Hypnotherapy for treatment of irritable bowel syndrome (Review)

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[Intervention Review]

Hypnotherapy for treatment of irritable bowel syndrome

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ABSTRACT

Background

Irritable bowel syndrome (IBS) is a common functional gastrointestinal disorder of unknown aetiology. Current pharmacological treatments have limited value. Hypnotherapy has been reported to have beneficial effects for IBS symptoms.

Objectives

To evaluate the efficacy of hypnotherapy for the treatment of irritable bowel syndrome.

Search strategy

Published and unpublished randomised clinical trials and quasi-randomised clinical trials were identified through structured searches of MEDLINE (1966 to March 2006), EMBASE (1980 to March 2006), PsycINFO (1806 to March 2006), CINAHL (Cumulative Index to Nursing and Allied Health Literature, 1982 to March 2006), AMED (Allied and Complementary Medicine Database, 1985 to March 2006) and The Cochrane Central Register of Controlled trials. Conference proceedings from Digestive Disease Week (1980 to 2005) were also searched.

Selection criteria

Eligible studies included all randomised and quasi-randomised clinical studies comparing hypnotherapy for the treatment of irritable bowel syndrome with no treatment or another therapeutic intervention.

Data collection and analysis

All studies were evaluated for eligibility for inclusion. Included studies were assessed for quality and data were extracted independently by four authors. The primary outcome measure of interest was the overall bowel symptom severity score which combines abdominal pain, diarrhoea or constipation and bloating. Secondary outcomes included abdominal pain, diarrhoea, constipation, bloating, quality of life, patient's overall assessment of well-being, psychological measures as per validated questionnaires, and adverse events.

Main results

Four studies including a total of 147 patients met the inclusion criteria. Only one study compared hypnotherapy to an alternative therapy (psychotherapy and placebo pill), two studies compared hypnotherapy with waiting-list controls and the final study compared

hypnotherapy to usual medical management. Data were not pooled for meta-analysis due to differences in outcome measures and study design. The therapeutic effect of hypnotherapy was found to be superior to that of a waiting list control or usual medical management, for abdominal pain and composite primary IBS symptoms, in the short term in patients who fail standard medical therapy. Harmful side-effects were not reported in any of the trials. However, the results of these studies should be interpreted with caution due to poor methodological quality and small size.

Authors' conclusions

The quality of the included trials was inadequate to allow any conclusion about the efficacy of hypnotherapy for irritable bowel syndrome. More research with high quality trials is needed.

PLAIN LANGUAGE SUMMARY

Hypnotherapy (treatment by hypnosis) for the treatment of irritable bowel syndrome

Studies of hypnotherapy for treatment of IBS.

Only a small number of studies of hypnotherapy have been performed and the way these studies were carried out was not up to a high standard. Hypnotherapy was either compared with standard treatment of IBS, with supportive psychotherapy (discussion of symptoms and possible contributing emotional problems and stressful life events) or with no treatment in patients on a waiting list to be seen by a specialist.

What is IBS and could hypnotherapy work as treatment?

IBS is a common gastrointestinal disorder characterized by chronic abdominal pain and an abnormal pattern of bowel movements (i.e. diarrhea, constipation or mixed diarrhea and constipation). Hypnotherapy could provide benefit for IBS, by affecting parts of the brain that experience abdominal pain or influence the movement of the bowel.

What did the studies show?

The studies provide some evidence that suggests that hypnotherapy might be effective in treating IBS symptoms including abdominal pain. However the results of these studies should be interpreted with caution due to poor study quality and small size.

How safe is hypnotherapy?

Hypnotherapy was well tolerated and no serious side effects were reported in the studies.

What is the bottom line?

Although current data are promising, there is insufficient evidence to allow any conclusion about the effectiveness of hypnotherapy for the treatment of IBS. More research with well designed studies is needed.

BACKGROUND

Irritable bowel syndrome (IBS) is a common gastrointestinal disorder of unknown aetiology characterized by a chronic and relapsing course of abdominal pain or discomfort associated with disturbed defecation (Drossman 2006a; Drossman 2006b). It can also be classified on the predominant symptom i.e. diarrhoea, constipation or mixed diarrhoea and constipation. Its prevalence is similar in most industrialized countries (USA, Britain) affecting 14-24% of women and 5-19% of men (Drossman 1997). It is the most common gastrointestinal disorder diagnosed by gastroenterologists in the United States where IBS patients comprise 28% of all patients seen (Mitchell 1987). In the United States alone, the economic impact is estimated at $25 billion annually through direct costs of health care use and indirect costs such as work absenteeism (Camilleri 2000). IBS is a serious disorder that can cause a significant impairment of quality of life, comparable to that of patients with chronic renal failure or complicated diabetes (Gralnek 2000). There is a need to develop more effective treatment for this large affected population.

Recent research suggests that irritable bowel syndrome may have an organic component and therefore should not be dismissed as a "functional" or "non-organic" entity (Talley 2002). IBS is considered to be a biopsychosocial disorder where the mind and the body are part of a system where their dysregulation can produce illness (the persons experience of ill health) and disease. One model of functional gastrointestinal disorders conceptualises it as follows: affected individuals, who early in life, together with their genetic makeup, may be primed for developing IBS because of the occurrence of adverse environmental influences on psychosocial development. These environmental factors could include family influence on illness expression, abuse, major losses or exposure to infections, which may affect ones psychosocial development in terms of an individuals susceptibility to life stress or psychological state and coping skills, as well as susceptibility to gastrointestinal dysfunction, abnormal motility, altered mucosal immunity or visceral hypersensitivity. In other words, an individual with adaptive coping skills and illness behaviours may not develop the clinical syndrome of IBS (or be aware of it) or if it does develop may not seek medical attention. However another individual who has co-existent psychosocial co-morbidities, high life stress, abuse history, or maladaptive coping, may develop a syndrome (e.g. post infectious IBS), go to the physician frequently and generally have a poorer outcome (Drossman 2006a). It is, as if the maladapted individual, seeks reassurance from an external source (i.e. healthcare provider) as this ability to adaptively interpret physiological symptoms has not been modelled or has not developed or cannot occur due to current psychosocial comorbidity. Other processes which may be important in the pathophysiology of IBS include serotonin dysregulation (Coates 2004),central nervous system pain dysregulation (Mayer 2005) and bacterial overgrowth (Lin 2004).

Current pharmacological treatments are targeted at symptom control and have limited value (Jones 2000). No single drug is effective in relieving all of the symptoms of IBS over a sustained period of time. It is also well known that the immediate placebo response is high (averaging 47%) and is not sustained (Jones 2000). This leads to repeated medical consultations.

A meta-analysis of trials for the treatment of irritable bowel syndrome found the following (Lesbros 2004):

1) Most trials with antispasmodics were methodologically flawed and the clinical evidence supporting their use is weak.

2) Alosetron, a selective 5HT3 receptor antagonist, is recommended for women with severe diarrhoea predominant IBS who have failed conventional therapy. Tegaserod, a partial 5- HT4-receptor agonist was recommended for women with constipation predominant IBS (however subsequent to the publication of this systematic review tegaserod was removed from the market in March 2007 because of cardiovascular adverse events).

2) Antidepressants are recommended for diarrhoea predominant IBS with severe refractory symptoms.

3) There is not enough evidence to recommend the use of bulking agents in IBS except as adjuvants in painless constipation.

4) Loperamide, an anti-diarrhoeal agent, is effective for painless diarrhoea.

5) The use of prokinetic agents, stimulating laxatives, peppermint oil or benzodiazepines is not recommended in IBS.

6) Current studies do not support the routine use of probiotics in IBS patients.

7) Elimination diet cannot be recommended except in patients with proven food intolerance.

8) The role of psychotherapy in IBS has not been established.

Hypnotherapy:

Hypnotherapy may provide benefit for IBS, possibly due to its effects on central nervous system pain processing regions (Rainville 1997).

Hypnotherapy was first used in medicine during the nineteenth century as an anaesthetic for orthopaedic surgery. Hypnotic capacity is defined as, "the ability to focus narrowly and intensify one's concentration and perception while reciprocally diminishing awareness of all other stimuli" (Sugarman 1996). It appears that during this state the conscious critical mind is placed "on hold" and therapeutic suggestions can more readily be accepted and incorporated into the subconscious mind. The individual may then modulate some physiological processes previously thought to be only under involuntary control.

