

Systematic review: the effectiveness of hypnotherapy in the management of irritable bowel syndrome

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SUMMARY

Aim

To systematically review the literature evaluating hypnotherapy in the management of irritable bowel syndrome (IBS).

Methods

Electronic databases were searched (Cochrane Library, Medline, CINAHL, AMED, Embase, PsycINFO, CISCOP, TRIP and the Social Science Citation index), bibliographic references scanned and main authors contacted. No restrictions were placed on language or publication year. Eligible studies involved adults with IBS using single-component hypnotherapy. All studies, except single case or expert opinion, were sought and all patient-related outcomes eligible.

Results

Out of 299 unique references identified, 20 studies (18 trials of which four were randomized, two controlled and 12 uncontrolled) and two case series were eligible. These tended to demonstrate hypnotherapy as being effective in the management of IBS. Numbers of patients included were small. Only one trial scored more than four out of eight on internal validity.

Conclusion

The published evidence suggests that hypnotherapy is effective in the management of IBS. Over half of the trials (10 of 18) indicated a significant benefit. A randomized placebo-controlled trial of high internal validity is necessary to establish the effectiveness of hypnotherapy in the management of IBS. Until such a trial is undertaken, this form of treatment should be restricted to specialist centres caring for the more severe forms of the disorder.

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INTRODUCTION

Irritable bowel syndrome (IBS) is a chronic disorder affecting 10–20% of the population.^{1, 2} It is estimated that a general practitioner in the UK sees eight patients with IBS every week³ and these patients constitute up to 50% of gastroenterology referrals.^{4–7} The quality of life (QOL) of patients with IBS is surprisingly poor, particularly in the population seeking professional health care,⁸ with over 40% of those referred to hospital out-patients reporting avoidance of some activities⁹ and some studies have indicated that the impact of IBS on QOL is as great as that observed for congestive heart failure¹⁰ and stroke.¹¹ Health service costs, both direct^{12, 13} and indirect,^{14–16} are high.

Conventional therapy leaves up to 25% of sufferers without relief of symptoms¹⁷ and many patients have been reported to turn to alternative therapies.¹⁸ 'Gut-directed hypnotherapy' (GDH), a type of hypnosis, is one of the alternative therapies most frequently reported to have a demonstrable beneficial therapeutic impact on IBS symptoms.^{19, 20} GDH is based on the use of hypnotic induction, using progressive relaxation and other techniques, followed by imagery directed towards control and normalization of gut function.²⁰ Therapy also aims to teach autohypnosis, to enable patients to manage their own symptoms without ongoing reliance on primary or secondary care, although occasional refresher sessions may be required.

The first paper to report an evaluation of GDH in the management of IBS was published 20 years ago²⁰ and indicated a significant benefit over placebo, in patients referred to a specialist centre for the management of refractory IBS. A more recent audit of patients treated in this hypnotherapy unit, reported that GDH may also confer longer term benefits and reduced health care costs as a result of lower consultation rates and medication use.²¹ Such studies suggest benefits would be achieved by the more widespread use of GDH in the management of IBS.

Four reviews of the published evidence relating to the role of hypnotherapy in the management of IBS have been previously published with conflicting conclusions.^{22–25} The first review²⁴ concluded that hypnotherapy was effective in the management of refractory IBS, with suggested models of implementation focusing on the training of primary and community care staff (nurses, physiotherapists and occupational therapists). However, this review limited searches to only

one database (CISCOM) and no detail was provided with respect to the search strategy or years searched, how inclusion criteria were applied, how judgements of validity were made or the process of data extraction. Spanier's review aimed to determine the effectiveness of alternative therapies,²⁵ including hypnotherapy, for the treatment of IBS but was also limited to only one bibliographic database (Medline) and excluded all non-English language studies; language restrictions may compromise the validity of a systematic review, but potentially more so in the areas of alternative therapy where major developments have occurred outside of the English speaking world.²⁶ This review concluded that the studies identified ($n = 3$) were of poor quality and further research was necessary to determine the efficacy of hypnotherapy. Two recent reviews have included differing studies; Tan *et al.*²² included six controlled trials and concluded that hypnosis consistently produces significant results, and, Whitehead²³ included five controlled studies and concluded that hypnosis has a substantial therapeutic impact on IBS.

