

Randomised clinical trial: individual versus group hypnotherapy for irritable bowel syndrome

Jenny Lövdahl¹  | Hans Törnblom¹  | Gisela Ringström¹ | Olafur S. Palsson² | Magnus Simrén¹

¹Department of Molecular and Clinical Medicine, Sahlgrenska Academy, Gothenburg, Sweden

²Division of Gastroenterology and Hepatology, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, USA

Correspondence

Jenny Lövdahl, Department of Molecular and Clinical Medicine, Gastrointestinal laboratory, Blå Stråket 3, 4th floor, SE 41345 Gothenburg, Sweden.
Email: jenny.lovdahl@vgregion.se

Funding information

This study was funded by the Healthcare Committee, Region Västra Götaland (grants VGFOUREG 855971 and VGFOUREG 930214), the Swedish Research Council (grant 2018-02566), the ALF-agreement (grants ALFGBG-726561 and 875,581) and the Faculty of Medicine, University of Gothenburg.

Summary

Background: Gut-directed hypnotherapy improves symptoms for patients with irritable bowel syndrome (IBS). Group hypnotherapy, as well as hypnotherapy administered by nurses, can increase treatment availability, but there are few comparisons between individual and group-based hypnotherapy.

Aim: We aimed to evaluate and compare the effectiveness of nurse-administered hypnotherapy for IBS delivered individually or in groups.

Methods: IBS patients were randomised to individual or group hypnotherapy (8 sessions, 12 weeks). The primary endpoint was changes in severity of IBS symptoms. A responder was defined as reduction of IBS severity scoring system (IBS-SSS) ≥ 50 points at the end of treatment compared to baseline. The effects on extracolonic and psychological symptoms, and quality of life were also assessed. Symptoms were also followed up 6 months after treatment start.

Results: A total of 119 patients were randomised (61 individual, 58 group hypnotherapy). Patients reported improvements in IBS symptoms (IBS-SSS) (individual: 332 (273–401) (median, IQR), versus 216 (140–308), ($p < 0.0001$), group: 315 (239–382), versus 217 (149–314), ($p < 0.0001$)), with no differences between the groups ($p = 0.16$). Extracolonic symptoms, psychological symptoms and quality of life also improved, without clear differences between the groups. Sixty-nine percent of the individual hypnotherapy patients were responders after treatment versus 57% of the group hypnotherapy patients ($p = 0.25$). Symptom improvements were also seen at follow-up.

Conclusions: Nurse-administered gut-directed hypnotherapy, delivered individually or in groups, relieves IBS symptoms, improves psychological symptoms and quality of life. Group hypnotherapy can be an efficacious alternative, enabling more patients to benefit from the treatment ([ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT03432078) ID no of study: NCT03432078).

The Handling Editor for this article was Professor Alexander Ford, and it was accepted for publication after full peer-review.

This is an open access article under the terms of the [Creative Commons Attribution-NonCommercial](https://creativecommons.org/licenses/by-nc/4.0/) License, which permits use, distribution and reproduction in any medium, provided the original work is properly cited and is not used for commercial purposes.

© 2022 The Authors. *Alimentary Pharmacology & Therapeutics* published by John Wiley & Sons Ltd.

1 | INTRODUCTION

Irritable bowel syndrome (IBS) is a common gastrointestinal disorder, affecting approximately 4% of the population in the world according to epidemiological studies using the Rome IV diagnostic criteria, although widely different prevalence estimates have been published in the past due to different survey methodologies and changing diagnostic criteria.¹⁻³ It is one of the most common of the disorders of gut-brain interaction (previously called functional gastrointestinal disorders), and is defined based on a combination of abdominal pain and altered bowel habits, that is, constipation or diarrhoea, or a mix of these. IBS patients also frequently complain of other gastrointestinal (GI) symptoms such as bloating and abdominal distension, as well as extracolonic symptoms, such as back pain, headache and fatigue.^{4,5} The pathophysiology of IBS is incompletely understood, but the biopsychosocial model enables viewing this diagnosis as an entity wherein different possible causes are taken into consideration, psychological as well as physiological. Both may influence symptoms and how patients experience and cope with these in their daily life.⁶ Furthermore, the presence of psychological distress often worsens the patients' experience of their IBS symptoms and psychological factors influence health care seeking.⁷ It is common that the patients report an association between anticipatory anxiety and worsening of the current symptoms,⁸ and the patient's coping abilities may have an impact on symptom experience and health care-seeking behaviour.⁹