Hypnosis has been used successfully for a number of conditions in childhood including reducing nausea and vomiting associated

with chemotherapy, reducing pain and anxiety during painful procedures and reducing the frequency of childhood migraine (Zeltzer 1984; Dinges 1997; Olness 1987). Hypnosis has also been shown to enable children to modulate physiological processes such as increasing the production of salivary immunoglobulin A (Sugarman 1996).

In adults hypnotherapy has been shown to alter a number of physiological mechanisms. Suggestion of relaxation by hypnosis has resulted in a significant reduction of unstimulated as well as betazole stimulated acid secretion and a decrease in gastric motility (Stacher 1975).

Hypnotherapy has been studied for the treatment of irritable bowel syndrome in a number of randomised controlled trials in adults (Whorwell 1984; Galovski 1998; Forbes 2000; Palsson 2002a; Palsson 2002b; Simren 2004; Roberts 2006; Whorwell 1984).

OBJECTIVES

To evaluate the efficacy of hypnotherapy for the treatment of irritable bowel syndrome.

METHODS

Criteria for considering studies for this review

Types of studies

Eligible studies include all randomised and quasi-randomised clinical studies comparing hypnotherapy for the treatment of irritable bowel syndrome with no treatment or another therapeutic intervention. Studies comparing two types of hypnotherapy for IBS were not included. Quasi randomised studies are those studies which are intended to be randomised by using methods of allocation such as alternation, date of birth, or case record number.

Types of participants

Male or female patients, of any age or ethnic origin, who had been diagnosed with IBS and who did not have an organic cause for their gastrointestinal symptoms. IBS can be diagnosed on the basis of one of the following three criteria:
Manning criteria (abdominal pain relieved with defecation, looser and/or more frequent stools with the onset of pain and abdominal distension (Manning 1978));
Rome I criteria (at least three months of continuous or recurrent symptoms of abdominal pain or discomfort that is relieved with defecation; and/or associated with a change in frequency of stool; and two or more of the following, at least on one-fourth of occasions or days: altered stool frequency, stool form, and stool passage, passage of mucus; and/or bloating or feeling of abdominal distension (Thompson 1989)); or
Rome II criteria (at least 12 weeks, not necessarily consecutive, in the preceding 12 months, of abdominal discomfort or pain that has two of three features: relieved with defecation, and/or onset associated with a change in frequency of stool; and/or onset associated with a change in form/appearance of stool (Thompson 1999)).

Types of interventions

Interventions which involve hypnotherapy versus a control therapy such as standard medical therapy, psychological therapies (e.g. cognitive behavioral, psychotherapy or counseling), no treatment or wait-list controls were considered for inclusion.
It was required that the trials should describe the methods of the intervention to ascertain that hypnotherapy was performed rather than guided imagery or a relaxation technique. In addition, if studies were not explicit as to the specific elements used in the hypnotic technique but stated that hypnotherapy was performed, these too will be included. A tape may be provided for reinforcement of the session.

Hypnotherapy should be performed by an appropriately qualified therapist and incorporate most of the following principals:
i. education and testing of hypnotic susceptibility in the subject, explanation of hypnosis and discussion of common misconceptions;
ii. performance of an induction procedure, such as using eye fixation;
iii. deepening techniques, such as progressive muscular relaxation and/or breathing relaxation;
iv. therapeutic suggestions, such as guided imagery, anchoring techniques and ego-strengthening (post-hypnotic suggestions can also be used especially to facilitate self hypnosis), and gut focussed scripts may be specifically used to target bowel symptoms; and
v. an alerting phase, involving orientation to the surroundings.

Types of outcome measures

The primary outcome measure of interest was the mean change in the overall bowel symptom severity score which combines abdominal pain, diarrhoea or constipation and bloating. Although the overall assessment of patients' well being is often used as the primary outcome in drug trials of IBS, the overall bowel symptom severity score is more commonly used in trials assessing psychological treatments for IBS. Secondary outcomes include mean changes in individual symptoms of abdominal pain, diarrhoea, constipation, bloating, quality of life, patient's overall assessment of well-being, psychological measures as per validated questionnaires, and adverse events.

Search methods for identification of studies

A. Electronic searching
Relevant randomised clinical trials and quasi-randomised clinical trials were found through structured searches of MEDLINE (1966 to March 2006), EMBASE (1980 to March 2006), PsycINFO

(1806 to March 2006), CINAHL (Cumulative Index to Nursing and Allied Health Literature, 1982 to March 2006), AMED (Allied and Complementary Medicine Database, 1985 to March 2006) and The Cochrane Central Register of Controlled trials.
The Cochrane Complementary Medicine Field was also contacted for additional citations. This entity within the Cochrane Collaboration focuses on unconventional interventions for preventing ill health, or promoting health.
The details of the search strategy were as follows:
MeSH headings:
Colonic diseases/or colonic diseases, functional/or irritable bowel syndrome/exp hypnosis
Text words:
Irritable bowel.mp
Hypnotherp$ or hypnos$ or mesmerism$ or imagery$ or autohypnos$ or auto hypnos$.mp
The above search terms were combined with the Cochrane expert search filter for randomized controlled trials:
1. randomized controlled trial.pt.
2. randomized controlled trials/
3. random allocation/
4. controlled clinical trial.pt.
5. clinical trial.pt.
6. exp clinical trials/
7. (clin$ adj5 trial$).tw.
8. double blind method/
9. single blind method/
10. ((singl$ or doubl$ or trebl$ or tripl$) adj5 (blind$ or mask$)).tw.
11. placebos/
12. placebo$.tw.
13. random$.tw.
14. research design/
15. follow up studies/
16. exp evaluation studies/
17. prospective studies/
18. retrospective studies/
19. comparative study/
20. Cross-Sectional Studies/
21. (control$ or prospectiv$ or volunteer$).tw.
22. or/1-21
The search filter and MeSH headings were adapted for each database used.
B. Reference searching
The references of all identified studies were also inspected for more trials.
C. Personal contact
The first author of each included study was contacted for information regarding unpublished trials.
D. Conference proceedings /hand searching
Hand searching of conference proceedings from Digestive Disease Week (1980 to 2005) was also conducted.
Studies in languages other than English were included and duplicate publications of the same trial were identified through reading the articles in question and contacting the authors if required.

Data collection and analysis

Study selection:
Four authors independently screened the titles of abstracts resulting from the literature searches. Study eligibility for inclusion in the review were assessed against defined criteria. Any disagreement amongst authors was resolved by consensus agreement and/or discussion with the Cochrane IBD/FBD review group.
Quality assessment:
The quality of included trials was assessed by examining the individual attributes of the trials rather than giving trials an overall quality score.
Study quality was assessed using the following criteria:
i. generation of the random sequence: adequate (computer generated random numbers, table of random numbers or similar) or inadequate (other methods or not described);
ii. allocation concealment: adequate (central independent unit, sealed envelopes, or similar) or inadequate (not described or open table of random numbers or similar), or not used;
iii. blinding: adequate (identical or similar therapies) or inadequate (placebo not performed or no comparator described). Blinding of participants, study investigations and assessors to be recorded; and
iv. follow-up: adequate (number and reasons for drop-out and withdrawal) described or inadequate (number or reasons for drop-outs or withdrawals not described).
Data extraction:
Each author independently extracted data from the included studies. Any disagreement among reviewers was resolved by consensus agreement. Authors of primary studies were contacted to clarify necessary data and to provide missing information.
Statistical analysis:
RevMan was used to analyse data. Analyses were performed by intention to treat where possible.
All of the outcome measures studied were continuous variables. Therefore, the standardised mean difference (SMD) and 95% confidence intervals were used to compare different measurement scales of the same outcome.
If studies compared outcome measures by using exactly the same measures or scales the weighted mean difference (WMD) with 95% confidence intervals were used to assess the effect of treatment between groups.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies.