The number of primary studies and reviews suggesting that GDH may have significant value in the management of IBS and the lack of a high quality systematic review, provided the impetus to conduct this systematic review, which addresses the question of whether hypnotherapy is effective in the management of IBS.

METHODS

The search strategy aimed to identify all studies evaluating the management of IBS using single-component hypnotherapy. After preliminary work using a broad-search strategy, a relatively precise group of key terms were identified and searches were completed (Table 1). To maximize the possibility of identifying all relevant publications, nine electronic databases were used. Where relevant publications were identified, citation searches were completed. The authors of all eligible papers were contacted to ascertain their knowledge of further published, unpublished or ongoing studies. The controlled trials register was searched and the bibliographies of all studies identified as relevant to the purpose of the review were scanned. No restrictions were placed on the search either by type of publication, publication date, country or language.

All papers evaluating hypnotherapy in the management of patients categorized as having IBS, irrespect-

Table 1. Search strategies and electronic databases accessed

Search terms

Text words

irritable bowel syndrome
 irritable adj5 bowel
 Hypnotherapy
 Hypnosis
 Trance

Index terms

IRRITABLE BOWEL SYNDROME –
 CINAHL and PsycINFO
 COLONIC DISEASES FUNCTIONAL –
 Medline and Cochrane library
 COLONIC DISEASE – AMED
 IRRITABLE COLON – Embase
 HYPNOSIS

Database

Medline 1966–January 2006
 CINAHL (Cumulative Index to Nursing and
 Allied Health Literature)
 1982–January 2006
 PsycINFO 1985–January 2006
 Cochrane Library (2002/6) including: Cochrane
 Database of Systematic Reviews (CDSR), Database
 of Abstracts of Reviews of Effectiveness (DARE),
 The CENTRAL and Cochrane Controlled Trials
 Register (CCTR), Cochrane Reviews Methodology Database
 Embase 1980–January 2006
 AMED (Allied and Complementary Medicine) 1985 – December 2005
 Social Science Citation Index (SSCI) cited authors – Whorwell PJ,
 Harvey RF, Blanchard EB, Houghton LA, Galovski TE
 CISCOM
 TRIP database, including the Health Technology Assessment (HTA)

Search engine

OVID
 OVID

 OVID
 National electronic library for health

 OVID
 OVID
 Web of Science

<http://www.rccm.co.uk/ciscom>
<http://www.tripdatabase.com>

ive of the criteria for diagnosis, were included. Multiple component therapies were excluded. Any patient-related outcome measure was deemed eligible for inclusion. All study designs, except single case studies or expert opinion, were included in an attempt to capture all the available data.

Citations identified were downloaded into Reference Manager 9. The titles of all identified publications were scanned independently by two of the authors and the eligibility criteria applied. Those that could confidently be judged to be irrelevant based on the title and/or abstract alone were excluded. Full papers were obtained for all those where exclusion was not possible based on the information available in the abstract and/or title alone (Figure 1).

Eligibility, internal validity and data extraction forms were predetermined and completed independently by two researchers. All disagreements were reviewed by a third person and consensus reached. A scoring system was used to assess the internal validity for randomized and controlled trials; the usual 10-point scale²⁷ was modified to omit the concealment

criteria (blinding not being possible in trials of psychological interventions) (Table 2). The scoring (out of a possible eight points) took into account proper randomization (four possible points), reporting of dropouts (one point), method of analysis (one point), similarity of the groups at baseline (one point) and whether the groups were treated comparably in all respects other than the intervention (one point). The assessment of the quality of non-randomized trials is problematic and few quality assessment tools exist.²⁸ Uncontrolled studies are recognized to be methodologically weaker than randomized controlled trials (RCT). We assessed the quality of the uncontrolled trials (UT) by extracting data according to a four-point scoring system that took into account the availability of before and after data (one point), assessment of confounders (one point) and dropouts (two points).