The efficacy of available treatment options for patients with IBS is limited.¹⁰ Medical treatments targeting the predominant symptoms can be helpful, but a large proportion of patients do not find drug treatment effective to a satisfactory extent.¹⁰ Dietary interventions, such as traditional diet advice and the low FODMAP diet, have been shown to improve IBS symptoms,¹¹⁻¹³ but existing trials have been criticised and long-term effects remain uncertain.¹⁴ Patients can also benefit from education about IBS, which can lead to both symptom improvement and a better quality of life, but the effects on IBS symptoms are relatively limited.¹⁵ Psychological therapies have also been reported to be efficacious in patients with IBS, but availability is a limiting factor.¹⁶ Hence, there is certainly an unmet need for widely available treatment options that can improve outcomes for patients with IBS.

Gut-directed hypnotherapy was developed in the 1980s by Professor Peter Whorwell, and was used for IBS patients, with positive effects on IBS symptoms and quality of life.¹⁷⁻¹⁹ Since then, numerous additional published clinical trials have confirmed the effectiveness of this form of psychological intervention for improving IBS symptoms,^{20,21} and the treatment has become more common in Western countries, although availability is still a problem. In many countries gut-directed hypnotherapy is usually delivered by psychologists or other mental health professionals, and in many communities, these clinicians are not available except perhaps in major tertiary care centres. Using a standardised protocol enables a broader range of health care professionals to provide the treatment,²² thereby increasing availability. We have tested the

feasibility of nurse-administered hypnotherapy with results comparable to the already existing data of other studies.²³ There are only two other reports of nurse-administered hypnotherapy for IBS,^{24,25} and although both demonstrate positive results, differences in primary endpoints and the variance of study settings (primary or secondary/tertiary care) make direct comparisons between the studies difficult. To further make the treatment more time-efficient and with higher availability, delivering it in a group setting could be an efficacious solution. A few studies have reported positive effects of group hypnotherapy, with both short-term symptom improvements and durable therapeutic benefit lasting up to 1 year after the end of treatment.²⁶⁻²⁸ However, only one larger randomised controlled study has been reported, comparing the two ways of delivering hypnotherapy.²⁹ In that multi-centre study, group hypnotherapy was not found to be inferior to individual hypnosis treatment and both hypnotherapy groups had more symptom relief after treatment than a control group receiving educational supportive therapy. The patients in this trial were recruited from both primary and secondary care, so the results might not be applicable to the tertiary care patients.

The aim of the present randomised controlled study was to compare the efficacy of nurse-administered gut-directed hypnotherapy, administered either individually or in groups, in a secondary/tertiary care setting. Primarily we focused on improvement of IBS symptoms, but also on psychological and extracolonic symptoms, as well as quality of life. Furthermore, we also aimed to identify predictors of treatment response to individual or group hypnotherapy.

2 | MATERIALS AND METHODS

2.1 | Study participants

Patients with IBS according to the Rome III criteria,⁴ with bowel symptoms that had been refractory to usual medical treatment, were consecutively recruited to the study at a gastroenterology outpatient clinic at Sahlgrenska University Hospital, Gothenburg, Sweden. The study participants were included by the two gastroenterologists in the study (MS and HT) from 2011 to 2015. They confirmed the IBS diagnosis based on detailed clinical history and appropriate tests as needed, and study eligibility was assessed based on inclusion and exclusion criteria (Table 1). Before the treatment started, patients met the nurse responsible for the hypnotherapy treatment (JL), receiving further verbal and written information about hypnotherapy and the study procedure. Patients were instructed not to test other treatments (medical or other) for their IBS symptoms during the study period. Written informed consent was obtained from all study participants prior to treatment. The study was approved by the Regional Ethical Review Board in Gothenburg (no 686-11), and registered at [ClinicalTrials.gov](https://clinicaltrials.gov) (ID no: NCT03432078).

Randomisation was performed by a statistician at Gothia Forum, a regional coordinating research unit. For every 14-16 patients included in the study, a new block randomisation was carried out,

assigning half of the new study participants into one of the two treatment arms. Before treatment initiation, patients were asked to complete baseline questionnaires concerning IBS and extracolonic symptom severity, psychological symptoms and quality of life,³⁰⁻³⁵ as detailed below. IBS symptom severity assessment was repeated every other week during the treatment according to the study protocol (Figure 1). At visit 8 (end of treatment), as well as at

follow-up (6 months after treatment initiation), IBS symptoms, extracolonic symptoms, psychological symptoms and quality of life were reassessed.