The literature search identified 25 relevant studies. Twenty one studies identified on review of abstracts were excluded on review of the full text publication (Table of characteristics of excluded studies). Fifteen studies (Flammer 2003; Gonsalkorale 2003; Gonsalkorale 2004; Houghton 1996; Lea 2003; Palsson 2006; Prior 1989; Roy 1995; Schafer 1997; Stockbrugger 1999; Taylor 2004; Vidakovic-Vukic 1999; Whorwell 1987; Whorwell 1991; Zimmerman 2003) were not randomised controlled studies. Five studies were observational studies of patients with IBS evaluated before and after hypnotherapy (Gonsalkorale 2004; Lea 2003; Prior 1989; Taylor 2004; Vidakovic-Vukic 1999). In one of these observational studies IBS patients were compared to control patients with IBS (Prior 1989). Three papers (Flammer 2003; Roy 1995; Whorwell 1991) presented reviews of hypnotherapy in IBS and gastrointestinal disorders whilst one paper (Stockbrugger 1999) discussed psychological and psychiatric factors in IBS. One paper presented a case series of hypnosis for inflammatory bowel disease (Schafer 1997). Zimmerman 2003 presented a case study of hypnotherapy for IBS. Four studies compared two types of hypnotherapy for IBS (Barabasz 2006; Flammer 2003; Palsson 2002b; Harvey 1989). These studies were excluded as the purpose of this review was to compare hypnotherapy with another type of therapy or placebo/wait-list control. Three studies were follow-up studies assessing the efficacy of hypnotherapy in a cohort of patients after a period of time, rather than randomised controlled studies (Gonsalkorale 2003; Houghton 1996; Whorwell 1987). One study did not include hypnotherapy as an intervention (Boyce 2003). Four randomised trials (Whorwell 1984; Galovski 1998; Palsson 2002a; Roberts 2006) including 147 adult patients were identified and included in the review (Table of characteristics of included studies). No quasi-randomised studies were identified.

The included studies evaluated the treatment of irritable bowel syndrome with hypnotherapy. Whorwell 1984 compared hypnotherapy to supportive psychotherapy. Two studies compared hypnotherapy to wait-list controls (Palsson 2002a; Galovski 1998). Roberts 2006 compared the combination of hypnotherapy and usual medical therapy with usual medical therapy alone. All studies used gut focussed hypnotherapy; two studies (Palsson 2002a; Galovski 1998) used scripts based on the hypnosis techniques developed by Whorwell 1984. In the Whorwell 1984 study, hypnotherapy consisted of seven half hour sessions over a three month period. In the Palsson 2002a study, hypnotherapy was performed for seven 45 minute sessions over 12 weeks. In the Galovski 1998 study 12 half hour to one hour sessions were performed over 12 weeks. In the Roberts 2006 study hypnotherapy was performed for five weekly 30 minute sessions.

All patients were independently diagnosed with IBS by their gastroenterologist or treating physician. Patients had symptoms for at least 6 months in two studies (Palsson 2002a; Galovski 1998). Eligible patients in the Roberts 2006 study had been consulting their general practitioner for IBS for more than 6 weeks, and had failed to manage their symptoms using one or more conventional treatments. In the Whorwell 1984 study, patients had been under the care of their physician for 12 months and had not responded to any previous therapy. Rome 1 criteria were applied to patients for the diagnosis of IBS in the Palsson 2002a study. Correspondence with the primary author of the Galovski 1998 study clarified that Rome criteria had been used to diagnose patients with IBS. In the Whorwell 1984 study, IBS was defined by the presence of abdominal pain, a disordered bowel habit (diarrhoea, constipation, or alternating diarrhoea and constipation) and abdominal distension. The Whorwell 1984 study predated the Rome criteria. For the Roberts 2006 study, IBS was independently diagnosed by a gastroenterologist but the criteria used to make the diagnosis were not stated. Correspondence with the primary author, clarified that the Rome criteria were not applied to the study population. The author stated that the study was to be primary care based and therefore a general practitioner diagnosis of IBS was used. This was deemed important by the author to enable generalisability to the primary care population. GP diagnosis had to have been given more than 6 weeks prior to enrolment and patients had to have tried at least one conventional therapy and failed to manage symptoms adequately. However the clinical signs, symptoms or investigations used to diagnose IBS by GPs were not provided and therefore the exact nature of the IBS diagnosis is unclear.

Outcome measures differed between the studies (see Table of characteristics of included studies). In the Whorwell 1984 study all patients were asked to keep a diary card, on which they recorded the daily frequency and severity of abdominal pain and abdominal distension. The severity items were scored as follows: 0 = none, 1 = mild, 2 = moderate and 3 = severe. Bowel habit and general wellbeing were also recorded and abnormality expressed on a similar 0 to 3 scale. The data for 7 days were totaled and the scores analysed separately using repeated analysis of variance. Post therapy comparisons were made by means of a Tukey multiple comparison test and were adjusted for pre-treatment levels. Galovski 1998 assessed change in the Composite Primary Reduction Score (CPRS). The CPRS equals the diarrhoea reduction score + constipation reduction score, divided by 2 (or 3) depending on the number of primary symptoms present. The diarrhoea reduction score equals the average pretreatment diarrhoea ratings minus the average post treatment diarrhoea ratings divided by the average pretreatment diarrhoea ratings. Palsson 2002a evaluated 14 day diary symptom scores at each assessment time period (baseline, 2 weeks after completing treatment and 4 months later) for abdominal pain, bloating, proportion of hard/loose stools per day and bowel movement frequency. Roberts 2006 assessed a composite symptom score containing three dimensions (pain, constipation and diarrhoea) and an IBS-specific quality of life measure with eight dimensions (dysphoria, interference with activity, body image, health worry, food avoidance, social reaction, sexual function, and relationships) at baseline, 3, 6, and 12 months post -randomi-

sation.

Risk of bias in included studies

The quality of included trials is shown in table of characteristics of included studies.

SELECTION BIAS

The four randomised controlled trials (RCTs) were assessed for allocation concealment. Three studies (Whorwell 1984; Galovski 1998; Palsson 2002a) were not clear with respect to randomisation methods and so the primary authors were contacted to clarify this. Correspondence with the primary author of the first study (Whorwell 1984) clarified that randomisation was performed by using a sealed envelope with the treatment allocation inside. This method was deemed adequate (A) for allocation concealment. Correspondence with Palsson 2002a revealed that randomisation was conducted using a randomisation computer program, and used immediately after individuals had completed a consent form and had formally enrolled in the study. Allocation concealment was unclear in the Palsson 2002a study. Correspondence with the primary author of the Galovski 1998 study revealed that both names of each matched pair in the study were put into a "hat" and the first name drawn was randomised to the control condition .These names were drawn by an independent person not associated with the study. The process was repeated until all members of each pair were assigned. This method was not optimal (C) for ensuring adequate allocation concealment. In the final study (Roberts 2006) blocked randomisation was by sealed envelope and was overseen in all clinics by both a consultant gastroenterologist and one of the research team. This method was deemed adequate (A) for ensuring allocation concealment.

DETECTION BIAS

The blinding of patients and investigators was not used in the Palsson 2002a study. However as symptom ratings were completed at home daily by patients over a two-week period, these outcome measures were not influenced by the investigators judgement or bias. The primary author was the assessor and the therapist in the Galovski 1998 study and therefore was not blinded to outcome measures. This introduces the potential for detection bias in this study. In the Roberts 2006 study author correspondence confirmed that outcomes were patient completed (returned by post) and therefore no assessor was involved. In the Whorwell 1984 study author correspondence clarified that the person performing the outcome assessments undertook them completely blind to what treatment the patient was receiving.

ATTRITION BIAS

Three studies (Galovski 1998; Palsson 2002a; Roberts 2006) documented reasons for exclusion and numbers of dropouts that were lost to follow-up. Whorwell 1984 specified inclusion criteria but no exclusion criteria. Correspondence with the author clarified that there no dropouts.

PERFORMANCE BIAS

The blinding of the clinician to treatment allocation in studies of hypnotherapy would not be feasible due to the nature of the intervention and the fact that the operator cannot be blinded to the specific clinical technique that they are performing on the patient. It is possible that an independent clinician not involved in the study or responsible for measuring or analysing outcome variables may limit bias. This did not occur in any of the included studies and the therapist performing hypnotherapy was also the person assessing outcome variables and analysing data. Therefore there is the potential for performance bias. The blinding of patients was not feasible due to the nature of the intervention. In the Roberts 2006 study the patient's general practitioner was also informed of the randomisation arm and requested to continue usual management for all participants, as the effectiveness of hypnotherapy was being assessed as a complementary, rather than an alternative therapy. However, this could introduce the potential for bias on the part of the general practitioner depending upon whether they have an affinity or aversion to hypnotherapy. Correspondence with the author of this study (Roberts 2006) indicated that outcomes were patient completed and returned by post and therefore no assessor was involved. In the Whorwell 1984 study author correspondence clarified that the same therapist performed the hypnotherapy as well as the supportive psychotherapy. The potential for bias with this method was acknowledged by the author as it is conceivable that if the same practitioner performs both hypnotherapy and psychotherapy, bias may be introduced into one arm of the study depending on which therapy the practitioner favoured.