Data extraction aimed to establish study size, patient demographics, details of interventions, outcome measures, duration of follow-up and results. The raw data necessary for calculating effect sizes and confidence intervals were also sought. Where these data were not

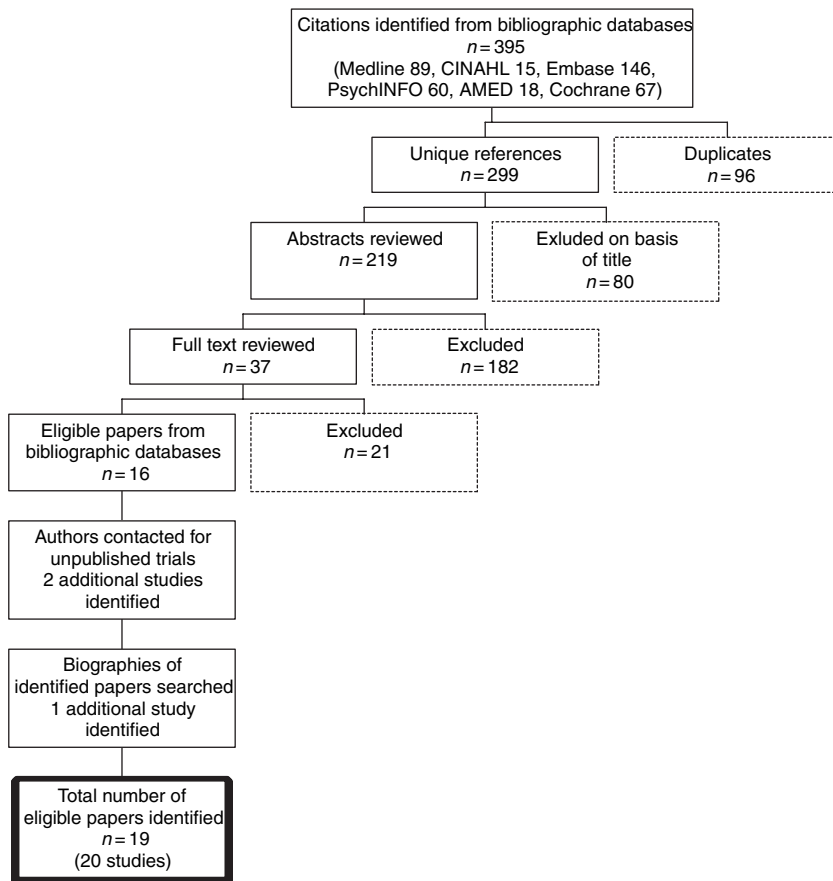


Figure 1. Search results.

available in the publication, the authors were contacted and the information requested. Final searches of the literature were undertaken in January 2006.

RESULTS

Searches of six of the electronic bibliographic databases identified 395 citations potentially relevant to the purposes of this review (Figure 1). Three further sources (CISCOM, TRIP and SSCI) revealed no additional studies. After excluding duplicates, 299 publications formed the basis of this review. Eighty publications were excluded on the basis of the title alone, 182 were determined not to be eligible after reviewing the abstract and a further 21 excluded after reviewing the complete paper. Correspondence with the authors of the remaining 16 eligible publications, citation searches and a review of the bibliographies of these studies identified a further three eligible studies that had not been identified by searching the electronic databases.

Nineteen eligible papers, describing 20 studies (one paper¹⁹ described two studies, and two papers^{21, 29}

were based on the same cohort of patients and therefore only included once) (Table 3) were identified. The 20 studies included in the review comprised 18 trials [four RCT, two non-randomized controlled trials (CT), 12 UT] and two case series. All of the identified studies indicated hypnotherapy to be effective in the management of IBS.

Eight of the trials were reported as RCTs, however, we have classified four of these^{19, 30-32} as UTs as the intervention evaluated by the RCTs was not the effectiveness of GDH, and therefore outcome data relating to effectiveness did not have a control group for comparison. In three of these trials,^{19, 30, 32} symptom scores were available pre- and post-therapy for both intervention and control subjects combined. In the fourth trial,³¹ outcomes data were reported only for the intervention group (the author was contacted in an attempt to retrieve the data for the control group, but this was unavailable).

Three studies were reported as controlled trials³³⁻³⁵ although for one of these³⁵ results relating to the effectiveness of GDH were given only for the intervention group; we have therefore classified this as an UT.

