate (e.g., central randomization, coded drugs etc.)	.5
b) probably adequate (e.g., sealed envelope)	depends
c) other:	0
d) inadequate concealment	0
e) no or unclear information	
3. Baseline comparability	1
a) important baseline factors listed and comparable	.5

**Table 1. Linde Internal Validity Scale (LIVS): items** (Continued)

b) baseline comparability fairly credible	0
c) important baseline differences	0
d) no or unclear information	
4. Blinding of patients	1
a) placebo/control indistinguishable	.5
b) blinding only stated	0
c) placebo likely to be distinguishable	0
d) patients not blinded	0
e) no or unclear information	
5. Blinding of evaluators	1
a) blinding described and likely to be successful	.5
b) blinding only stated	0
c) evaluators not blinded	0
d) no or unclear information	
6. Handling of withdrawals	1
a) no or minimal withdrawals/drop-outs	1
b) less than 20% loss to follow up and intent-to-treat-analysis	.5
c) careful handling/description of withdrawals, substantial bias	0
d) major flaws	0
e) no or unclear information	

**Table 2. Linde Internal Validity Scale: score**

Study ID	1.	2.	3.	4.	5.	6.	LIVS score
Fireman 2001	1	0	0	1	1	.5	3.5
Forbes 2005	1	.5	1	1	1	.5	5
Liao 2000	1	0	0	0	0	0	1
Liu 1995	1	0	0	0	0	0	1
Liu 1997	1	0	0	0	0	0	1
Lowe 2000	1	0	.5	.5	.5	0	2.5

**Table 3. Jadad Quality of Methodology Scale: items**

Quality items
1A. Was the study described as randomized?
1B. If answer to above is yes, was method of generating randomization sequence appropriate?

**Table 3. Jadad Quality of Methodology Scale: items** (Continued)

2A. Was the study described as double blind?
2B. If answer to above is yes, was the method of double blinding appropriate?
3. Was there a description of dropouts and withdrawals?
Note: A+B+C+D+E = possible 5 points on Jadad scale. Low quality = 0 to 2; high quality = 3 to 5.

**Table 4. Jadad Methodological Quality Scale: score (Yes=1, No=0)**

Study ID	1A	1B	2A	2B	3	Jadad score
Fireman 2001	1	0	1	1	1	4
Forbes 2005	1	1	1	1	1	5
Liao 2000	1	0	0	0	0	1
Liu 1995	1	0	0	0	0	1
Liu 1997	1	0	0	0	0	1
Lowe 2000	1	0	1	1	0	3

For the blinding of patients, there were different kinds of sham acupuncture applied in the three studies. [Fireman 2001](#) stimulated the BL-60 acupoint which was assumed to be unrelated to IBS treatment. [Forbes 2005](#) inserted acupuncture needles on nonexistent acupoints which were deemed to have no therapeutic value. [Lowe 2000](#) applied the tapping of the blunt needle on the skin for the control group, and tapped all acupoints for both groups after treatment so the puncture point could not be seen by patients.

[Forbes 2005](#) attempted to blind the evaluator by separating the 'diagnosing acupuncturist' from the 'treating acupuncturist'. Blind to the random allocation, the diagnosing acupuncturist prescribed the acupuncture formula and evaluated the patients' condition after each treatment session. The treating acupuncturist carried out the treatment according to instructions issued by the diagnosing acupuncturist or using sham points depending on the randomization.

Some studies were regarded to handle acupuncture technique appropriately, stimulating 3 to 8 acupoints with 'De Qi' sensation in each treatment session ([Forbes 2005](#); [Liao 2000](#); [Liu 1997](#)), and

giving 2 to 5 treatments per week ([Liao 2000](#); [Liu 1997](#); [Lowe 2000](#)). [Fireman 2001](#) used only one acupoint (LI-4) and performed just two true acupuncture sessions during the total treatment period, which was considered to be insufficient for the treatment of chronic disease. For the statistical analysis, the P-values reported in [Fireman 2001](#) were not identical to the P-values that were re-calculated in this review using means, SDs, and numbers of patients in each group.

### Effects of interventions

The studies used different control groups and different types of outcome measures, precluding the pooling of data with the exception of one dichotomous outcome (the proportion of responders with clinically recognized improvement in symptoms) common to [Forbes 2005](#) and [Lowe 2000](#). The proportion of responders which were assessed respectively from the global symptom score ([Forbes 2005](#)) and the patient-determined treatment success rate ([Lowe 2000](#)) did not show a significant difference between the acupuncture and the sham acupuncture group with a pooled relative risk

of 1.28 (95% CI 0.83 to 1.98).

In [Fireman 2001](#), acupuncture treatment was not significantly more effective than sham acupuncture for either overall general well-being or any of the individual symptoms (e.g., abdominal pain, defecation difficulties, diarrhea, and bloating) according to calculations made for this review. However, the author stated that two of the items (i.e. overall general well-being, and alternating diarrhea and constipation) showed statistically significant differences in VAS scores between the acupuncture and the sham acupuncture groups.

[Forbes 2005](#) presented the number of improved patients assessed by a blinded clinician and the EuroQol score, and neither of these measures showed statistically significant differences between the two groups. Also, in [Lowe 2000](#), the acupuncture group showed marked improvement in the McGill pain score and the IBS-36 scores; however, the sham acupuncture group improved markedly as well; consequently there were no statistically significant differences between the two groups.

For two of the trials without a sham control ([Liao 2000](#); [Liu 1997](#)), acupuncture was more effective than control treatment for the improvement of symptoms: acupuncture was slightly more effective than herbal medication at the end of treatment with a RR of 1.14 (95% CI 1.00 to 1.31, [Liao 2000](#)); acupuncture plus psychotherapy was slightly more effective for symptom improvement than psychotherapy alone with a RR of 1.20 (95% CI 1.03 to 1.39, [Liu 1997](#)), and this intervention was also beneficial in terms of 'no symptom recurrence' at the 6 month follow up with a RR of 3.26 (95% 1.22 to 8.69, [Liu 1997](#)). These results, however, should be interpreted with caution because of the poor methodological quality of these trials. Interestingly, in [Liu 1997](#), acupuncture alone was less effective for symptom improvement and less beneficial for the 'no symptom recurrence' than psychotherapy alone.

In [Liu 1995](#), ear acupuncture treatment was reported to be more effective than an unclearly specified combination of diazepam, perphenazine or domperidone. However this comparison was not statistically significant with a RR of 1.49 (95% CI 0.94 to 2.34) according to the re-calculation performed for this review.

Only one study collected information on adverse events, and no adverse events directly attributable to the acupuncture were reported ([Forbes 2005](#)).

## DISCUSSION

The six trials included in this review were generally of poor quality. The trials enrolled small numbers of patients and there may have been a lack of power to show a statistically significant difference between acupuncture and comparators should one exist. The trials were also extremely heterogeneous in interventions, controls, and outcomes measured. With the exception of one outcome in common between two trials, data were not combined. Therefore,

it is still inconclusive whether acupuncture is more effective than sham acupuncture or other interventions for treating IBS.

In spite of relatively high quality scores, methodological factors may have contributed to an underestimate of the effect of acupuncture in the [Fireman 2001](#) and [Forbes 2005](#) studies. The number of acupuncture points and sessions in [Fireman 2001](#) was smaller than has been recommended by some authors ([Birch 1997](#); [Ezzo 2000](#)). For the sham acupuncture, [Fireman 2001](#) inserted a needle at the BL-60 acupoint. However, according to the meridian theory on which [Fireman 2001](#) chose the acupoints, BL (urinary bladder) meridian controls the body fluid and may, consequently, affect the absorption of intestinal fluid. Therefore BL-60 cannot be assumed to be absolutely unrelated with intestinal condition. The sham treatment used in the [Forbes 2005](#) trial involved inserting needles at distant nonacupuncture points; however, some recent large trials ([Brinkhaus 2006](#); [Linde 2005](#)) suggest that such needle penetrating sham acupuncture may have some physiological or analgesic effects.

Although this review did not intend to compare Western and Chinese studies, interesting differences were found between these two groups in terms of the reporting of research methods. Chinese studies failed to report the minimum requirements for the selection criteria, randomization and blinding, whilst Western studies generally reported insufficient details of the acupuncture technique, such as needling depth, needle stimulation, De Qi sensation, type of needle used, and names of acupoints. This indicates that not only the basic guidelines for reporting clinical trials such as the CONSORT statement ([Begg 1996](#)), but also the specific guidelines for the reporting of acupuncture trials, namely the STRICTA recommendation ([MacPherson 2001](#)), should be better disseminated to improve the design, performance and reporting of future clinical trials of acupuncture.