ADDITIONAL QUALITY ASSESSMENT

Sample size calculation: Three trials did not report a sample size calculation (Whorwell 1984; Galovski 1998; Palsson 2002a). In the Roberts 2006 study a sample size calculation was performed. Using previous estimates of variance for quality of life (Drossman 2000) it was calculated that 50 patients in each arm would enable a medium change in scores (standard difference = 0.60) to be detected with 90% power at the 5% significance level, that is, a change in mean quality of life score from 63 to 77.

Definition of inclusion/exclusion criteria: Inclusion and exclusion criteria were stated clearly in the Palsson 2002a and Roberts 2006 studies. Exclusion criteria were not clearly stated in the Whorwell 1984 and Galovski 1998 studies. Correspondence with Galovski 1998 clarified that patients were diagnosed with IBS by their physicians using Rome criteria. In the Roberts 2006 study IBS was independently diagnosed by a gastroenterologist but the criteria used to make the diagnosis were unclear.

Completeness of follow-up: There were no dropouts and all patients completed the trial in the Whorwell 1984. A 20% drop-out rate was reported in the Palsson 2002a study. In the Galovski 1998 study reasons for drop-outs were provided. Numbers and reasons for exclusions and dropouts were stated in the Roberts 2006 study.

Control and treatment groups comparable at entry: Although

the study by Galovski 1998 had a small sample size (n = 12) the study design ensured that all patients were matched for concurrent psychiatric diagnoses, susceptibility to hypnosis and various demographic factors. In the Palsson 2002a study all patients were similar and had IBS for at least one year and fulfilled Rome criteria. In the Roberts 2006 study all patients had been consulting their general practitioner for IBS for more than six weeks. It is uncertain that control and treatment patients were matched in terms of clinical criteria for IBS.

Experience of the therapist: The level of experience of the therapist performing hypnotherapy was clearly stated in three studies (Galovski 1998; Palsson 2002a; Roberts 2006). This was not clearly stated in the Whorwell 1984 study. However the therapeutic hypnosis technique was described in detail and the scripts and style of hypnotherapy have subsequently has been used by several other studies.

Type of hypnotherapy used: "Gut directed" hypnotherapy was performed in all four studies (Whorwell 1984; Galovski 1998; Palsson 2002a; Roberts 2006). Gut directed hypnotherapy refers to specific suggestions being included in the scripts that were directed to symptoms within the gastrointestinal tract in addition to general ego-strengthening type suggestions. Hypnotic induction in the Palsson 2002a study was conducted verbatim following written scripts developed by one of the authors. A script partly modelled on the hypnosis techniques developed by Whorwell 1984 was then used to provide hypnotic gut specific suggestions, overall physical relaxation, reduced perception of life threat and lessened attention to gut discomfort. The Galovski 1998 study utilized a hypnotherapy script provided by Whorwell 1984 and therefore attempted to replicate Whorwell's original study. Hypnosis was induced in the Roberts 2006 study using a standard preliminary hypnotic induction technique (usually eye fixation) followed by standard deepening procedures. Therapeutic hypnotic suggestions were patient directed, with visualisations used according to the patient's predominant symptoms. Patients were encouraged to use images that they felt comfortable with and represented the symptoms they experienced. All four studies gave patients tapes of the sessions to practice daily auto-hypnosis at home.

Effects of interventions

Four studies including a total of 147 patients met the inclusion criteria for the review, although their methodological quality was low. Data were not pooled for meta-analysis due to differences in outcomes and study design. The primary outcome measure of interest for this review was the mean change in the overall bowel symptom severity score which combined the primary symptoms of IBS: abdominal pain, diarrhoea or constipation and bloating. Although the overall assessment of patients' well being is often used as the primary outcome in drug trials of IBS, the overall bowel symptom severity score is more commonly used in trials assessing psychological treatments for IBS (Francis 1997). Two studies utilized overall symptom severity scores (Roberts 2006; Galovski 1998). Data were not pooled for this outcome because different parameters were used to calculate the scores. Secondary outcomes included changes in individual symptoms of abdominal pain, diarrhoea, constipation, bloating, quality of life, patient's overall assessment of well-being, psychological measures as per validated questionnaires, and adverse events.

The Whorwell 1984 study compared hypnotherapy with supportive psychotherapy. The supportive psychotherapy group received a placebo tablet and 7 half hour sessions of supportive psychotherapy. The hypnotherapy group was treated with seven half hour sessions of hypnotherapy of decreasing frequency over a three month period. Patients were given a tape of their hypnotherapy session after the third visit to continue practicing at home between sessions. Whorwell 1984 reported a benefit in the hypnotherapy group at 3 months for abdominal pain, bowel habit, abdominal distension and general well being. Correspondence with the author revealed that the data were not available for analysis. The study was performed over 20 years ago and the data were stored on discs which are not compatible with todays technology. Also hard copies of the data were destroyed when the hospital changed sites.

In the Galovski 1998 study one patient in each of six matched pairs was randomly assigned to a hypnotherapy treatment arm or a wait-list control arm where symptoms were monitored for six weeks. This control group was then crossed over to the treatment arm after six weeks. The primary outcome was a composite measure of IBS symptoms (CPRS) and showed that treatment was superior to symptom monitoring. Using the daily symptom monitoring diaries, a single index, called the Composite Primary Symptom Reduction (CPSR) score, was calculated following the method of Blanchard and Schwartz (Blanchard 1988). This score is an index of overall change in symptom level and also provides a means for describing clinically significant improvements in symptomatology. One patient in the treatment group dropped out due to a change in diagnosis and was not included in the statistical analysis. Results from the treatment condition (n = 5) revealed that three subjects (60%) were improved, one subject (20%) was somewhat improved, and one subject (20%) was unimproved. The symptom monitoring condition's (n = 6) results revealed that all six subjects were unimproved. The hypnotherapy subjects (n = 5) were found to be significantly (P = 0.0005) more improved (CPSR score of -0.55 and SD = 0.33) than the symptom monitoring wait-list controls (CPSR score of 0.32 and SD = 0.49) with a WMD of -0.87 and a 95% CI of -1.36 to -0.38.

Patients in the Palsson 2002a study were randomly assigned to immediate hypnotherapy (IM, n = 15) or delayed hypnotherapy (DL, n = 15) a waiting list control. Six patients in the DL group 20%) dropped out after enrollment due to scheduling difficulties, relocation away from the study area, or unrelated medical problems. The IM group received hypnosis treatment immediately following a two-week symptom recording baseline data. They were then retested two weeks after completing treatment, and a third time approximately four months after completing treatment.

Group DL (delayed), the waiting-list control group, received no hypnosis treatment for the first four months and were retested at a time corresponding to the end of treatment for group IM. The hypnotherapy group received seven 45-minute sessions of individual hypnosis treatment over approximately 12 weeks (one session every other week). Results favoured the hypnotherapy treatment group only for proportion of bowel movements rated as hard or watery (WMD = -0.25, 95% CI -0.38 to -0.12). It did not show a statistically significant difference for frequency of bowel movements (WMD = 0.20, 95% CI -1.06 to 1.46), bloating (WMD = -0.16, 95% CI -6.44 to 6.12) or abdominal pain (WMD = -3.90; 95% CI -10.60 to 2.80).