2.2 | Hypnotherapy

Patients received eight sessions of gut-directed hypnotherapy during a period of 12 weeks. The first four sessions were administered weekly and the last four sessions every second week. Treatment was given by a nurse specialised in cognitive behavioural therapy and hypnotherapy, with a long-standing experience in managing patients with disorders of gut-brain interaction (JL).

The North Carolina Protocol³⁶ was used in both treatment arms. The first part of the hypnotherapy session, the induction, was adjusted to fit in a group format and individual suggestions (eye-fixation induction) were exchanged to a more general relaxation induction. After deepening the relaxed state further by different techniques, according to the standardised script, the therapist described different beautiful sceneries, often in nature, that were used as metaphors to induce feelings of pleasantness, tranquillity and protection or distancing from discomfort and stressors for the patients. This was followed by therapeutic suggestions to normalise gut sensations, enhance gut function and improve symptoms.

Patients in the individual treatment arm received hypnotherapy lying down in a comfortable chair with a footstool in one of the rooms at the gastroenterology unit. The groups (consisting of six to eight patients) were given hypnotherapy lying down on mattresses placed on the floor in a larger room in the hospital area. They received blankets and pillows for comfort. Patients were informed of the possibility to leave the room at any time if needed, even during

TABLE 1 Inclusion and exclusion criteria

Inclusion criteria
1. Signed written informed consent
2. IBS according to the Rome III criteria
3. Age 18–67 years
4. Ability to understand the Swedish language and to comply with study procedures
Exclusion criteria
1. Pregnancy or trying to become pregnant during the time of the study
2. Severe psychiatric disease
3. Ongoing participation in another clinical study
4. Other disease that could affect the gastrointestinal symptoms
5. Gut-directed hypnotherapy treatment prior to study participation
6. Changes in medical treatment of relevance for IBS symptoms during the last 3 months
7. Recent or ongoing life changing experience such as loss of a close family member or divorce
8. Ongoing psychotherapy

Study eligibility according to the inclusion and exclusion criteria was assessed by the gastroenterologist (MS, HT) before the patients were entered into the randomised controlled study.

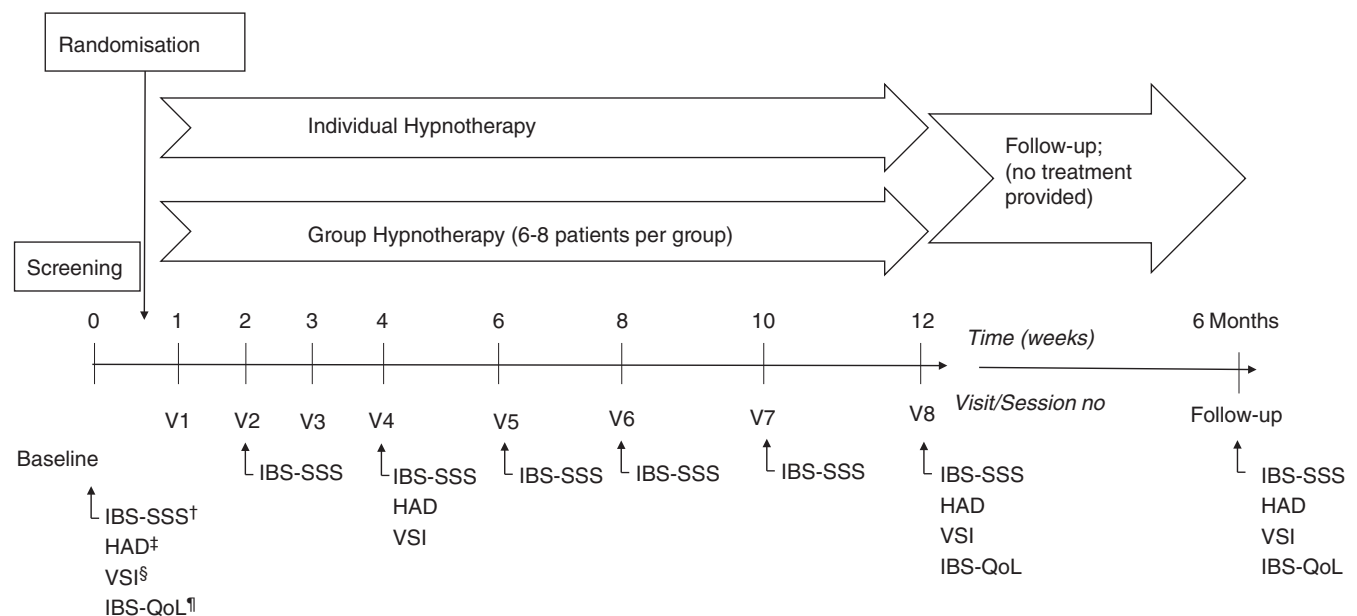


FIGURE 1 Timeline illustrates the visits of the treatment period as well as follow-up, and the patient reported outcome measures assessed at specific time points. [†]IBS-SSS, IBS Severity Scoring System, [‡]HAD, Hospital Anxiety and Depression scale, [§]VSI, Visceral Sensitivity Index, [¶]IBSQoL, Irritable Bowel Syndrome Quality of Life questionnaire