Also, it is necessary to give special attention to evaluating the quality of the three Chinese language studies. Although these studies mentioned the use of randomization and presented control group data, it is not known for certain if these are randomized controlled trials. First, data collection periods in these studies were either not clear [e.g. 'recent 1 year' ([Liu 1995](#)) and 'recent 2 year' ([Liu 1997](#))], or much longer than would be expected, considering the sample size (i.e., 15 years, [Liao 2000](#)). Second, there were absolutely no withdrawals during the treatment period in these studies ([Liao 2000](#); [Liu 1995](#); [Liu 1997](#)), that is, the number of patients allocated and the number of patients reported in the results were exactly identical, which is unusual in trials of long-term follow-up. In this context, we can not eliminate the possibility that Chinese trialists did not fully understand randomization, and that the studies were performed retrospectively. According to a recent telephone survey among Chinese trialists whose associated publications (n=384) all noted the use of random allocation, it was found that 69% of studies actually used a method that was not random allocation (e.g., "random sampling" or "allocating according to the

day, month, or year”), whereas another 23% used a method that only loosely approximated random allocation (e.g., alteration or coin tossing) (Wu 2005; Manheimer 2006).

## AUTHORS' CONCLUSIONS

### Implications for practice

Given the poor quality of the studies, there is no evidence to support the use of acupuncture for treating IBS; therefore, neither positive nor negative recommendation can be made based on this review.

### Implications for research

To improve trial quality and enhance the evidence of the effect of acupuncture on IBS, we recommend:

- 1) Researchers designing and reporting acupuncture RCTs follow guidelines such as the CONSORT statement (Begg 1996) and STRICTA recommendation (MacPherson 2001).
- 2) Researchers designing RCTs evaluating treatments for IBS use standardized outcome measures such as the IBS' QoL or IBS-36.
- 3) Researchers continue to work on the development of proper protocols for placebo acupuncture (Streitberger 1998).

Acupuncture treatment based on meridian theory deserves further examination in high-quality trials.

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\* Indicates the major publication for the study

## CHARACTERISTICS OF STUDIES

### Characteristics of included studies [ordered by study ID]

#### Fireman 2001

Methods	<p>Design: Cross over</p> <p>Blinding: Yes</p> <p>Attempt to confirm patient blinding?: Not stated</p> <p>Dropouts/withdrawals: 4 before the first session, 3 after first session</p> <p>Jadad score: 1-0-1-1-1</p> <p>LIVS score: 1-0-0-1-1-0.5</p> <p>Total duration: 4 weeks (from baseline)</p> <p>Type of analysis reported: Available case</p>
Participants	<p>Setting: Hospital outpatient, Israel</p> <p>Mean age (+/-SD or Range): 45+/-12.3 (range:20-75) for entire population</p> <p>Men/Women (n/n): -14/11</p> <p>Recruitment method: Call for bulletin</p> <p>Duration of IBS symptoms before enrollment: 10 yrs (range: 2-15)</p> <p>Diagnosis of IBS required to be eligible? (if yes, describe how patients were verified to have IBS): Yes, Rome I criteria was used</p> <p>Evaluation to rule out organic gastrointestinal disease: Reported</p> <p>Hospital inpatients? (Y/N; if Y list number inpatients): Yes, 32</p> <p>Were people with a history of acupuncture treatment excluded?: Not stated</p> <p>Other important inclusion criteria: Not stated</p> <p>Important exclusion criteria: Organic diseases</p>
Interventions	<p>ACUPUNCTURE</p> <p>N allocated to acupuncture: 25</p> <p>Style of acupuncture: Chinese</p> <p>Points selection: Formula</p> <p>Points stimulated: LI-4</p> <p>Total length of treatment period (weeks): 4</p> <p>Number of sessions target (mean): 2</p> <p>Times per week:2 over 4 weeks</p> <p>Number of points used (mean): 1</p> <p>Insertion depth: Not stated</p> <p>Was De Qi reportedly sought?: Not stated</p> <p>Duration (mins): 30</p> <p>Method of stimulation: Not stated</p> <p>Acupuncturist's opinion about the acupuncture treatment: 1. Choice of acupoints; inadequate, 2. Number of sessions; inadequate, 3. Needling technique; don't know, 4. Acupuncturist's experience; don't know</p> <p>Total follow-up period: Not stated</p> <p>CONTROL GROUP A INTERVENTION (sham, if used): Sham acupuncture with penetrating needle</p> <p>N allocated to control group A: 25</p> <p>Points selection: Formula</p> <p>Points stimulated: BL-60</p> <p>Total length of treatment period: 4 weeks</p> <p>Number of sessions target (mean): 2</p> <p>Times per week: 2 over 4 weeks</p>

**Fireman 2001** (Continued)

	<p>Number of points used: 1          Insertion depth: Not stated          Was De Qi sought?: Not stated          Duration (mins): 30          Method of stimulation: Not stated          Any co-interventions in all groups?: None</p>	
Outcomes	<p>Outcomes abstracted for systematic review;          Measurement time points:          Overall general well-being (VAS 1-significant deterioration - 5-significant improvement): After 1st acupuncture session; acupuncture 4.1+/-0.86, sham 3.62+/-0.84 (p=0.05), After 2nd session; acupuncture 4.06+/-0.88, sham 3.72+/-0.82 (p=0.15)          Abdominal pain: After 1st session; acupuncture 4.2+/-0.9, sham 3.5+/-0.96 (p=0.26), After 2nd session; acupuncture 4.11+/-0.89, sham 3.81+/-0.95 (p=0.04)          Defecation difficulties: After 1st session; acupuncture 4.15+/-0.9, sham 3.43+/-0.66 (p=0.56), After 2nd session; acupuncture 3.91+/-1.08, sham 3.75+/-0.75 (p=0.34)          Diarrhea: After 1st session; acupuncture 4.22+/-0.93, sham 4.0+/-0.89 (p=0.56), After 2nd session; acupuncture 4.18+/-0.87, sham 3.9+/-0.83 (p=0.34)          Alternating diarrhea and constipation: after 1st session; acupuncture 4.19+/-0.89, sham 3.47+/-0.73 (p=0.027), after 2nd session; acupuncture 4.05+/-1.05, sham 3.77+/-0.73 (p=0.3)          Bloating: After 1st session; acupuncture 3.7+/-0.93, sham 3.5+/-0.87 (p=0.35), After 2nd session; acupuncture 3.8+/-0.81, sham 3.6+/-0.93 (p=0.5)          Type of outcome data reported: Difference in post-treatment values between acupuncture and control group          Author's conclusion: Therapeutic benefit of acupuncture in IBS was not shown.          Additional outcomes reported in the trial but not abstracted: Patients' assessments for 'abdominal discomfort relieved by defecation' and 'stool with mucus'          Adverse effects: Not stated          Notes:          * Only data assessed after 1st session were included in the analysis.          * For the statistical analysis, the p-values reported in Fireman 2001 were different from the p-values that were re-calculated using means, SDs, and numbers of patients in each group. Because the number of patients in each group for each outcome was not described in the text, we applied various combinations of patient's numbers in each outcome; however we did not re-calculate any p-values identical with those reported in the text, and all p-values that we re-calculated were greater than 0.05.</p>	
Notes	<p>Comments: Numbers of acupoints and sessions were too small to expect beneficial treatment effect. No difference was found between the two groups by statistical analysis overall after the wash-out, although the improvements in patients' symptoms were consistently better in the true acupuncture group compared to sham.          It is interesting to point out that neither sham nor true acupuncture worsened any of the patient's symptoms, and no additional adverse effects were reported. The decrease in symptoms experienced in patients in the sham group may be due to the insertion of needles in non-colonic/bladder meridian points versus placebo effects.          Weak points: small number of treatment sessions, small sample size</p>	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>

**Fireman 2001** (Continued)

Allocation concealment?	Unclear	B - Unclear
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**Forbes 2005**