The Roberts 2006 study compared an intervention group (hypnotherapy and usual medical management) with a control group who received usual medical management and only the research clinic assessment and follow-up questionnaires. The usual medical management was provided by the patients' general practitioner. The hypnotherapy group received five half hour sessions approximately one week apart. At three months the hypnotherapy group (n = 34) had greater improvements in overall symptom scores (mean change from baseline 13.0 for hypnotherapy group (SD = 10.5) versus control group -4.5 (SD = 13.90), WMD -8.5, 95% CI -14.53 to -2.47). There was also a weaker but significant improvement in the abdominal pain score in the hypnotherapy group (n = 30, mean change from baseline -21.20, SD = 18.6) as compared to the control group (n = 26, mean change from baseline -6.80, SD = 20.4) with WMD -14.4 and 95% CI -24.69 to -4.11)). This study failed to show a benefit of hypnotherapy at 12 months for all outcome measures.

The presence of harmful adverse events was not mentioned in any study.

DISCUSSION

Four randomised clinical trials with a total of 147 patients, comparing hypnotherapy with another therapy or waiting-list control for treatment of IBS met the inclusion criteria for this review. Only two studies reported on the primary outcome measure specified for this review but different individual parameters were used to obtain the final symptom severity score and therefore precluded meta-analysis. Only one study compared hypnotherapy to an alternative therapy or placebo (Whorwell 1984). None of the included studies looked at hypnotherapy as first line therapy for IBS. The four included studies all studied IBS patients who had failed medical therapy. One was a primary care based study (Roberts 2006) whilst three (Whorwell 1984; Galovski 1998; Palsson 2002a) were from specialist gastroenterology settings.

The included studies have several methodological limitations. Adequacy of blinding and intention to treat analysis were clearly stated in only one trial (Roberts 2006) however the diagnosis of IBS in this study population is uncertain as the clinical signs, symptoms or investigations used to diagnose IBS by GPs were not provided. The research methods (method of randomisation, blinding, allocation concealment) were not clearly outlined or were inadequate in the remaining three studies. Three of the trials did not calculate sample size a priori and were comprised of small patient numbers. The potential for bias (detection, performance, attrition) was evident in all of the trials as the hypnotherapist was also the person assessing outcome variables in three studies (Whorwell 1984; Galovski 1998; Palsson 2002a) and in the Roberts 2006 study the patients' GP was aware of treatment assignment and therefore the potential to introduce bias was also evident in this study.

A formal meta-analysis was not possible due to differences in outcome measures and study design in the four included studies (Whorwell 1984; Galovski 1998; Palsson 2002a; Roberts 2006) and loss of data in one study (Whorwell 1984). In the Roberts 2006 study abdominal pain was improved in the hypnotherapy group when compared with wait list controls at 3 months. In two studies (Galovski 1998; Roberts 2006) an overall IBS symptom score improved with hypnotherapy when compared to wait-list control at 3 months. In only one study was long term outcome measured at 12 months and this did not show a sustained benefit for hypnotherapy (Roberts 2006). Hypnotherapy appears to be a safe intervention as adverse events were not reported in any of the included studies. However, the results of the included studies need to be interpreted with caution due to small size and methodological limitations.

In patients who fail medical treatment, hypnotherapy could be considered as a therapeutic intervention for abdominal pain and composite primary IBS symptoms. However even though the studies in this review suggest a beneficial effect in the short term, this has not been convincingly proven. The long term benefits of hypnotherapy are also uncertain as only one primary care based study, measured long term (12 months) outcomes in a systematic method and no benefit was found (Roberts 2006).

AUTHORS' CONCLUSIONS

Implications for practice

Although the four small studies in this review suggested a beneficial effect in the short term, this has not been convincingly proven. The results of the included studies need to be interpreted with caution due to the small size and methodological flaws of the included studies. Long term efficacy is uncertain as it has only been evaluated in the one study (Roberts 2006) and this did not show a sustained benefit for hypnotherapy. However, hypnotherapy appears to be a safe intervention and could be tried in patients who fail standard medical therapy.

Implications for research

Given the paucity of high quality randomised controlled studies (RCTs) in this population, further RCTs are warranted, especially those with longer term follow-up. These RCTs should use a study design which assures high internal validity. They should also:

- consider evaluating the use of hypnotherapy in newly diagnosed IBS patients as opposed to patients who fail medical therapy;
- undertake randomised controlled trials comparing hypnotherapy to an alternative therapy, as opposed to wait list controls;
- evaluate the benefit of "booster" hypnotherapy to sustain efficacy of therapy and the validity of autohypnosis at home;
- enroll children and adolescents;
- calculate sample size a priori;
- use standardized criteria (e.g. Rome III) to diagnose patients with IBS;
- state clear inclusion and exclusion criteria;
- use appropriate randomisation methods and allocation concealment to minimise selection bias;
- describe patient withdrawal and dropouts and modify statistical analysis if appropriate;
- attempt to blind assessors of treatment groups or use independent outcome assessors; and
- follow up study participants in both control and hypnotherapy groups at prolonged intervals to ascertain whether initial effects are sustained.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Galovski 1998

Methods	Randomised cross over clinical trial conducted in the USA. Blinding of treatment allocation was unclear. Reasons for withdrawal of patient (n=1) stated. Reasons for excluding subject (n=1) for analysis stated.
Participants	N=13 patients. Age range 23 to 58 years. 13 participiants interviewed, one excluded because of concurrent bipolar disorder and current manic state. 12 subjects (10 females, 2 males) matched to form six pairs. One member of each pair assigned to treatment or control group.

Galovski 1998 (*Continued*)

Interventions	Hypnotherapy vs. symptom monitoring (wait-list) control.
Outcomes	Composite primary reduction score (CPRS) = Diarrhoea reduction score + constipation reduction score, divided by 2(or 3) depending on the number of primary symptoms present). Diarrhoea reduction score = average pretreatment diarrhoea ratings minus average posttreatment diarrhoea ratings divided by average pretreatment diarrhoea ratings.
Notes	Rome criteria used for diagnosis of IBS by a physician (author correspondence).

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	No	C - Inadequate

Palsson 2002a

Methods	Randomised controlled study conducted in the USA. Computer generated randomisation (author correspondence).
Participants	N=24 patients. 15 females 9 males, Mean age 39.1 years IBS Rome 1, refractory to standard medical therapy, exclusion of organic disease.
Interventions	IM (immediate) hypnotherapy group vs DL (delayed therapy - wait list control).
Outcomes	Abdominal pain Proportion of hard bowel movements Watery bowel movements Bloating Frequency bowel movements.
Notes	

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	B - Unclear

Roberts 2006

Methods	Randomised controlled trial conducted amongst general practice patients in UK.
Participants	N=81 randomised. 12 males, 68 females Age range 18 to 65 years, mean age 41.6 years. Diagnosis of IBS by GP at least 6 weeks prior to randomisation and failure to respond to at least one conventional therapy.
Interventions	Intervention group received 5 weekly sessions of gut directed hypnotherapy in addition to their usual medical therapy, control group received only research clinic assessment and follow up questionnaires and were managed with usual medical therapy by general practitioner.
Outcomes	Primary outcome measures were IBS-specific quality of life (QOL) measure and a full symptom score based on Rome 2 criteria. Outcomes recorded at 3, 6, and 12 months post randomisation. Symptom score had 3 dimensions: pain, constipation, and diarrhoea. QOL score had eight dimensions.
Notes	Rome criteria not used. Criteria used for GP diagnosis of IBS not specified.

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Yes	A - Adequate

Whorwell 1984

Methods	Randomised controlled study conducted in Manchester, UK. Randomisation using sealed envelopes.
Participants	N=30 (26 Females, 4 Male; aged 24 to 53 years). All patients had IBS for at least 1 year and had not responded to any therapy (mean = 6 therapies per patient).
Interventions	Gut focussed hypnotherapy versus psychotherapy and placebo.
Outcomes	Primary outcome measures were frequency and severity of abdominal pain and abdominal distension. These were given a score of 0=none, 1=mild, 2=moderate and 3=severe. Bowel habit and general wellbeing were also recorded and abnormality expressed on a similar 0 to 3 scale. The data for 7 days were totalled and the scores analysed seperately with a repeated analysis of variance. Post therapy comparisons were made by means of a Tukey multiple comparison test and were adjusted for pre-treatment levels.
Notes	Data not available for analysis as no standard deviations or means were able to be supplied by author.