the hypnosis session. The treatment procedure was the same for both treatment arms: the only thing that differed was the individual or group-oriented format. At the second session, patients received an audio file of a hypnotic relaxation exercise, and were instructed to use it daily at home throughout the treatment period.

2.3 | Questionnaires

IBS Severity Scoring System (IBS-SSS) is a validated questionnaire developed to measure GI symptoms as well as extracolonic symptoms in IBS patients. An overall IBS severity score is calculated from five items of GI symptoms (each scored 0–100): pain severity, pain frequency, abdominal bloating severity, bowel habit dissatisfaction and life interference. The overall extracolonic score is measured by 10 items including nausea/vomiting, early satiety, headaches, backache, excess wind, heartburn, body aches, urinary symptoms, thigh pain and lethargy. The two subscores range from 0 to 500 and the higher the score, the more severe are the symptoms. A reduction of 50 points or more on the IBS symptom subscale is considered an improvement of clinical relevance.^{30,34}

Visceral Sensitivity Index (VSI) is a questionnaire created with the purpose of assessing GI-specific anxiety. It consists of 15 items, using a 6-point Likert scale. Total scores range from 0 to 75, 0 indicating no GI-specific anxiety and 75, the most severe GI-specific anxiety.^{31,35}

The *Hospital Anxiety and Depression Scale (HAD)* was developed in a medical outpatient setting to measure the presence of depression and anxiety. It consists of two subscales; each subscale consists of seven items using a 4-point Likert scale (scoring from 0 to 3), creating a subscale score ranging from 0 to 21. A higher score indicates more pronounced anxiety or depression. Scores of 11 or higher indicate with reasonable accuracy a clinically significant anxiety or depression.³²

Irritable Bowel Syndrome Quality of Life (IBSQoL) is a validated disease-specific, health-related quality of life questionnaire consisting of 30 questions and nine domains: emotional functioning, mental health, sleep, energy, physical functioning, diet, social role, physical role and sexual relations. Scores for each subscale are transformed to a score between 0 and 100, the higher the score, the better health-related quality of life.³³

2.4 | Statistical procedures

Before study start, we calculated that, in order to detect a difference in IBS-SSS of 50 between the groups (SD 90), with 80% statistical power at $\alpha = 0.05$, we needed to include at least 51 patients in each treatment arm. The primary endpoint was change in overall IBS symptom severity measured with IBS-SSS. We also assessed the percentage of patients in each arm who reduced their IBS-SSS score ≥ 50 at the end of treatment compared with baseline, who were defined as treatment responders. These comparisons were also

performed for data collected at follow-up, that is, 6 months after the hypnosis treatment started. Intention-to-treat (ITT) analyses for IBS symptoms were performed in order to take into account treatment dropouts.

The collected data regarding symptoms and group assignments were entered in the database by a person otherwise not involved in the study. In case of missing responses to questions in a questionnaire, current methods to compensate for this were used. Values for missing responses were imputed based on the other answers in the questionnaire if less than 25% was missing. For missing data on an entire questionnaire at a visit, the last-data-carried-forward principle was used. The first author performed all the statistical analyses.

The secondary endpoints were effects on extracolonic symptoms, psychological symptoms and quality of life at the end of treatment compared with baseline. These assessments were analysed by Per Protocol (PP) analyses, that is, only patients who completed the treatment were included in the calculations. All patients who had attended at least 7 of the 8 hypnotherapy sessions were considered to have completed the treatment and were included in the PP analyses. The change in symptom severity was analysed both within- and between the groups, using Mann-Whitney U and Wilcoxon signed ranks tests respectively. In addition, a mixed between-within subjects ANOVA was conducted in order to assess the impact of the two different interventions on IBS symptom severity (IBS-SSS) across the entire treatment period. Responder rates in the two treatment arms were compared by chi-squared tests. Continuous variables are presented by median and interquartile range (IQR), categorical data by proportion (%).