Methods	<p>Design: Parallel          Blinding: Yes          Attempt to confirm patient blinding?: Not stated          Dropouts/withdrawals: 1 before randomization, 8 after randomization          Jadad score: 1-1-1-1-1          LIVS score: 1-0.5-1-1-1-0.5          Total duration: 13 weeks (from baseline)          Type of analysis reported: Intention to treat analysis</p>
Participants	<p>Setting: Hospital outpatient, UK          Mean age (+/-SD or Range): 43.0 (range:19-67) for acupuncture group, 44.4 (range:17-79) for control group          Men/Women (n/n): 20/39          Recruitment method: Personal approach in the hospital clinics          Duration of IBS symptoms before enrollment: More than 3 months          Diagnosis of IBS required to be eligible? (if yes, describe how patients were verified to have IBS): Yes, Manning criteria &amp; Rome II criteria were used.          Evaluation to rule out organic gastrointestinal disease: Reported          Hospital inpatients? (Y/N; if Y list number inpatients): No          Were people with a history of acupuncture treatment excluded?: Not stated          Other important inclusion criteria: Age of over 16 years, existence of symptoms for at least 3 months before enrollment, and failure to respond to standard therapies          Important exclusion criteria: Other physical disease, psychiatric disease, use of psychotropic drugs during study period, or pregnant women</p>
Interventions	<p>ACUPUNCTURE          N allocated to acupuncture: 27          Style of acupuncture: Chinese          Points selection: Flexible formula for specific symptoms          Points stimulated: Names of points were not stated          Total length of treatment period (weeks): 13          Number of sessions target (mean): 10          Times per week: 1          Number of points used (mean): 4-8 points (8-16 needles for both sides)          Insertion depth: Not stated          Was De Qi reportedly sought?: Yes          Duration (mins): ~25min          Method of stimulation: Manipulation          Acupuncturist's opinion about the acupuncture treatment: 1. Choice of acupoints; don't know, 2. Number of sessions; adequate, 3. Needling technique; adequate, 4. Acupuncturist's experience; adequate          Total follow-up period: Not stated          CONTROL GROUP A INTERVENTION (sham, if used): Sham acupuncture with penetrating needles          N allocated to control group A: 32          Points selection: formula</p>

**Forbes 2005** (Continued)

	<p>Points stimulated: Nonacupuncture points in three different areas on the body          Total length of treatment period: 13 weeks          Number of sessions target (mean): 10          Times per week: 1          Number of points used: Not stated          Insertion depth: Not stated          Was De Qi sought?: No          Duration (mins): -25          Method of stimulation: Manipulation          Any co-interventions in all groups?: Specific dietary and lifestyle advice</p>	
Outcomes	<p>Outcomes abstracted for systematic review;          Measurement time points: Overall well-being: Global symptom score: Baseline; acupuncture 13.5+/-4.51, sham 13.1+/-4.30, 13 weeks after baseline; acupuncture 11.6+/-5.13, sham 11.2+/-4.17          Number of patients with symptoms score reduction: 13 weeks after baseline; acupuncture 16 (59.2%), sham 21 (65.6%)          Number of patients with symptoms score reduction at least 4 points: 13 weeks after baseline; acupuncture 11 (40.7%), sham 10 (31.2%)          GI symptoms: Number of patients with pain: Baseline; acupuncture 13, sham 15, 13 weeks after baseline; acupuncture 13, sham 10          Number of patients with bloating: Baseline; acupuncture 14, sham 14, 13 weeks after baseline; acupuncture 9, sham 11          Number of patients with diarrhea: Baseline; acupuncture 11, sham 11, 13 weeks after baseline; acupuncture 8, sham 10.5          Number of patients with constipation: Baseline; acupuncture 16, sham 11, 13 weeks after baseline; acupuncture 15, sham 8          HAD score (<math>\bar{x}</math>±SD): 13 weeks after baseline; acupuncture 11 (41%), sham 15 (47%)          EuroQol: Baseline; acupuncture 59.4%, sham 64.6%, 13 weeks after baseline; acupuncture 64.6%, sham 65.6%          Type of outcome data reported: Changes from baseline in each acupuncture and control group, and difference of post treatment values between two groups          Author's conclusion: Acupuncture is relatively ineffective in IBS.          Additional outcomes reported in the trial but not abstracted: Symptom improvement assessed by blinded clinician          Adverse effects: No direct adverse effect was reported</p>	
Notes	<p>Comments: Carefully worked, especially for the blinding of evaluator          Weak points: small sample size</p>	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Allocation concealment?	Yes	A - Adequate

**Liao 2000**

Methods	<p>Design: Parallel group            Blinding: No            Attempt to confirm patient blinding?: No            Dropouts/withdrawals: Unclear            Jadad score: 1-0-0            LIVS score: 1-0-0-0-0-0            Total duration: Not stated            Type of analysis reported: NA</p>
Participants	<p>Setting: Hospital inpatient &amp; outpatient departments, China            Mean age (+/-SD or Range): Range of 16-58 for entire population, 30.5 yrs (range:16-58) for acupuncture group, 29.8 yrs (range:22-50) for control group            Men/Women (n/n): 76/56 for entire population, 65/32 for acupuncture group, 11/24 for control group            Recruitment method: Not stated            Duration of IBS symptoms before enrollment: 5 mons-32 yrs            Diagnosis of IBS required to be eligible? (if yes, describe how patients were verified to have IBS): Not stated            Evaluation to rule out organic gastrointestinal disease: Reported (not explicit)            Hospital inpatients? (Y/N; if Y list number inpatients): Yes (number was not stated)            Were people with a history of acupuncture treatment excluded?: Not stated            Other important inclusion criteria: Not stated            Important exclusion criteria: Organic diseases</p>
Interventions	<p>ACUPUNCTURE            N allocated to acupuncture: 97            Style of acupuncture: Chinese            Points selection: Flexible formula for specific symptoms            Points stimulated: BL-20, BL-21, BL-23, ST-36, LR-3, PC-6, ST-25            Total length of treatment period (weeks): Not stated            Number of sessions target (mean): 10            Times per week: 5            Number of points used (mean): 4-5            Insertion depth: Not stated            Was De Qi reportedly sought?: Yes            Duration (mins): 30            Method of stimulation: Manipulation            Acupuncturist's opinion about the acupuncture treatment: 1. Choice of acupoints; adequate, 2. Number of sessions; adequate, 3. Needling technique; adequate, 4. Acupuncturist's experience; don't know            Total follow-up period: Not stated            CONTROL GROUP A INTERVENTION (sham, if used): Chinese herbal medication (Tong Xie Yao Fang)            N allocated to control group A: 35            Total length of treatment period: Not stated            Number of sessions target (mean): 7 days of daily medication Times per week: Duration (mins):            Any co-interventions in all groups?: Psychotherapy</p>
Outcomes	<p>Outcomes abstracted for systematic review;            Measurement time points: Improvement of symptoms (3-point scoring system): At the end of treatment;            1) cured: Clinical symptoms disappeared, formed stool, no mucus, normal frequency of bowel movement;            Treatment group: 32/97; Control group: 11/35</p>

**Liao 2000** (Continued)

	<p>2) improved: Clinical symptoms subsided, stool generally formed with small amount of mucus; Treatment group: 63/97; Control group: 19/35</p> <p>3) no effect: no symptoms change after five courses of treatment; Treatment group: 2/97; Control group: 5/35</p> <p>Type of outcome data reported: Difference in post treatment values between acupuncture and control group</p> <p>Author's conclusion: Acupuncture plus psychotherapy is better than Chinese herbs plus psychotherapy</p> <p>Additional outcomes reported in the trial but not abstracted: None</p> <p>Adverse effects: Not stated</p>	
Notes	<p>Comments: The result is inconclusive due to poor research methodology and lack of detailed description of the treatment procedure.</p> <p>There is a possibility that this study was not a randomized trial setting because the duration of the study was too long (3 to 4 yrs) and both inpatients and outpatients were included.</p> <p>Weak point: Low research quality</p>	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Allocation concealment?	Unclear	B - Unclear

**Liu 1995**

Methods	<p>Design: Parallel group</p> <p>Blinding: No</p> <p>Attempt to confirm patient blinding?: NA</p> <p>Dropouts/withdrawals: Unclear</p> <p>Jadad score: 1-0-0</p> <p>LIVS score: 1-0-0-0-0-0</p> <p>Total duration: Not stated</p> <p>Type of analysis reported: NA</p>	
Participants	<p>Setting: Hospital outpatient, China</p> <p>Mean age (+/-SD or Range): Range of 21-58 for entire population</p> <p>Men/Women (n/n): 12/36 for entire population, 9/28 for acupuncture group, 3/8 for control group</p> <p>Recruitment method: Not stated</p> <p>Duration of IBS symptoms before enrollment: 3 months to 11 yrs</p> <p>Diagnosis of IBS required to be eligible? (if yes, describe how patients were verified to have IBS): Verified by symptoms</p> <p>Evaluation to rule out organic gastrointestinal disease: Reported explicitly</p> <p>Hospital inpatients? (Y/N; if Y list number inpatients): Not stated</p> <p>Were people with a history of acupuncture treatment excluded?: Not stated</p> <p>Other important inclusion criteria: Not stated</p> <p>Important exclusion criteria: Not stated</p>	
Interventions	<p>ACUPUNCTURE</p> <p>N allocated to acupuncture: 37</p> <p>Style of acupuncture: Other (Ear acupuncture)</p>	

Liu 1995 (Continued)