Risk of bias

Whorwell 1984 (*Continued*)

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

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

Barabasz 2006	Compares two types of hypnotherapy induction methods for IBS. Four patients were quasi-randomly assigned (by order of scheduling) to a tailored hypnotic induction condition and 4 patients to a manualized standard induction in combination with Palsson's (Palsson 1998) manualized hypnotherapeutic protocol for seven treatment sessions over a 11 to 13 week treatment period.
Boyce 2003	A randomised controlled study comparing CBT, relaxation therapy or standard care. Does not have hypnotherapy as an intervention.
Flammer 2003	Not a randomised controlled trial. A meta-analysis on the efficacy of hypnosis.
Forbes 2000	Randomised study which compares two methods of hypnotherapy (individual and audiotape) in 52 patients.
Gonsalkorale 2003	Not a randomised controlled trial. Questionnaire administered up to 6 years after hypnotherapy to assess symptoms.
Gonsalkorale 2004	Not a randomised controlled trial. Observational study of 78 patients with IBS evaluated before and after hypnotherapy over a 3 month period.
Harvey 1989	Randomised study which compares two methods of hypnotherapy (individual and group).
Houghton 1996	Not a randomised controlled trial. Twenty-five patients with IBS treated with hypnotherapy 1 year previously were compared with 25 control IBS patients.
Lea 2003	Not a randomised controlled trial. Twenty-three patients assessed before and after 12 weeks of hypnotherapy.
Palsson 2002b	Randomised study comparing two types of hypnotherapy for patients with IBS.
Palsson 2006	Not a randomised controlled trial. Twenty-five patients with IBS were enrolled for hypnotherapy and were compared to matched IBS patients not in the study. Control patients were 57 systematically selected Rome 2 IBS patients from a seperate observational study of standard medial care (Whitehead 2004)
Prior 1989	Not a randomised controlled trial. Anorectal manometry assessed in 15 patients with IBS, before and after hypnotherapy. This was compared to 15 control patients with IBS.

(*Continued*)

Roy 1995	Not a randomised controlled trial. Review of hypnotherapy for IBS.
Schafer 1997	Not a randomised controlled trial. Use of hypnosis for inflammatory bowel disease. Case studies.
Simren 2004	A randomised controlled trial in IBS patients, however as the outcome measures were not symptom related this study was not included for the purposes of this review. Outcome measures included colonic sensory thresholds before and after duodenal lipid infusion in controls and patients given hypnotherapy.
Stockbrugger 1999	Not a randomised controlled study. Review of psychosocial and psychiatric factors in IBS.
Taylor 2004	Not a randomised controlled trial. Combined group cognitive-behaviour therapy and hypnotherapy in 158 patients before and after treatment.
Vidakovic-Vukic 1999	Not a randomised controlled trial. Observational study in 27 patients using gut-focussed hypnotherapy.
Whorwell 1987	Not a randomised controlled trial. Prospective cohort study assessing the efficacy of hypnotherapy in 15 patients 18 months post intervention with hypnotherapy for IBS.
Whorwell 1991	Not a randomised controlled trial. Review of hypnotherapy in gastrointestinal disease.
Zimmerman 2003	Not a randomised controlled trial. Case study (n=1) using hypnotherapy for IBS.

DATA AND ANALYSES

Comparison 1. Hypnotherapy and usual medical therapy versus usual medical therapy alone

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Overall change in QOL score at 12 months	1	53	Mean Difference (IV, Fixed, 95% CI)	2.70 [-7.59, 12.99]
2 Overall symptom score at 3 months	1	65	Mean Difference (IV, Fixed, 95% CI)	-8.06 [-14.53, -2.47]
3 Abdominal pain change score at 3 months	1	56	Mean Difference (IV, Fixed, 95% CI)	-14.40 [-24.69, -4.11]
4 Constipation change score at 3 months	1	66	Mean Difference (IV, Fixed, 95% CI)	-2.40 [-11.61, 6.81]
5 Diarrhoea change score at 3 months	1	65	Mean Difference (IV, Fixed, 95% CI)	-7.90 [-16.27, 0.47]
6 Overall symptom change score at 12 months	1	53	Mean Difference (IV, Fixed, 95% CI)	-2.70 [-10.48, 5.08]
7 Abdominal pain change score at 12 months	1	53	Mean Difference (IV, Fixed, 95% CI)	-0.60 [-13.29, 12.09]
8 Constipation change score at 12 months	1	53	Mean Difference (IV, Fixed, 95% CI)	-3.09 [-15.91, 8.31]
9 Diarrhoea change score at 12 months	1	53	Mean Difference (IV, Fixed, 95% CI)	-1.06 [-10.82, 7.82]
10 Quality of life score at 12 months	1	53	Mean Difference (IV, Fixed, 95% CI)	9.60 [-3.77, 22.97]

Comparison 2. Hypnotherapy versus wait list control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Abdominal pain score	1	24	Mean Difference (IV, Fixed, 95% CI)	-3.90 [-10.60, 2.80]
2 Composite Primary Symptom Reduction (CPSR) Score.	1	11	Mean Difference (IV, Fixed, 95% CI)	-0.87 [-1.36, -0.38]
3 Proportion of hard/watery bowel movements	1	24	Mean Difference (IV, Fixed, 95% CI)	-0.26 [-0.38, -0.12]
4 Proportion of subjects with bloating	1	24	Mean Difference (IV, Fixed, 95% CI)	-0.17 [-6.44, 6.12]
5 Frequency of bowel motions	1	24	Mean Difference (IV, Fixed, 95% CI)	0.20 [-1.06, 1.46]

Analysis 1.1. Comparison 1 Hypnotherapy and usual medical therapy versus usual medical therapy alone, Outcome 1 Overall change in QOL score at 12 months.

Review: Hypnotherapy for treatment of irritable bowel syndrome

Comparison: 1 Hypnotherapy and usual medical therapy versus usual medical therapy alone

Outcome: 1 Overall change in QOL score at 12 months

Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Roberts 2006	29	13.6 (16.2)	24	10.9 (21.07)		100.0 %	2.70 [-7.59, 12.99]
Total (95% CI)	**29**		**24**			**100.0 %**	**2.70 [-7.59, 12.99]**

Heterogeneity: not applicable

Test for overall effect: Z = 0.51 (P = 0.61)

Analysis 1.2. Comparison 1 Hypnotherapy and usual medical therapy versus usual medical therapy alone, Outcome 2 Overall symptom score at 3 months.

Review: Hypnotherapy for treatment of irritable bowel syndrome

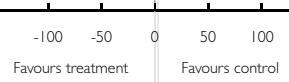
Comparison: 1 Hypnotherapy and usual medical therapy versus usual medical therapy alone

Outcome: 2 Overall symptom score at 3 months

Study or subgroup	Hypnotherapy N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Roberts 2006	34	-13 (10.5)	31	-4.5 (13.9)		100.0 %	-8.50 [-14.53, -2.47]
Total (95% CI)	**34**		**31**			**100.0 %**	**-8.50 [-14.53, -2.47]**

Heterogeneity: not applicable

Test for overall effect: Z = 2.76 (P = 0.0058)

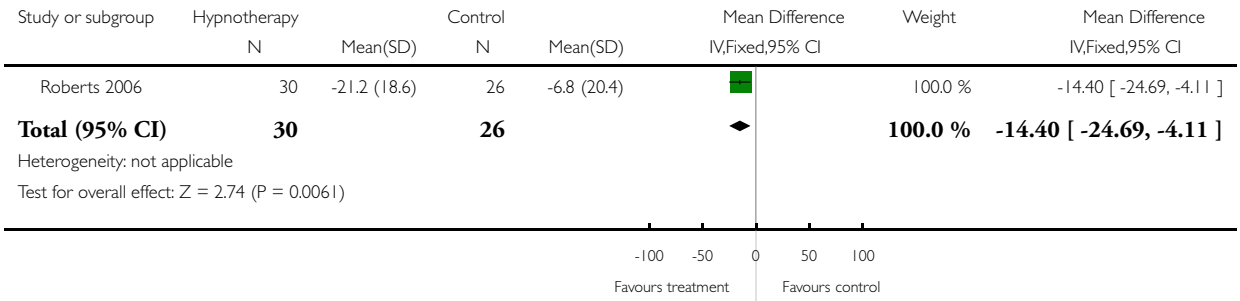


Analysis 1.3. Comparison 1 Hypnotherapy and usual medical therapy versus usual medical therapy alone, Outcome 3 Abdominal pain change score at 3 months.