Baseline characteristics as well as symptom severity half-way through the treatment period were compared between responders and non-responders in order to investigate potential predictors of treatment response (Table 2). A $p < 0.05$ was considered statistically significant.

3 | RESULTS

3.1 | Participants

In total, 144 patients were assessed for eligibility for the study. Out of these, 25 patients were not included, mainly because of social reasons (e.g. no possibility to combine work and treatment appointments, living too far from treatment location and not motivated enough to start treatment). Other reasons included pregnancy and recent medication changes that could affect GI symptomatology. A total of 119 participants (mean age 41, 20–67 years, 87 females) entered the study and were randomised to one of the two study arms (61 patients to individual and 58 patients to group hypnotherapy). Baseline characteristics were similar for both groups, apart from the distribution of IBS subtypes (Table 2). The first patients received hypnosis in 2011 and the final study participants finished the hypnotherapy treatment in 2016. A total of 110 patients, 57 in the individual hypnotherapy arm and 53 in the group hypnotherapy arm, completed the trial and attended at least seven or all of the

eight sessions. Nine patients (7.5% of all patients, 4 in the individual-treatment arm, 5 in the group-treatment arm), dropped out prior to completion of treatment. The reported reasons for discontinuing the treatment included lack of time to participate in the study, lack of improvement of symptoms during treatment or other reasons, such as new employment. These patients did not differ significantly compared with the others regarding severity of IBS symptoms or anxiety, although the dropouts were younger and more frequently male and tended to have higher depression scores at baseline (Table S1). The study flow data are summarised in Figure 2.

One patient (individual hypnotherapy) had a minor anxiety reaction during the first hypnotherapy session. The patient completed the treatment and attended the following sessions without any further discomfort. No other adverse reactions during treatment were reported.

TABLE 2 Baseline characteristics of the randomised patients

Variables	Hypnotherapy treatment form	
	Individual (n = 61)	Group (n = 58)
Females, n (%)	44 (72)	43 (74)
Age, mean (range)	43 (20–67)	39 (20–67)
IBS subtype, n (%)		
IBS with diarrhoea	16 (26)	29 (50)
IBS with constipation	17 (28)	12 (21)
Mixed IBS	28 (46)	17 (29)
IBS-SSS, median (IQR)	332 (273–401)	315 (239–382)
Mild (score ≤175), n (%)	4 (7)	5 (9)
Moderate (score 176–299), n (%)	20 (33)	18 (31)
Severe (score ≥300), n (%)	37 (61)	35 (60)
HAD anxiety, median (IQR)	9 (7–12)	10 (6–14)
HAD depression, median (IQR)	6 (3–9)	6 (3–9)
VSI, median (IQR)	47 (37–57)	47 (34–59)

Abbreviations: IBS-SSS, IBS Severity Scoring System; HAD, Hospital Anxiety and Depression scale; VSI, Visceral Sensitivity Index.

* $p < 0.05$ between the two treatment groups.

3.2 | IBS symptoms

Baseline IBS symptom severity data was compared to the assessments completed at the end of the treatment period (visit 8). Improvement in the overall severity of IBS symptoms was seen for both group- and individual hypnotherapy (Table 3 and Figure 3) and the improvement did not differ between the groups ($p = 0.16$). The improvement in IBS symptom severity was also seen at follow-up for both treatment groups, with no differences between the groups (Table 3). Furthermore, significant improvement in the severity of IBS symptoms compared with pre-treatment scores was seen at all time points during gut-directed hypnotherapy and in both treatment groups compared with baseline ($p < 0.0001$), (Figure 4). The IBS symptom reduction improved gradually over time during the 12 weeks of treatment. In agreement with this, the mixed between-within subjects ANOVA showed a main effect for time for both groups (Wilks' Lambda = 0.46, $F [6, 112] = 21.6$, $p < 0.001$), with a large effect size (partial eta squared = 0.54). The main effect comparing the two interventions was not significant ($F [1, 117] = 0.83$, partial eta squared = 0.00), again supporting no difference between the two ways of delivering hypnotherapy. There was no significant interaction between group and time (Wilks' Lambda = 0.96, $F [6, 112] = 0.87$, $p = 0.52$, partial eta squared = 0.05).

Forty-two (69%) of the patients receiving individual hypnotherapy were defined as responders (reduction of the IBS-SSS score ≥ 50 at the end of treatment compared to baseline), as compared with 33 (57%) in the group hypnotherapy arm ($p = 0.25$ between groups). At follow-up 6 months after start of the intervention, 39 (64%) of the patients who had received individual hypnotherapy fulfilled the responder criterion, as compared with 35 (60%) of the group hypnotherapy patients. Both treatment groups also demonstrated reduced scores in all of the five items of the IBS-SSS (i.e. frequency and severity of abdominal pain, severity of bloating, dissatisfaction with bowel habits and life interference from bowel symptoms) following hypnotherapy ($p < 0.0001$), with no differences between the two groups (Figure 5).