	<p>Points selection: Formula          Points stimulated: Ear acupuncture points; sympathetic nerve (08), shenmen (07), stomach (03), subcortex (17)          Total length of treatment period (weeks): 9          Number of sessions target (mean): 30          Times per week: 3-4          Number of points used (mean): 4          Insertion depth: Piercing cartilage but not penetrating opposite skin          Was De Qi reportedly sought?: Yes          Duration (mins): 10          Method of stimulation: Electrical          Acupuncturist's opinion about the acupuncture treatment: 1. Choice of acupoints; adequate, 2. Number of sessions; adequate, 3. Needling technique; adequate, 4. Acupuncturist's experience; don't know          Total follow-up period: Not stated          CONTROL GROUP A INTERVENTION (sham, if used): Western medication (Diazepam, Perphenazine, Domperidon)          N allocated to control group A: 11          Total length of treatment period: Not stated          Number of sessions target (mean): Not stated          Times per week: Not stated          Duration (mins):          Any co-interventions in all groups?: None</p>	
Outcomes	<p>Outcomes abstracted for systematic review:          Measurement time points:          Improvement of symptoms (4-point scoring system): At the end of treatment;          1) marked effective: All major clinical symptoms disappeared; treatment group: 10/37; control group: 1/11          2) effective: 2 of the major clinical symptom disappeared; treatment group: 19/37; control group: 2/11          3) improved: one of the major clinical symptoms disappeared, and other symptoms subsided: treatment group: 6/37; control group: 4/11          4) no effect: no change of any clinical symptoms: treatment group: 2/37; control group: 4/11          *Modified outcome (symptoms change-more than improved); treatment group: 35/37, control group: 7/11          Type of outcome data reported: Differences in post-treatment values between two groups          Author's conclusion: Ear acupuncture is better than western medication in IBS treatment.          Additional outcomes reported in the trial but not abstracted: Number of patients with reduction of each symptom, Change of electric current of Ear acupuncture points          Adverse effects: Not stated</p>	
Notes	<p>Comments: This result is inclusive due to poor research methodology. Conclusion is unclear/un-interpretable.          Weak point: Small sample size, low research quality</p>	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Allocation concealment?	Unclear	B - Unclear

**Liu 1997**

Methods	<p>Design: Parallel group            Blinding: No            Attempt to confirm patient blinding?: No            Dropouts/withdrawals: At the end of Tx, explicitly no dropouts for all groups, but the number of baseline is unreliable; At 26week follow-up, 27 drop-outs in intervention group (acupuncture and psychological Tx), 25 for acupuncture group and 25 for psychological group            Jadad score: 1-0-0            LIVS score: 1-0-0-0-0-0            Total duration: Not stated            Type of analysis reported: NA</p>
Participants	<p>Setting: Not stated, China            Mean age (+/-SD or Range): 16-64 for entire population, 19-64 for acupuncture plus psychotherapy group, 16-62 for acupuncture group, 22-58 for psychotherapy group            Men/Women (n/n): 89/61            Recruitment method: Not stated            Duration of IBS symptoms before enrollment: 3 mons-32 yrs            Diagnosis of IBS required to be eligible? (if yes, describe how patients were verified to have IBS): Only stated that "all patients had IBS."            Evaluation to rule out organic gastrointestinal disease: Reported (not explicit)            Hospital inpatients? (Y/N; if Y list number inpatients): Not stated            Were people with a history of acupuncture treatment excluded?: Not stated            Other important inclusion criteria: Not stated            Important exclusion criteria: Organic diseases</p>
Interventions	<p>ACUPUNCTURE + PSYCHOTHERAPY            N allocated to acupuncture: 50            Style of acupuncture: Chinese            Points selection: Flexible formula for specific symptoms            Points stimulated: ST-36, PC-6, CV-12, ST-25, LR-3, BL-20, BL-23, GV-4 / CV-8 (Moxibustion)            Total length of treatment period (weeks): 3-21 weeks            Number of sessions target (mean): 10-60 for acupuncture treatment            Times per week: 3            Number of points used (mean): 3-4            Insertion depth: Not stated            Was De Qi reportedly sought?: Yes            Duration (mins): 30            Method of stimulation: Manipulation            Acupuncturist's opinion about the acupuncture treatment: 1. Choice of acupoints; adequate, 2. Number of sessions; adequate, 3. Needling technique; adequate, 4. Acupuncturist's experience; don't know            Total follow-up period: 26 weeks            Psychotherapy procedure: 1-2 sessions per week, 2 sessions comprise 1 course (Each session was performed ahead of acupuncture)            CONTROL GROUP A INTERVENTION (sham, if used): Acupuncture only            N allocated to control group A: 50            Points selection: Flexible formula for specific symptoms            Points stimulated: ST-36, PC-6, CV-12, ST-25, LR-3, BL-20, BL-23, GV-4 / CV-8 (Moxibustion)            Total length of treatment period: 3-21 weeks            Number of sessions target (mean): 10-60</p>

Liu 1997 (Continued)

	<p>Times per week: 3          Number of points used (mean): 3-4          Insertion depth: Not stated          Was De Qi sought?: Yes          Duration (mins): 30          Method of stimulation: Manipulation          CONTROL B INTERVENTION (sham, if used): Psychotherapy only          N allocated to control group A: 50          Total length of treatment period: Not stated          Number of sessions target(mean): Not stated          Times per week: 1-2          Duration (mins): Not stated          Any co-interventions in all groups?: Moxibustion therapy (acupuncture plus psychotherapy group and acupuncture group)</p>	
Outcomes	<p>Outcomes abstracted for systematic review;          Measurement time points:          Symptoms improvement;          At the end of treatment: Improvement (3-point scoring system)          1) cured: Clinical symptoms disappeared, formed stool 1-2/day, no mucus          acupuncture alone (control): 20/50, psychotherapy alone (control): 6/50, acupuncture plus psychotherapy (treatment group): 36/50          2) improved: Clinical symptoms subsided, stool generally formed with small amount of mucus          acupuncture alone (control): 22/50, psychotherapy alone (control): 34/50, acupuncture plus psychotherapy (treatment group): 12/50          3) no effect: no symptoms change after two courses of treatment.          acupuncture alone (control): 8/50, psychotherapy alone (control): 10/50, acupuncture plus psychotherapy (treatment group): 2/50; Follow up (6 months after the treatment):          1) symptoms remain improved:          acupuncture alone (control): 9/25, psychotherapy alone (control): 4/25, acupuncture plus psychotherapy (treatment group): 12/23          2) symptoms reoccurred          acupuncture alone (control): 16/25, psychotherapy alone (control): 21/25, acupuncture plus psychotherapy (treatment group): 11/23          Type of outcome data reported: Difference in post treatment values between treatment and control groups          Author's conclusion: Acupuncture plus psychotherapy is better than either alone in the treatment of IBS.          Additional outcomes reported in the trial but not abstracted: None          Adverse effects: Not stated</p>	
Notes	<p>Comments: Acupuncture alone seems no better than psychotherapy alone          Weak point: Low research quality, small sample size</p>	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Allocation concealment?	Unclear	B - Unclear

**Lowe 2000**

Methods	<p>Design: Parallel group            Blinding: Yes (only stated)            Attempt to confirm patient blinding?: Not stated            Dropouts/withdrawals: Not stated            Jadad score: 1-0-1-1-0            LIVS score: 1-0-0.5-0.5-0.5-0            Total duration: 3month (from baseline)            Type of analysis reported: NA</p>
Participants	<p>Setting: Not stated, Canada            Mean age (+/-SD or Range): Range of 18-73 for entire population; age not provided for each arm, text states "two groups were well-matched for age"            Men/Women (n/n): 80% female in entire population; sex not provided for each arm            Recruitment method: Not stated            Duration of IBS symptoms before enrollment: NA            Diagnosis of IBS required to be eligible? (if yes, describe how patients were verified to have IBS): Yes, Rome criteria was used, but year or version was not stated.            Evaluation to rule out organic gastrointestinal disease: Not reported            Hospital inpatients? (Y/N; if Y list number inpatients): Not stated            Were people with a history of acupuncture treatment excluded?: Not stated            Other important inclusion criteria: Not stated            Important exclusion criteria: Not stated</p>
Interventions	<p>ACUPUNCTURE            N allocated to acupuncture: 28            Style of acupuncture: Chinese            Points selection: Formula            Points stimulated: Names of points were not stated            Total length of treatment period (weeks): 4            Number of sessions target (mean): 8            Times per week: 2            Number of points used (mean): 9            Insertion depth: Not stated            Was De Qi reportedly sought?: Not stated            Duration (mins): 20            Method of stimulation: Not stated            Acupuncturist's opinion about the acupuncture treatment: 1. Choice of acupoints; don't know, 2. Number of sessions; adequate, 3. Needling technique; don't know, 4. Acupuncturist's experience; don't know            Total follow-up period: 8 weeks            CONTROL GROUP A INTERVENTION (sham, if used): Sham acupuncture with blunt needles            N allocated to control group A: 22            Points selection: formula            Points stimulated: Names of points were not stated            Total length of treatment period: 4 weeks            Number of sessions target (mean): 8            Times per week: 2            Number of points used: 9            Insertion depth: 0            Was De Qi sought?: No</p>