Review: Hypnotherapy for treatment of irritable bowel syndrome

Comparison: 1 Hypnotherapy and usual medical therapy versus usual medical therapy alone

Outcome: 3 Abdominal pain change score at 3 months

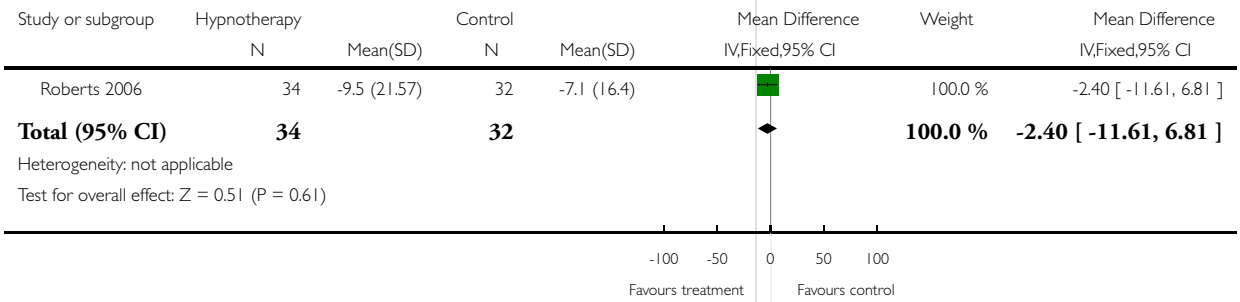


Analysis 1.4. Comparison 1 Hypnotherapy and usual medical therapy versus usual medical therapy alone, Outcome 4 Constipation change score at 3 months.

Review: Hypnotherapy for treatment of irritable bowel syndrome

Comparison: 1 Hypnotherapy and usual medical therapy versus usual medical therapy alone

Outcome: 4 Constipation change score at 3 months



Analysis 1.5. Comparison 1 Hypnotherapy and usual medical therapy versus usual medical therapy alone, Outcome 5 Diarrhoea change score at 3 months.

Review: Hypnotherapy for treatment of irritable bowel syndrome

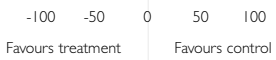
Comparison: 1 Hypnotherapy and usual medical therapy versus usual medical therapy alone

Outcome: 5 Diarrhoea change score at 3 months

Study or subgroup	Hypnotherapy N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Roberts 2006	34	-10.2 (15.1)	31	-2.3 (18.9)		100.0 %	-7.90 [-16.27, 0.47]
Total (95% CI)	**34**		**31**			**100.0 %**	**-7.90 [-16.27, 0.47]**

Heterogeneity: not applicable

Test for overall effect: Z = 1.85 (P = 0.064)



Analysis 1.6. Comparison 1 Hypnotherapy and usual medical therapy versus usual medical therapy alone, Outcome 6 Overall symptom change score at 12 months.

Review: Hypnotherapy for treatment of irritable bowel syndrome

Comparison: 1 Hypnotherapy and usual medical therapy versus usual medical therapy alone

Outcome: 6 Overall symptom change score at 12 months

Study or subgroup	Hypnotherapy N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Roberts 2006	29	-9.1 (14)	24	-6.4 (14.7)		100.0 %	-2.70 [-10.48, 5.08]
Total (95% CI)	**29**		**24**			**100.0 %**	**-2.70 [-10.48, 5.08]**

Heterogeneity: not applicable

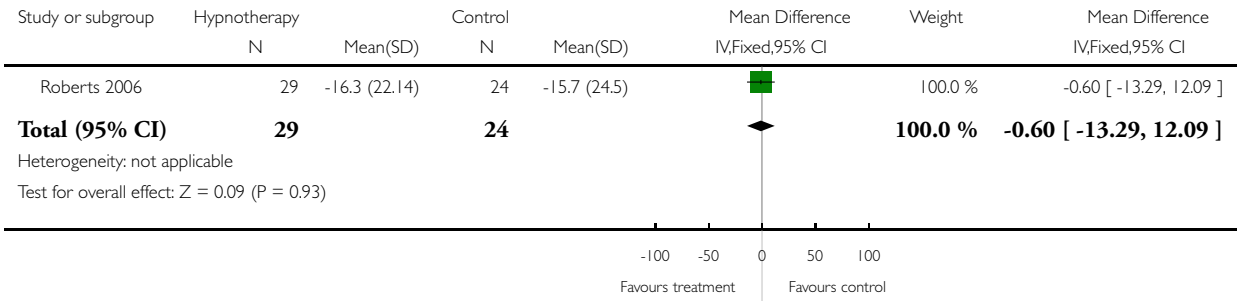
Test for overall effect: Z = 0.68 (P = 0.50)

Analysis 1.7. Comparison 1 Hypnotherapy and usual medical therapy versus usual medical therapy alone, Outcome 7 Abdominal pain change score at 12 months.

Review: Hypnotherapy for treatment of irritable bowel syndrome

Comparison: 1 Hypnotherapy and usual medical therapy versus usual medical therapy alone

Outcome: 7 Abdominal pain change score at 12 months

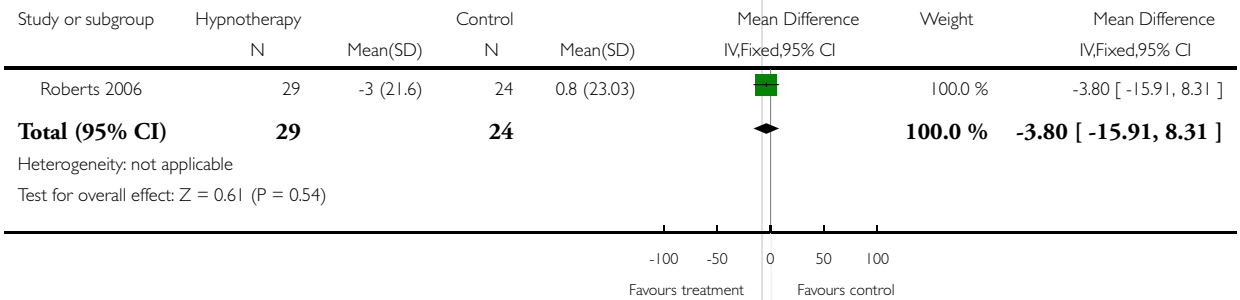


Analysis 1.8. Comparison 1 Hypnotherapy and usual medical therapy versus usual medical therapy alone, Outcome 8 Constipation change score at 12 months.

Review: Hypnotherapy for treatment of irritable bowel syndrome

Comparison: 1 Hypnotherapy and usual medical therapy versus usual medical therapy alone

Outcome: 8 Constipation change score at 12 months



Analysis 1.9. Comparison 1 Hypnotherapy and usual medical therapy versus usual medical therapy alone, Outcome 9 Diarrhoea change score at 12 months.

Review: Hypnotherapy for treatment of irritable bowel syndrome

Comparison: 1 Hypnotherapy and usual medical therapy versus usual medical therapy alone

Outcome: 9 Diarrhoea change score at 12 months

Study or subgroup	Hypnotherapy N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Roberts 2006	29	-8.4 (16.74)	24	-6.9 (17.64)		100.0 %	-1.50 [-10.82, 7.82]
Total (95% CI)	**29**		**24**			**100.0 %**	**-1.50 [-10.82, 7.82]**

Heterogeneity: not applicable

Test for overall effect: Z = 0.32 (P = 0.75)

Analysis 1.10. Comparison 1 Hypnotherapy and usual medical therapy versus usual medical therapy alone, Outcome 10 Quality of life score at 12 months.