Table 2. Scoring schedules

Internal validity: controlled trials	(maximum score 8)
Generation of allocation schedule	
A1 Was the trial described as 'randomized'?	Yes +1
A2 Was allocation truly random? (random numbers, coin toss, shuffle, etc.)	Yes +3
or	
Was allocation quasi-random? (patient number, date of birth)	Yes +2
or	
Was allocation systematic (alternate)	Yes +1
or	
Was the method of randomization not stated or unclear	Yes 0
Completeness of the trial	
C1 Were the number of drop-outs in each group stated?	Yes +1 (no or unsure = 0)
C2 Was an intention-to-treat analysis performed?	Yes +1 (no or unsure = 0)
C3 Were groups similar at the start?	Yes +1 (no or unsure = 0)
C4 Aside from experimental intervention were groups treated equally?	Yes +1 (no or unsure = 0)
Internal validity: uncontrolled trials	(maximum score 4)
Were before and after data provided?	Yes +1 (no or unsure = 0)
Was there any assessment of confounders?	Yes +1 (no or unsure = 0)
Were dropouts recorded?	Yes +1 (no or unsure = 0)
Were dropouts followed up?	Yes +1 (no or unsure = 0)

A further seven trials of GDH were identified, which had no control group.^{29, 36-41} None of the controlled trials had more than 25 patients in each arm.

The characteristics and results of the identified studies are detailed in Table 3. These studies utilized a wide variety of outcome measures. Most studies used a symptom score of some form; however, the range of symptoms studied varied. Nevertheless, the majority of studies used the classical triad, namely abdominal pain, distension and altered bowel habit as outcomes.

The absence of standardized outcome measures and limited response to requests for additional data (only one of the five authors that were contacted replied) prohibited quantitative data synthesis.

Critique of the controlled trials

All six controlled trials^{19, 20, 33, 34, 42, 43} reported that GDH was beneficial in the management of IBS and five of the six (83%) indicated a statistically significant benefit. However, only two trials scored more than four, out of a maximum of eight, on the quality

score. Although four trials were reported as RCTs, only one described the method of randomization⁴³ and none of the RCTs provided the evidence that the randomization process had generated a balanced sample with respect to baseline symptomatology or demographic variables. One RCT⁴³ reported comparability between the groups with respect to age and symptom scores at baseline; although differences did exist in some of the QOL dimensions recorded, and more males were included in the intervention group. A further RCT²⁰ reported that for two of the three recorded symptoms there was comparability between groups before treatment, but no attempt was made to assess other potential confounding factors such as age and sex, another RCT⁴² reported comparability between the trial arms with respect to demographic variables. Two of the trials^{33, 34} were not randomized and are therefore subject to allocation bias. In the Houghton trial,³⁴ the control group patients were IBS sufferers who were still on the waiting list for GDH whilst the intervention group were those who had the therapy a year previously. In the Voirol *et al.* study,³³ it was unclear

Table 3. Included studies

Author (year of publication) and location	Population	Age (years); sex (M:F)	Intervention	Control	Outcome	Results	Trial period follow-up data	Score
Randomized controlled trials (RCT)								
Whorwell (1984), ²⁰ UK, out-patients department (OPD)	IBS refractory to conventional treatment Intervention $n = 15$ Control $n = 15$	24–53; 4:26	GDH: Seven 30-min sessions	Seven 30-min sessions supportive psychotherapy	Symptom scores	GDH group improved more than control group ($P < 0.0001$)	12 week trial 14–21 months all GDH in remission ³⁶	2/8 (4/8)*
Galovski (1998), ⁴² US	IBS symptoms 3 days per week, >6 months Intervention $n = 6$ Control $n = 6$	23–58; mean 38.8; 2:10	GDH: Twelve 30–60 min sessions	Symptom monitoring	Symptom scores Overall improvement/wellbeing Composite primary reduction score (CPSR)	Symptom scores in the GDH group improved more than control group ($P = 0.016$) when using the CPSR score but when looking at individual symptoms (for all individuals $n = 11$) from baseline to post-treatment, only flatulence was significantly improved GDH group improved more than control group ($P = 0.002$)	12-week trial 2 months later, all patients had been treated; 56% (five of nine) maintained improvement	4/8
Palsson (2002), ¹⁹ (study 2)†, US	Rome I, refractory IBS for more than 1 year Intervention $n = 15$ Control $n = 15$	Mean 39.1; 9:15	GDH: Seven 45-min sessions	Symptom monitoring Physiological measures	Symptom score		12-week trial At 10 months, 70% remained stable	2/8
Roberts (2005), ⁴³ UK, Primary care	Diagnosis of IBS refractory to conventional treatment Intervention $n = 40$ Control $n = 41$	18–65; Mean 41.6; 12:69	GDH: Five 30-min sessions & usual GP management	Usual GP management	Symptom score IBS specific quality of life	GDH group had greater improvement in overall symptoms than control group at 3 months ($P = 0.008$) No significant differences between groups in quality of life	12 months Differences between groups not maintained at 6 months	7/8