**Lowe 2000** (Continued)

	Duration (mins): 20 Method of stimulation: None Any co-interventions in all groups?: None	
Outcomes	<p>Outcomes abstracted for systematic review; Measurement time points: Individual patient determined treatment success rate; At the end of treatment: Acupuncture group: 57%, Sham group: 45% (p=0.57) Increased Barostat rectal thresholds; At the end of treatment: Acupuncture group: 54%, Sham group: 40% (p=0.39) Improved McGill pain score (P-value for pre-post treatment change); Acupuncture group: p&lt;0.0001, Sham group: p=0.004 Improved IBS-36 score (P-value for pre-post treatment change); Acupuncture group; p&lt;0.0001, Sham; P=0.0005 Type of outcome data reported: Difference post treatment value between acupuncture and control groups/ Change from baseline reported in publication Author's conclusion: Acupuncture has no method-specific therapeutic benefit in the treatment of IBS. Additional outcomes reported in the trial but not abstracted: None Adverse effects: Not stated</p>	
Notes	<p>Comments: Improvement in pain scores and quality of life in both the treatment and control groups suggests that aspects of sham and true acupuncture may positively influence these measures - or that these are the effects of enrollment in the clinical trial. In the patients who did not attain their individual "success goals" there is no data presentation to indicate whether they experienced worsening of symptoms or adverse effects during the trial. Weak points: small sample size, lack of described information</p>	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Allocation concealment?	Unclear	B - Unclear

### Characteristics of excluded studies *[ordered by study ID]*

Chan 1997	Non-randomized pilot study with 7 patients
Gabuzian 1994	This study did not appear to be eligible based on the translated abstract, but we did not translate the full report to confirm this (Language barrier to Russian)
Kunze 1990	We could not determine whether this study was eligible based on the translated abstract (Language barrier to German)
Wang 2002	Complicated intervention: acupuncture with moxa on the tip of the needle, plus intra-rectum enema with Chinese herb solution
Xiao 2004	evaluation of the therapeutic effect of acupoint transcutaneous electrical nerve stimulation (TENS)
Yang 2000	Vit B1 point (ST-36) injection and Chinese massage

## Characteristics of ongoing studies *[ordered by study ID]*

### Ann Ouyang

Trial name or title	Effect of Acupuncture on Symptoms of Diarrhea and Pain in IBS
Methods	
Participants	36
Interventions	Acupuncture
Outcomes	Frequency of bowel movement Abdominal pain
Starting date	August 2001
Contact information	Ann Ouyang 717-531-8741 aouyang@psu.edu
Notes	

### Ted Kaptchuk

Trial name or title	Acupuncture for irritable bowel syndrome
Methods	
Participants	260
Interventions	Acupuncture
Outcomes	
Starting date	February 2004
Contact information	Ted Kaptchuk 617-384-8550 ted.kaptchuk@hms.harvard.edu
Notes	

### Ted Kaptchuk II

Trial name or title	Acupuncture for irritable bowel syndrome trial
Methods	

**Ted Kaptchuk II** (Continued)

Participants	287
Interventions	Acupuncture
Outcomes	
Starting date	
Contact information	Lisa A. Conboy 617-384-8565 lisa.conboy@hms.harvard.edu
Notes	

## DATA AND ANALYSES

### Comparison 1. Acupuncture versus sham acupuncture

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Global symptom score (Short-term outcome - end of treatment)	1	59	Std. Mean Difference (IV, Fixed, 95% CI)	0.09 [-0.43, 0.60]
2 Increased Barostat rectal sensory thresholds (Short-term outcome - end of treatment)	1	50	Risk Ratio (M-H, Fixed, 95% CI)	1.31 [0.71, 2.41]
3 Responder rate from 'Patient determined treatment success' & 'Global symptom score' (End of treatment)	2	109	Risk Ratio (M-H, Fixed, 95% CI)	1.28 [0.83, 1.98]
4 General well-being (After 1st session: i.e., Before cross-over)	1	25	Std. Mean Difference (IV, Fixed, 95% CI)	0.55 [-0.26, 1.35]
5 Abdominal pain (After 1st session: i.e., Before cross-over)	1	23	Std. Mean Difference (IV, Fixed, 95% CI)	0.73 [-0.12, 1.58]
6 Defecation difficulties (After 1st session: i.e., Before cross-over)	1	13	Std. Mean Difference (IV, Fixed, 95% CI)	0.84 [-0.32, 1.99]
7 Diarrhea (After 1st session: i.e., Before cross-over)	1	11	Std. Mean Difference (IV, Fixed, 95% CI)	0.22 [-0.97, 1.41]
8 Alternating diarrhea and constipation (After 1st session: i.e., Before cross-over)	1	14	Std. Mean Difference (IV, Fixed, 95% CI)	0.83 [-0.28, 1.94]
9 Bloating (After 1st session: i.e., Before cross-over)	1	20	Std. Mean Difference (IV, Fixed, 95% CI)	0.21 [-0.67, 1.09]
10 Symptom improvement assessed by blinded clinician (Short-term outcome - end of treatment)	1	59	Risk Ratio (M-H, Fixed, 95% CI)	1.54 [0.81, 2.94]

### Comparison 2. Ear acupuncture versus western medication

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Symptom improved (Short-term outcome - end of treatment)	1	48	Risk Ratio (M-H, Fixed, 95% CI)	1.49 [0.94, 2.34]

### Comparison 3. Acupuncture versus psychotherapy

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Symptom improved (Short-term outcome - end of treatment)	1	100	Risk Ratio (M-H, Fixed, 95% CI)	1.05 [0.87, 1.26]
2 No symptom recurrence (6 month after treatment)	1	50	Risk Ratio (M-H, Fixed, 95% CI)	2.25 [0.80, 6.36]

### Comparison 4. Acupuncture plus psychotherapy versus psychotherapy

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Symptom improved (Short-term outcome - end of treatment)	1	100	Risk Ratio (M-H, Fixed, 95% CI)	1.2 [1.03, 1.39]
2 No symptom recurrence (6 month after treatment)	1	48	Risk Ratio (M-H, Fixed, 95% CI)	3.26 [1.22, 8.69]

### Comparison 5. Acupuncture versus herbal medication

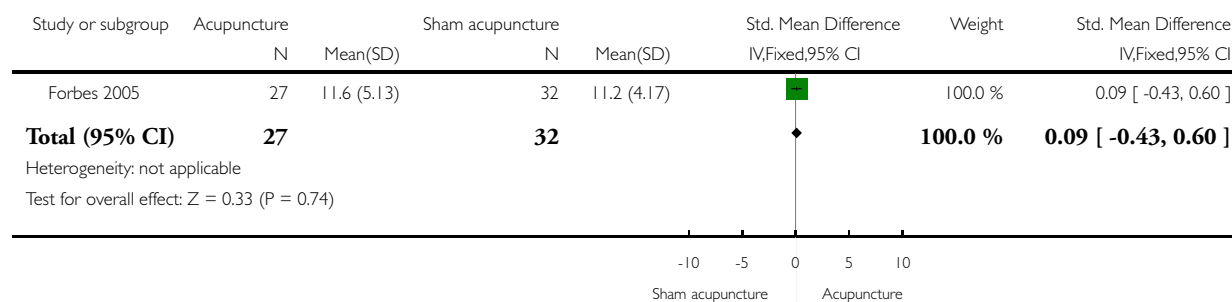
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Symptom improved (Short-term outcome - end of treatment)	1	132	Risk Ratio (M-H, Fixed, 95% CI)	1.14 [1.00, 1.31]

#### Analysis 1.1. Comparison 1 Acupuncture versus sham acupuncture, Outcome 1 Global symptom score (Short-term outcome - end of treatment).