Review: Hypnotherapy for treatment of irritable bowel syndrome

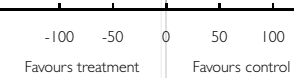
Comparison: 1 Hypnotherapy and usual medical therapy versus usual medical therapy alone

Outcome: 10 Quality of life score at 12 months

Study or subgroup	Hypnotherapy N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Roberts 2006	29	65.4 (23.76)	24	55.8 (25.5)		100.0 %	9.60 [-3.77, 22.97]
Total (95% CI)	**29**		**24**			**100.0 %**	**9.60 [-3.77, 22.97]**

Heterogeneity: not applicable

Test for overall effect: Z = 1.41 (P = 0.16)

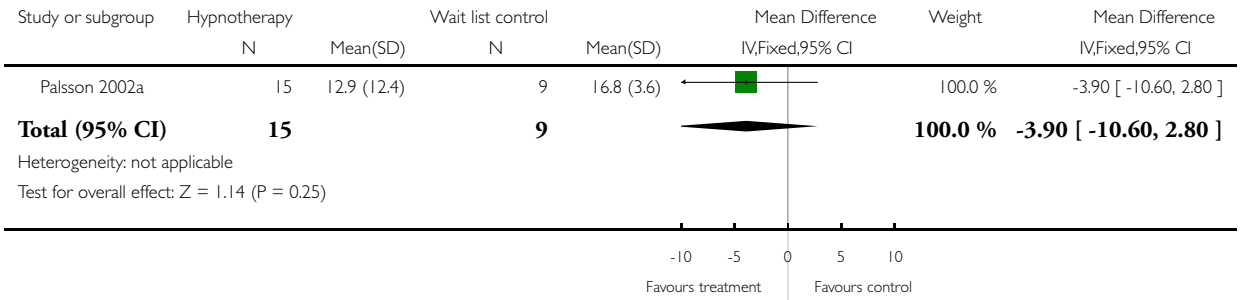


Analysis 2.1. Comparison 2 Hypnotherapy versus wait list control, Outcome 1 Abdominal pain score.

Review: Hypnotherapy for treatment of irritable bowel syndrome

Comparison: 2 Hypnotherapy versus wait list control

Outcome: 1 Abdominal pain score

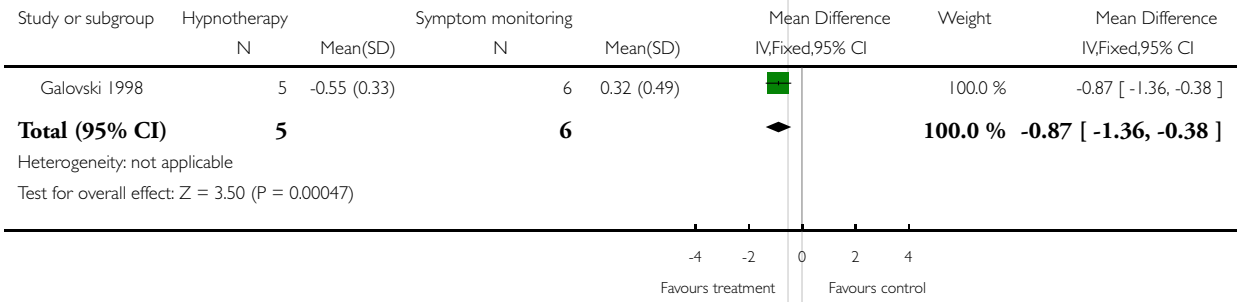


Analysis 2.2. Comparison 2 Hypnotherapy versus wait list control, Outcome 2 Composite Primary Symptom Reduction (CPSR) Score..

Review: Hypnotherapy for treatment of irritable bowel syndrome

Comparison: 2 Hypnotherapy versus wait list control

Outcome: 2 Composite Primary Symptom Reduction (CPSR) Score.

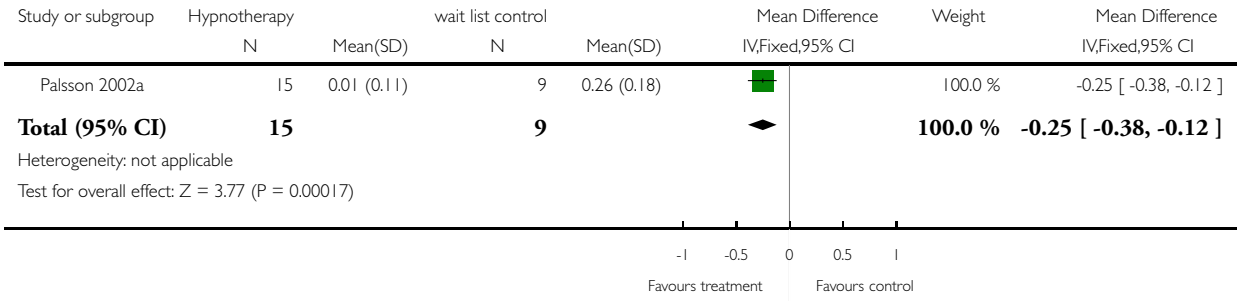


Analysis 2.3. Comparison 2 Hypnotherapy versus wait list control, Outcome 3 Proportion of hard/watery bowel movements.

Review: Hypnotherapy for treatment of irritable bowel syndrome

Comparison: 2 Hypnotherapy versus wait list control

Outcome: 3 Proportion of hard/watery bowel movements

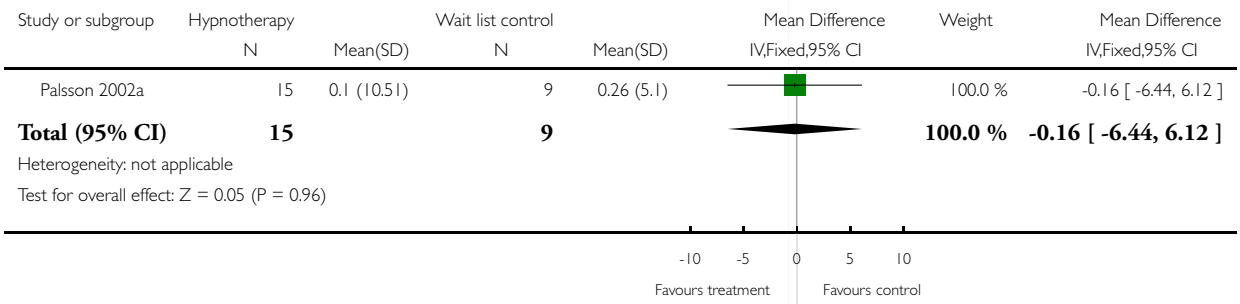


Analysis 2.4. Comparison 2 Hypnotherapy versus wait list control, Outcome 4 Proportion of subjects with bloating.

Review: Hypnotherapy for treatment of irritable bowel syndrome

Comparison: 2 Hypnotherapy versus wait list control

Outcome: 4 Proportion of subjects with bloating

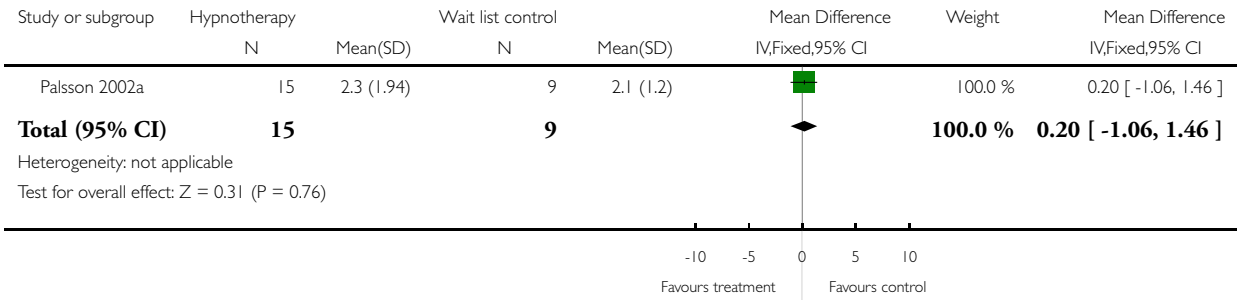


Analysis 2.5. Comparison 2 Hypnotherapy versus wait list control, Outcome 5 Frequency of bowel motions.

Review: Hypnotherapy for treatment of irritable bowel syndrome

Comparison: 2 Hypnotherapy versus wait list control

Outcome: 5 Frequency of bowel motions



WHAT'S NEW

Last assessed as up-to-date: 3 July 2007.

7 May 2008	Amended	Converted to new review format.

HISTORY

Protocol first published: Issue 1, 2005

Review first published: Issue 4, 2007

4 July 2007	New citation required and conclusions have changed	Substantive amendment

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- Murdoch Children's Research Institute, Australia.

External sources

- National Health & Medical Research Council, Australia.

INDEX TERMS

Medical Subject Headings (MeSH)

*Hypnosis; Irritable Bowel Syndrome [psychology; *therapy]; Randomized Controlled Trials as Topic

MeSH check words

Female; Humans; Male