Table 3. (Continued)

Author (Year)	Study Design	Intervention	Control	Not stated; not stated	GDH: number and length of sessions not stated	Conventional treatment	Consultation rate and medication use	Consultation rates fell from 53 to 41 in control group and 74 to 6 in intervention group. Medication use stopped in the intervention group post-therapy, no change in the control group	Trial length not stated
Voirol <i>et al.</i> (1987), ³³ Switzerland	Controlled trials (CT)	Long-term IBS sufferers, known to the service Intervention <i>n</i> = 10 Control <i>n</i> = 10							2/8 Follow-up to 40 months
Houghton <i>et al.</i> (1996), ³⁴ UK, OPD	Refractory IBS Intervention <i>n</i> = 25 Control <i>n</i> = 25			21–58; 6:44	GDH: Twelve 30-min sessions (1 year previously)	Symptom monitoring (on waiting list for GDH)	Symptom score Economic measure Quality of life	Classical symptoms improved more in the GDH group than in controls (<i>P</i> < 0.001)	3/8 Assessment at 12 months†
Uncontrolled trials (UCT)									
Harvey <i>et al.</i> (1989), ³⁰ UK, OPD	Refractory IBS, unresponsive conventional treatment <i>n</i> = 33			19–62; mean 38; 9:27	17 patients: four 40-min sessions of group GDH 16 patients: four 40-min sessions of individual GDH		Symptom score	At 3 months: 11/33 were symptom free, nine had some improvement and 13 showed no improvement	2/4 7 week trial 3 months follow-up
Prior <i>et al.</i> (1990), ³⁵ UK, OPD	Classical IBS Intervention <i>n</i> = 15 Control <i>n</i> = 15			18–49; 2:28	Anorectal manometry under GDH	Anorectal manometry without GDH	Symptom score Physiological measures	Fall in symptom scores in the GDH group: 13/15 much improved	1/4 3-months trial
Sjoberg <i>et al.</i> (1999), ³¹ Sweden	IBS > 5 years, Manning criteria <i>n</i> = 55			mean 37; 11:44	GDH: twelve 60–90 min sessions		Symptom score Overall improvement/wellbeing	71% of participants were improved post-therapy	0/4 5-month trial, control period 1 year
Forbes <i>et al.</i> (2000), ³² UK, OPD	Manning and Rome 1, symptoms >6 months, failed conventional treatment <i>n</i> = 52			19–71; mean 37; 15:37	27 patients: GDH via audiotape 25 patients: individual GDH		Symptom score	Symptom scores fell for 76% of patients receiving individual GDH and 56% of those receiving audiotape. No significant difference between the groups	3/4 12-week trial
Palsson <i>et al.</i> (2002), ¹⁹ (study 1) US	Rome 1, refractory IBS for at least 1 year <i>n</i> = 18			mean 37.6; 3:15	Nine patients: GDH with pain specific verbal suggestion (PSVS) for seven 45 min sessions Nine patients: GDH without PSVS for seven 45-min sessions		Symptom score Psychological/emotional measure	No difference between groups. Significant improvement for pain, bloating and bowel movements in both group's after GDH	2/4 12-week trial

Table 3. (Continued)