Review: Acupuncture for treatment of irritable bowel syndrome

Comparison: 1 Acupuncture versus sham acupuncture

Outcome: 1 Global symptom score (Short-term outcome - end of treatment)

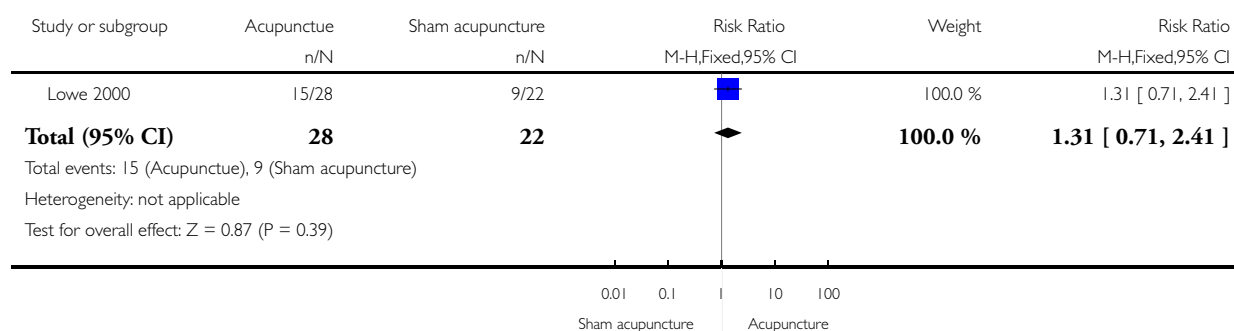


### Analysis 1.2. Comparison 1 Acupuncture versus sham acupuncture, Outcome 2 Increased Barostat rectal sensory thresholds (Short-term outcome - end of treatment).

Review: Acupuncture for treatment of irritable bowel syndrome

Comparison: 1 Acupuncture versus sham acupuncture

Outcome: 2 Increased Barostat rectal sensory thresholds (Short-term outcome - end of treatment)

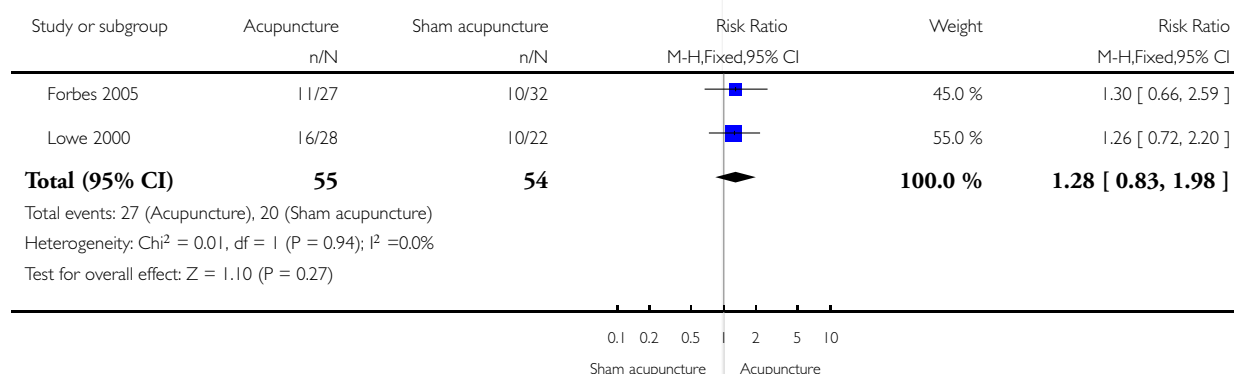


### Analysis 1.3. Comparison 1 Acupuncture versus sham acupuncture, Outcome 3 Responder rate from 'Patient determined treatment success' & 'Global symptom score' (End of treatment).

Review: Acupuncture for treatment of irritable bowel syndrome

Comparison: 1 Acupuncture versus sham acupuncture

Outcome: 3 Responder rate from 'Patient determined treatment success' % 'Global symptom score' (End of treatment)

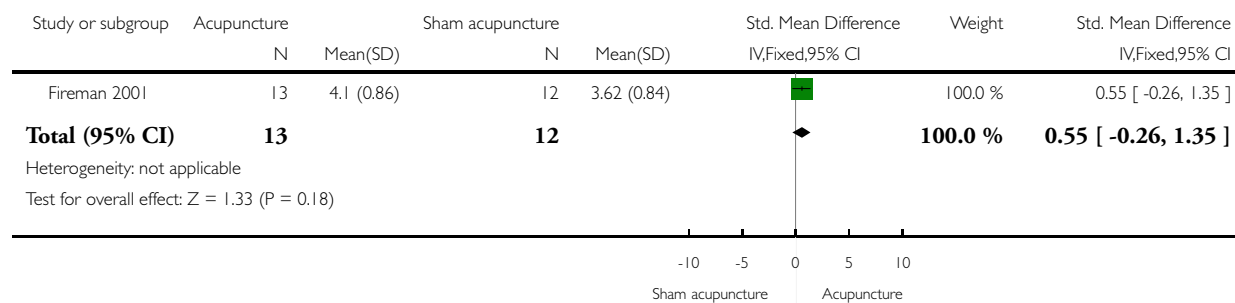


### Analysis 1.4. Comparison 1 Acupuncture versus sham acupuncture, Outcome 4 General well-being (After 1st session: i.e., Before cross-over).

Review: Acupuncture for treatment of irritable bowel syndrome

Comparison: 1 Acupuncture versus sham acupuncture

Outcome: 4 General well-being (After 1st session: i.e., Before cross-over)

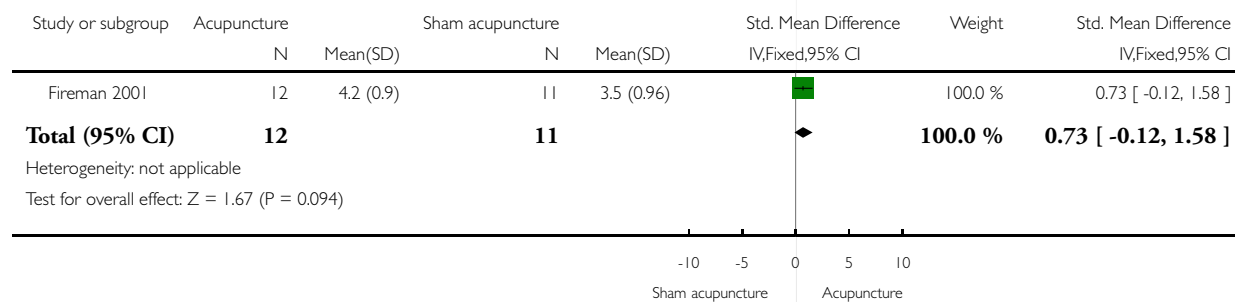


### Analysis 1.5. Comparison 1 Acupuncture versus sham acupuncture, Outcome 5 Abdominal pain (After 1st session: i.e., Before cross-over).

Review: Acupuncture for treatment of irritable bowel syndrome

Comparison: 1 Acupuncture versus sham acupuncture

Outcome: 5 Abdominal pain (After 1st session: i.e., Before cross-over)

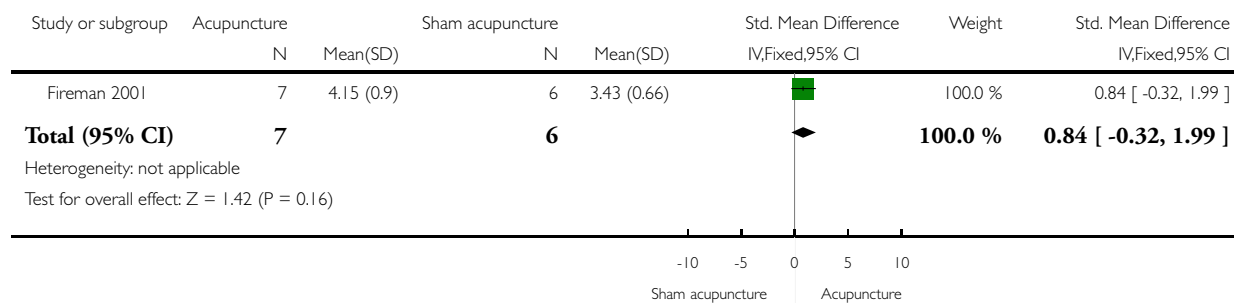


**Analysis 1.6. Comparison 1 Acupuncture versus sham acupuncture, Outcome 6 Defecation difficulties (After 1st session: i.e., Before cross-over).**

Review: Acupuncture for treatment of irritable bowel syndrome

Comparison: 1 Acupuncture versus sham acupuncture

Outcome: 6 Defecation difficulties (After 1st session: i.e., Before cross-over)