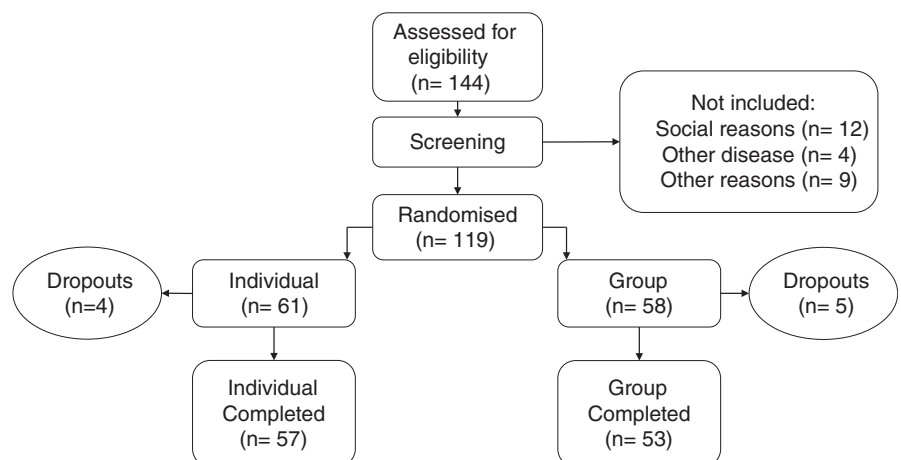


FIGURE 2 Flow chart demonstrating the number of patients during different phases of the study

TABLE 3 Symptom variables before, after the hypnotherapy treatment period (visit 8) and at follow-up (6 months)

Variables	Individual hypnotherapy (n = 57)			Group hypnotherapy (n = 53)			p-value—between groups	
	Baseline	Visit 8	Follow-up	Baseline	Visit 8	Follow-up	Baseline-visit 8	Baseline-follow-up
IBS-SSS score	332 (273–401)	216 (140–308)****	215 (130–334)****	315 (239–382)	217 (149–314)****	206 (130–298)****	0.16	0.45
IBS-SSS extracolonic score	201 (155–272)	145 (82–226)****	151 (75–239)****	180 (131–246)	116 (57–189)****	106 (55–190)****	0.94	0.41
VSI score	47 (37–57)	34 (22–43)****	30 (20–42)****	47 (34–59)	36 (27–50)****	30 (22–46)****	0.03*	0.56
HAD anxiety score	9 (7–12)	6 (4–10)****	7 (4–10)****	10 (5–14)	8 (4–13)**	6 (4–10)****	0.16	0.29
HAD depression score	6 (3–8)	3 (1–7)****	4 (1–7)**	6 (3–9)	5 (2–8)	4 (2–7)****	0.05	0.47

Note: ITT data for IBS-SSS score; Per Protocol data for other variables. Median (IQR).

Abbreviations: HAD, Hospital Anxiety and Depression scale; IBS-SSS, IBS Severity Scoring System; VSI, Visceral Sensitivity Index.

* $p < 0.05$ vs baseline; ** $p < 0.01$ vs baseline; *** $p < 0.001$ vs baseline; **** $p < 0.0001$ vs baseline.

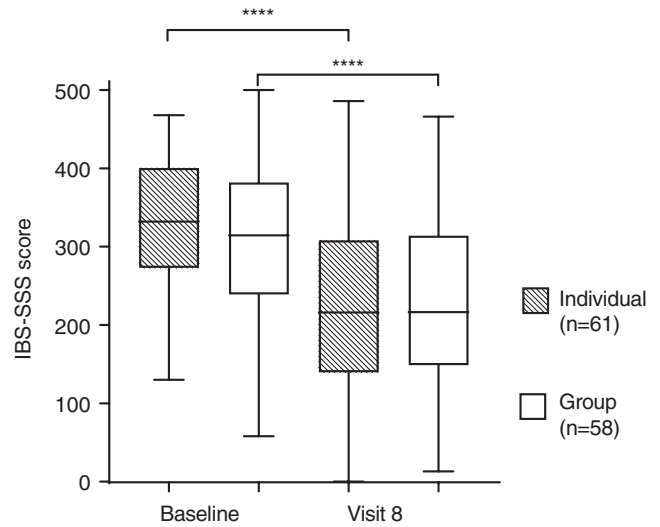


FIGURE 3 Severity of gastrointestinal symptoms before (baseline) and after (visit 8) hypnotherapy treatment assessed with the IBS severity scoring system (IBS-SSS) (median, IQR). **** $p < 0.0001$

3.3 | Extracolonic and psychological symptoms, and quality of life

Both treatment groups demonstrated significant improvement in overall severity of extracolonic symptoms after receiving hypnotherapy, relative to baseline assessments ($p < 0.0001$), with no difference between groups (Table 3).