Author (year of publication) and location	Population	Age (years); sex (M:F)	Intervention	Control	Outcome	Results	Trial period follow-up data	Score
Whorwell <i>et al.</i> (1987), ³⁶ UK, OPD	<i>n</i> = 50 (35 new patients and 15 from 1984 RCT) Patients subdivided into three groups: <i>group 1</i> , classical IBS; <i>group 2</i> , atypical IBS; <i>group 3</i> , classical IBS with significant psychopathology	23–65; 35 new; 4:31	GDH: 30-min sessions of GDH over 3 months		Symptom score Overall improvement/wellbeing	Overall 84% improved by group Group 1: 95% Group 2: 43% Group 3: 60%	3-month trial Further data confirmed an 85% success rate on 200 patients ⁴⁸	1/4
Taylor and Whorwell (1993), ³⁷ UK, OPD	Refractory IBS with a mean duration of 9 years <i>n</i> = 32	23–56; mean 35; 12:20	GDH: eight 30-min sessions		Symptom score Overall improvement/wellbeing	Reduction in symptoms, <i>P</i> < 0.001	8-week trial	3/4
Vidak-Vukic (1999), ³⁸ Amsterdam	Classical IBS; patients all symptomatic on conventional medication <i>n</i> = 27	18–86; 9:18	GDH: twelve 60-min sessions		Unclear – apparently symptom score	85% improved 4% still symptomatic 7% stopped treatment	12-week trial At 6–12 months, five followed up and all reported to be doing well	1/4
Gonsalkorale and Whorwell (2001), ³⁹ UK, OPD	IBS, not otherwise specified <i>n</i> = 45	Not specified; all female	GDH, no further details given		Symptom score Quality of life	Reduction in overall symptom scores, <i>P</i> < 0.001	Not stated	1/4
Gonsalkorale <i>et al.</i> (2002), ²⁹ and 2003, ²¹ Hypnotherapy Unit, UK	Rome I, Refractory IBS, duration >2 years <i>n</i> = 250	19–79; 50:200	Twelve 30-min sessions of GDH		Symptom score Overall improvement/wellbeing Quality of life	Reduction in overall symptom score, <i>P</i> < 0.001	3-months trial 178 followed up for 1–5 years: 83% no deterioration, 59% no medication ²¹	3/4
Gonsalkorale <i>et al.</i> (2004), ⁴⁰ Hypnotherapy Unit, UK	Rome I, Refractory IBS, duration >2 years <i>n</i> = 78	17–69; 16:62	Twelve sessions of GDH		Symptom score Quality of life Consultation rate and medication use	Reduction in overall and individual symptom scores <i>P</i> < 0.001	3-month period	1/4

Table 3. (Continued)

Lea <i>et al.</i> 2003, ⁴¹ UK	Rome I <i>n</i> = 23	24–72; mean 45; 7:16	Twelve 60-min sessions GDH	Symptom measure Physiological measures Age (years)	GDH effective at relieving symptoms, <i>P</i> = 0.002	12-week trial	1/4
Case studies	Sample size (<i>n</i>)	Location	Population			Sex (M:F)	
Byrne (1973), ⁴⁹ US	2	US	Refractory/atypical IBS	23 and 43		0:2	
Waxman (1988), ⁵⁰ UK	8	UK	IBS referred by GP	24–50		2:6	

* Score based on information arising from personal communication with the author.

† Two studies detailed in one paper.

‡ Unclear from publication, information from personal communication.

whether groups were similar at the start of the trial although personal communication with the author indicated comparability between the groups on a range of social and well being indices.

The total number of participants in the six controlled trials was 223 (mean 37.2, range 12–81). Dropouts were documented in five of the trials (range 17–30%) and only three^{20, 34, 43} undertook an intention-to-treat analysis. Only two trials (an RCT⁴² and a CT³⁴) specifically stated that control and intervention groups were treated equally. In common with many trials of psychological interventions, blinding was not possible and bias in the estimation of outcomes is a possibility.

Trials of management strategies for IBS, as with many healthcare interventions, are subject to placebo effects.⁴⁴ Despite the difficulties of blinding in trials of psychological interventions such as GDH, symptom monitoring (used in five of the six controlled trials) is inadequate as a control. Only one trial²⁰ used an appropriate comparator in the control group.

DISCUSSION

All of the published trials identified by this comprehensive systematic review provided evidence to suggest that GDH is effective in the management of IBS, with the main measured effect being a reduction in IBS symptom scores. More than half of the trials (56%, 10 of 18) and the majority of the controlled trials (83%, five of six) indicated a statistically significant benefit.