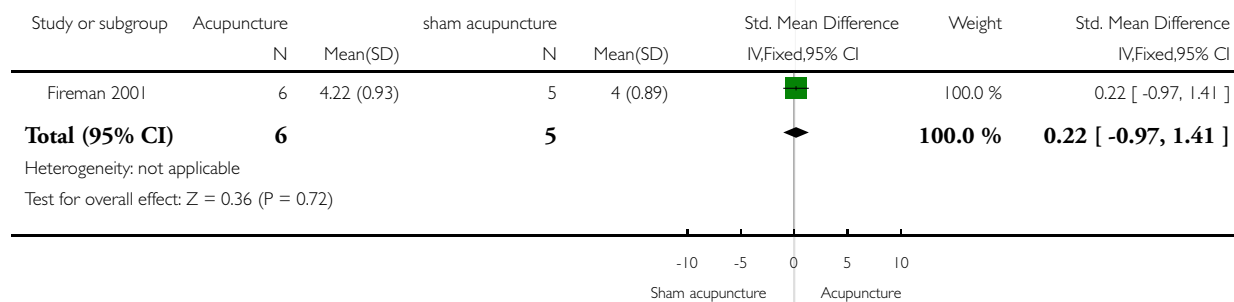


**Analysis 1.7. Comparison 1 Acupuncture versus sham acupuncture, Outcome 7 Diarrhea (After 1st session: i.e., Before cross-over).**

Review: Acupuncture for treatment of irritable bowel syndrome

Comparison: 1 Acupuncture versus sham acupuncture

Outcome: 7 Diarrhea (After 1st session: i.e., Before cross-over)

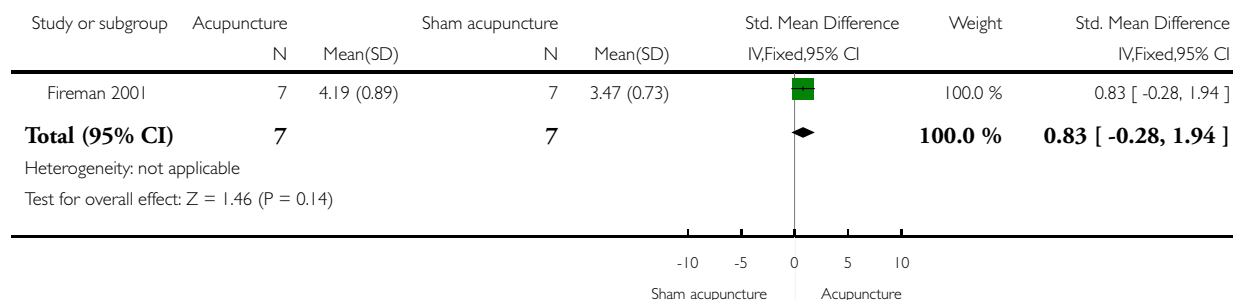


**Analysis 1.8. Comparison 1 Acupuncture versus sham acupuncture, Outcome 8 Alternating diarrhea and constipation (After 1st session: i.e., Before cross-over).**

Review: Acupuncture for treatment of irritable bowel syndrome

Comparison: 1 Acupuncture versus sham acupuncture

Outcome: 8 Alternating diarrhea and constipation (After 1st session: i.e., Before cross-over)

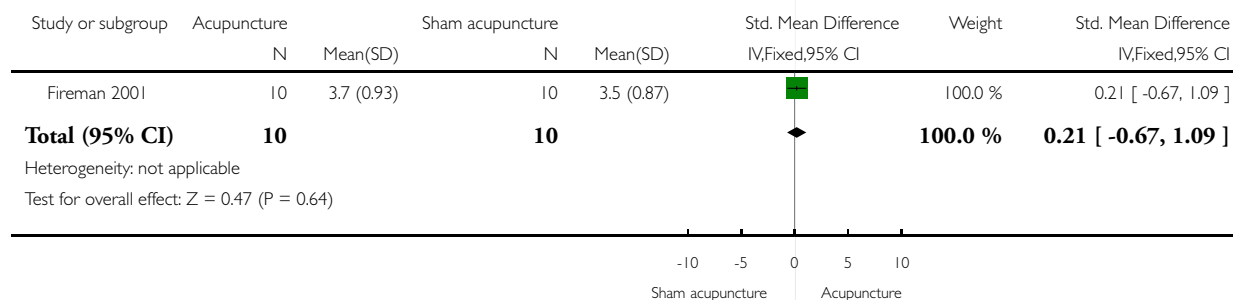


**Analysis 1.9. Comparison 1 Acupuncture versus sham acupuncture, Outcome 9 Bloating (After 1st session: i.e., Before cross-over).**

Review: Acupuncture for treatment of irritable bowel syndrome

Comparison: 1 Acupuncture versus sham acupuncture

Outcome: 9 Bloating (After 1st session: i.e., Before cross-over)

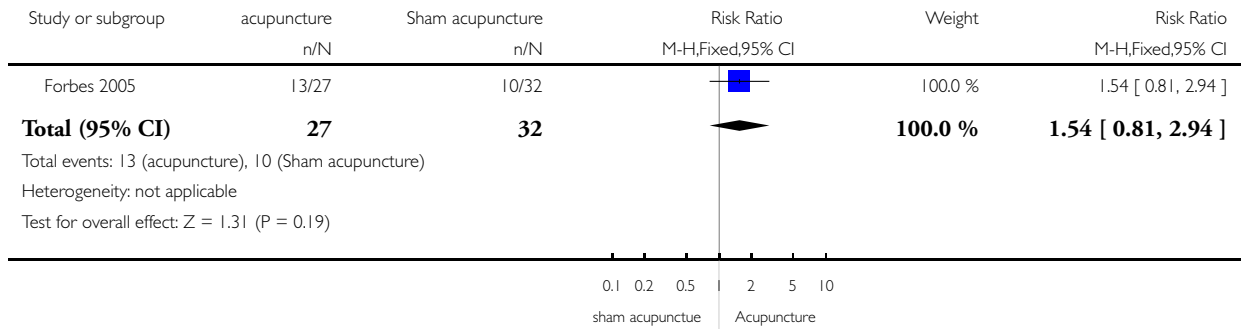


**Analysis 1.10. Comparison 1 Acupuncture versus sham acupuncture, Outcome 10 Symptom improvement assessed by blinded clinician (Short-term outcome - end of treatment).**

Review: Acupuncture for treatment of irritable bowel syndrome

Comparison: 1 Acupuncture versus sham acupuncture

Outcome: 10 Symptom improvement assessed by blinded clinician (Short-term outcome - end of treatment)

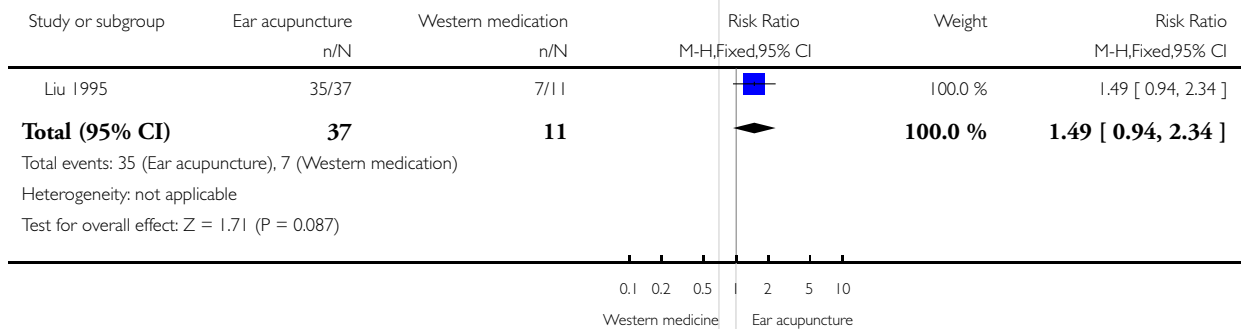


**Analysis 2.1. Comparison 2 Ear acupuncture versus western medication, Outcome 1 Symptom improved (Short-term outcome - end of treatment).**

Review: Acupuncture for treatment of irritable bowel syndrome

Comparison: 2 Ear acupuncture versus western medication

Outcome: 1 Symptom improved (Short-term outcome - end of treatment)

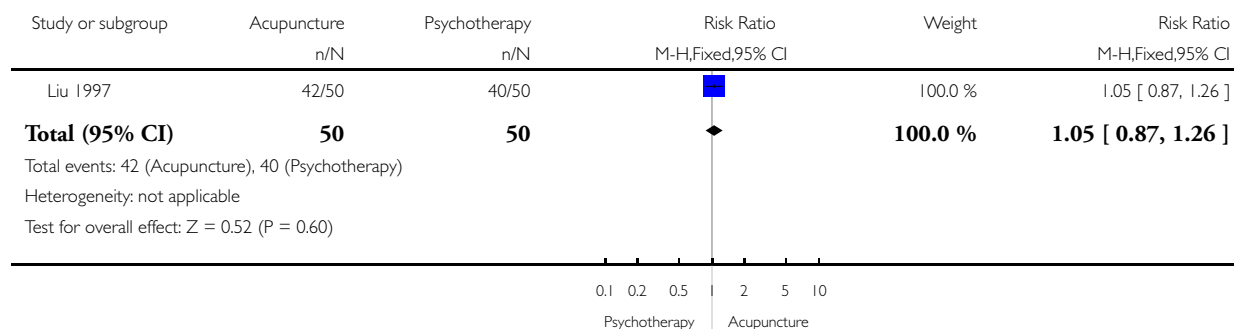


### Analysis 3.1. Comparison 3 Acupuncture versus psychotherapy, Outcome 1 Symptom improved (Short-term outcome - end of treatment).