GI-specific anxiety also improved in both groups after treatment, but with a slight tendency towards greater improvement after individual hypnotherapy immediately after the end of the treatment period. Anxiety and depression scores were significantly improved for patients receiving individual hypnotherapy, compared with baseline ($p < 0.0001$). More modest improvements were seen in depression scores directly after group hypnotherapy, but between-group comparisons were not significant ($p = 0.05$). At follow-up, both treatment groups demonstrated significant improvements regarding both anxiety and depression, compared with baseline scores, with no differences between the groups (Table 3).

Those receiving individual hypnotherapy demonstrated improved scores for all of the nine domains of the IBSQoL questionnaire after treatment, relative to the baseline. A similar positive change was seen for group hypnotherapy, with the exception of physical functioning. No significant differences between the groups regarding quality-of-life improvement were detected (Table 4).

3.4 | Early response to treatment

We investigated whether a positive treatment response at visit 5 (after six of the 12 weeks of the hypnotherapy treatment period) could predict a positive outcome at the end of the treatment. Our PP analysis showed that 71% of the patients receiving individual gut-directed

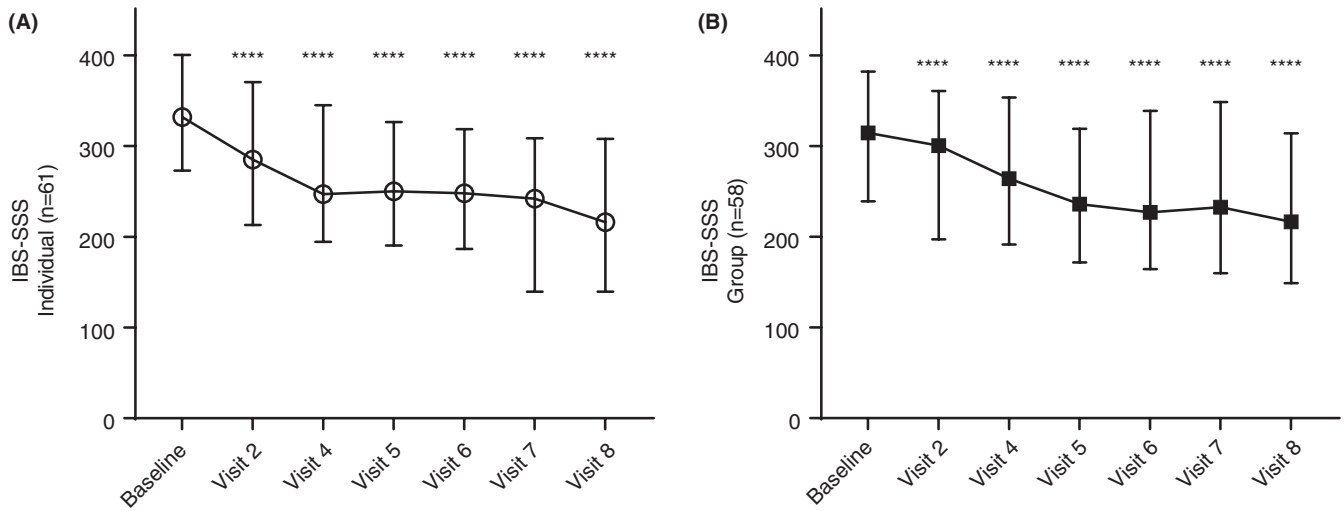


FIGURE 4 Severity of gastrointestinal symptoms (IBS-SSS; median, IQR), before (baseline), every second week during hypnotherapy, and after treatment (visit 8). A) individual hypnotherapy, B) group hypnotherapy. A mixed between-within subjects ANOVA demonstrated a significant effect of the hypnotherapy treatment ($p < 0.001$), but with no differences between the groups ($p = 0.83$). **** $p < 0.0001$ vs. baseline