Despite the identification of four RCTs and two CTs, no study was of sufficient power and internal validity to provide robust evidence of the benefit of GDH, and calculation of a combined estimate of the effect was not possible due to the diverse nature of the outcomes measured. The majority of the evidence available (12 of the 18 trials, 67%) was from UT where the effects of regression towards the mean and placebo responses cannot be established. Randomization is especially important in trials of fluctuating diseases like IBS where recruitment to a trial most commonly will occur during a period of increased symptomatology (i.e. when patients consult). UT have been included in this review for completeness, however, given their potential for bias, they have not been extensively critiqued.

Quality assessment scores for identifying trials of genuinely high quality have limitations.⁴⁵ However, reviewers all agreed with the study 'quality' based on

the scoring system used and so no deviation from this was deemed necessary.

Most of the trials used symptom monitoring via patient diaries as the primary outcome measure. However, there was considerable heterogeneity in the outcome measures studied and this made interpretation of the papers difficult and also prohibited the calculation of a summary measure of effect. Many studies attempted to assess the change in a wide range of symptoms; this resulted in analyses being undertaken on small (often single figure) numbers of patients and few of the authors utilized appropriate statistical methods to correct for the multiple comparisons.

Almost all of the trials identified were based in secondary care and the majority included only refractory cases of IBS and comprise a highly selected, slightly older and motivated group of sufferers with IBS of many years duration. The results of these trials cannot be generalizable to IBS patients as a whole; a significant proportion of whom are managed within the primary care setting.^{1, 3}

No studies were identified reporting negative results and all the published studies were small, suggesting the possibility of publication bias.⁴⁶ Out of the 20 studies identified, at least one negative result would be expected by chance alone. Unfortunately, the raw data necessary for the calculation of odds ratios and a funnel plot were not available despite personal communications with the authors.

Gut-directed hypnotherapy is a time-intensive intervention. The package of therapy was usually between six and 12 sessions, each of between 30 and 60 min, over a period of several months. Successful delivery of GDH therefore requires motivation from patients both to attend therapy sessions and to undertake autohypnosis at home. Even in the population recruited to the identified trials, with refractory IBS of a relatively long duration, dropout rates in some of the studies were relatively high (up to 30%); this suggests that offering treatment to a wider group of patients (less severe disease or shorter duration) may not be cost-effective. Cognizant of the barriers to more widespread use of GDH, the expense of multiple treatments and the lack of trained therapists, a recent study⁴⁷ recruited volunteers via advertisement to an assessment of the potential of home hypnotherapy (delivered using five audio compact disks). Participants completing follow-up, $n = 19$ of the 25 recruited, were compared with matched controls from a separate observational study ($n = 57$) and more patients were reported to

respond to treatment in the home hypnosis group (40%; 10 of 25) than the control group (26%, 15 of 57).

Follow-up was undertaken beyond the treatment period in some of the studies and ranged from 5 months to 6 years. However, only one study⁴³ reported 12 month follow-up of both the intervention and control groups, the remainder followed-up intervention patients only or control groups were crossed to intervention and both results combined in the follow-up data; thus, it is difficult to comment on the long-term effectiveness of GDH. No paper documented the length of time to recruit the small numbers of patients studied or provided evidence to demonstrate the representativeness of participants.

All of the published work that investigates the efficacy of GDH in the management of IBS suggests a benefit and some of the existing treatment centres have achieved remarkable results.^{20, 29, 40} This therapy appears to have potential in the management of refractory IBS of long duration, particularly where this is having a significant impact on the patient's QOL. However, extending the routine provision of GDH to either primary care or to additional secondary care settings cannot currently be justified given the lack of reliable research evidence. Despite several trials indicating that GDH may benefit patients, particularly those with refractory disease, no robust evidence of effect is available either from meta-analysis or from a single appropriately powered and well-designed randomized trial.

Irritable bowel syndrome is a common condition that has a significant impact on the QOL of sufferers and on NHS resources. In the light of the weight of the evidence available in favour of the therapy, from trials of low internal validity, it is essential that a well-conducted placebo controlled RCT is completed. Such a study should aim to determine the effectiveness of GDH in a range of settings (primary, secondary and tertiary care) and should stratify participants by duration and severity of disease.

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COMPETING INTERESTS

None of the authors have any competing interests to declare.

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