Review: Acupuncture for treatment of irritable bowel syndrome

Comparison: 3 Acupuncture versus psychotherapy

Outcome: 1 Symptom improved (Short-term outcome - end of treatment)

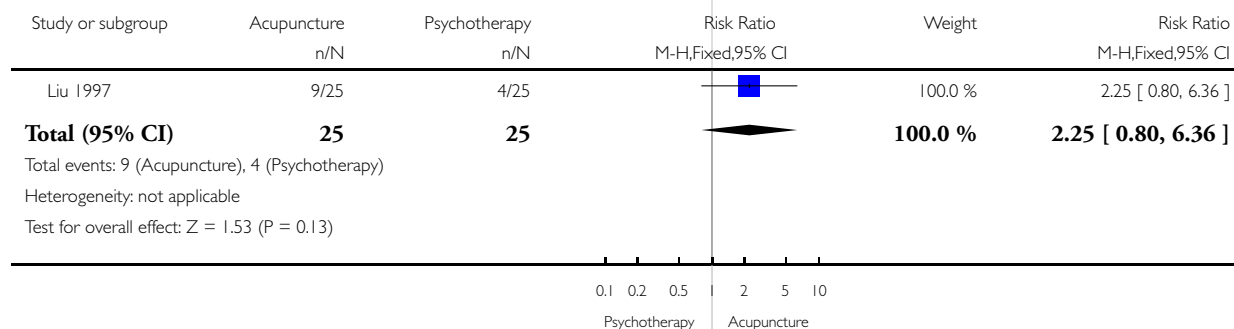


### Analysis 3.2. Comparison 3 Acupuncture versus psychotherapy, Outcome 2 No symptom recurrence (6 month after treatment).

Review: Acupuncture for treatment of irritable bowel syndrome

Comparison: 3 Acupuncture versus psychotherapy

Outcome: 2 No symptom recurrence (6 month after treatment)

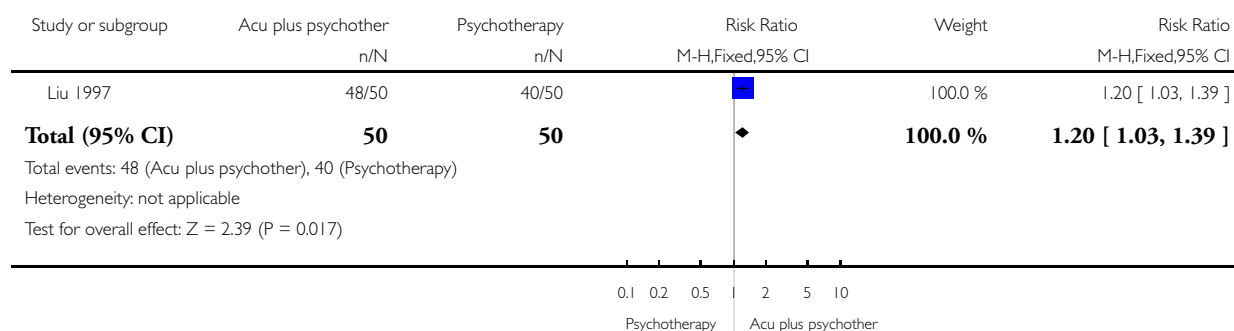


**Analysis 4.1. Comparison 4 Acupuncture plus psychotherapy versus psychotherapy, Outcome 1 Symptom improved (Short-term outcome - end of treatment).**

Review: Acupuncture for treatment of irritable bowel syndrome

Comparison: 4 Acupuncture plus psychotherapy versus psychotherapy

Outcome: 1 Symptom improved (Short-term outcome - end of treatment)

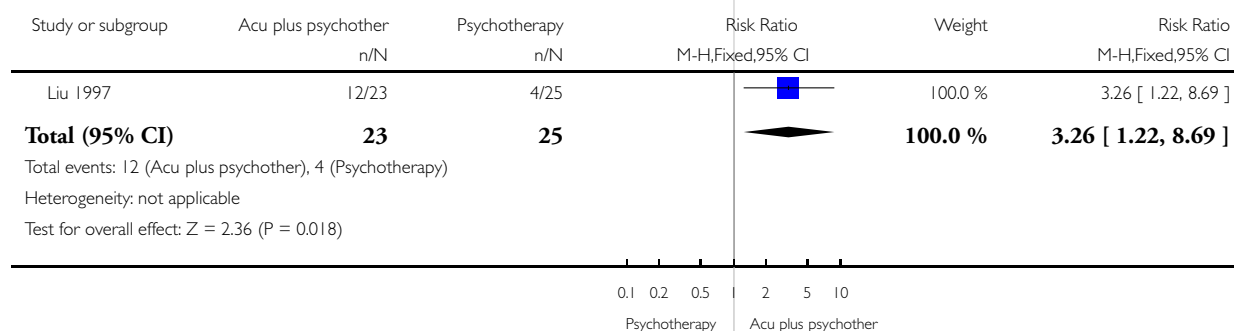


**Analysis 4.2. Comparison 4 Acupuncture plus psychotherapy versus psychotherapy, Outcome 2 No symptom recurrence (6 month after treatment).**

Review: Acupuncture for treatment of irritable bowel syndrome

Comparison: 4 Acupuncture plus psychotherapy versus psychotherapy

Outcome: 2 No symptom recurrence (6 month after treatment)

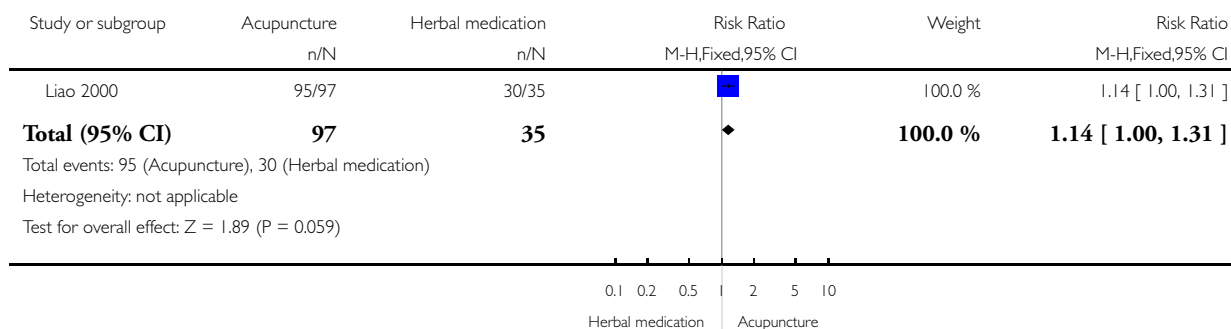


## Analysis 5.1. Comparison 5 Acupuncture versus herbal medication, Outcome 1 Symptom improved (Short-term outcome - end of treatment).

Review: Acupuncture for treatment of irritable bowel syndrome

Comparison: 5 Acupuncture versus herbal medication

Outcome: 1 Symptom improved (Short-term outcome - end of treatment)



## WHAT'S NEW

Last assessed as up-to-date: 16 August 2006.

12 June 2008	Amended	Converted to new review format.
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## HISTORY

Protocol first published: Issue 1, 2005

Review first published: Issue 4, 2006

17 August 2006	New citation required and conclusions have changed	Substantive amendment
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## CONTRIBUTIONS OF AUTHORS

Study concept and design: Eric Manheimer, Jianping Liu, Brian Berman

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Eric Manheimer and Byungmook Lim contributed equally to the preparation of this review and should officially be considered co-first authors

## **DECLARATIONS OF INTEREST**

None known

## **SOURCES OF SUPPORT**

### **Internal sources**

- No sources of support supplied

### **External sources**

- NIH National Center for Complementary and Alternative Medicine, R24 AT001293, USA.
- NIH National Center for Complementary and Alternative Medicine, 1R21 AT001943-01, USA.
- NIH National Center for Complementary and Alternative Medicine, 1U19AT003266-01, USA.
- Korea Research Foundation Grant, KRF-2005-214-E00056, Not specified.

## **INDEX TERMS**

### **Medical Subject Headings (MeSH)**

\*Acupuncture Therapy; Irritable Bowel Syndrome [\*therapy]; Randomized Controlled Trials as Topic

### **MeSH check words**

Humans