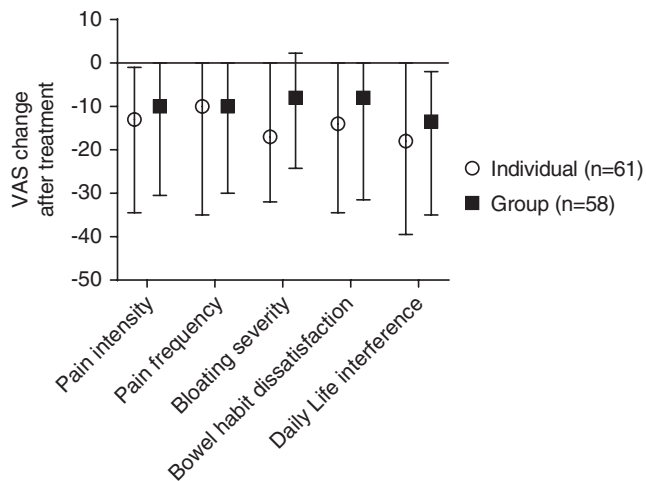


FIGURE 5 VAS change in each of the five components of the IBS-SSS after treatment, compared to baseline. ITT, median (IQR)

hypnotherapy and who were responders after the end of the treatment period, already fulfilled the responder criterion at visit 5. Fifty-three percent of the patients who did not have a favourable treatment response after treatment, were in the “non-responder group” at visit 5 ($p = 0.09$). Sixty percent of the responders after treatment in the group hypnotherapy arm fulfilled the responder criterion at visit 5, and the majority (70%) of the non-responders after treatment were consistent with the non-responder assessment at mid-treatment as well ($p = 0.03$). These findings are illustrated in Figure 6.

3.5 | Baseline predictors for treatment response

We assessed a number of baseline variables as potential predictors for a positive treatment response. No significant differences between

the responders and non-responders in the whole study population (individual and group hypnotherapy combined) were found regarding age, sex, baseline IBS symptom severity or psychological symptoms, (Table S2). However, when assessing each treatment group, only 25% (3/12) of the IBS patients with constipation who received group hypnotherapy, responded to treatment, compared with 70% (12/17) in the individual hypnotherapy arm. Otherwise, no potential predictors of treatment response were detected in the two treatment groups when assessed separately (Table 5).

Sixty-five percent of the male patients in the individual treatment group responded favourably. The proportion of male responders among those receiving group hypnotherapy was slightly lower with only 40% reporting a similar positive response ($p = 0.18$). This tendency of a lower response rate depending on treatment form were not seen among the female patients (70% vs 63%), (Table 5).

4 | DISCUSSION

This study demonstrated that nurse-administered hypnotherapy, delivered either individually or in groups, improved IBS symptoms in patients with IBS. No significant differences regarding improvement of IBS symptoms between the groups were observed, and we can therefore draw the conclusion that neither of the two treatments is clearly superior to the other from this respect, as they also have similar response rates in line with previous treatment studies in IBS. The reduction in overall IBS symptom severity occurred early in the treatment period and was persistent and further improved at all time points during treatment for both treatment groups. The IBS symptom improvement also seems to last, as patients in both treatment groups reported a similar symptom reduction at follow-up. There was a non-significant tendency towards a greater responder rate for patients receiving individual

TABLE 4 Quality of life before and after hypnotherapy

Domain	Individual hypnotherapy (n = 57)		Group hypnotherapy (n = 53)		p-value—between groups
	Baseline	Visit 8	Baseline	Visit 8	
Emotional functioning	44 (31–56)	69 (44–81)****	44 (31–56)	56 (44–63)**	0.07
Mental health	75 (55–80)	85 (70–90)****	65 (49–80)	78 (61–85)**	0.89
Sleep	67 (50–83)	75 (58–92)**	67 (58–92)	83 (71–92)****	0.52
Energy	50 (25–63)	63 (50–88)****	50 (25–59)	50 (50–87)****	0.55
Physical functioning	67 (46–92)	83 (58–100)****	75 (50–92)	83 (58–92)	0.10
Diet	53 (40–67)	67 (53–80)****	60 (40–67)	67 (57–80)****	0.75
Social role	56 (38–69)	69 (56–83)****	50 (31–75)	63 (47–81)*	0.05
Physical role	53 (27–75)	69 (45–86)****	50 (25–69)	63 (44–88)**	0.61
Sexual relations	58 (38–83)	75 (50–92)**	50 (40–77)	67 (38–88)*	0.86

Per protocol data, median (IQR).

* $p < 0.05$ vs. baseline.; ** $p < 0.01$ vs. baseline.; **** $p < 0.0001$ vs. baseline.

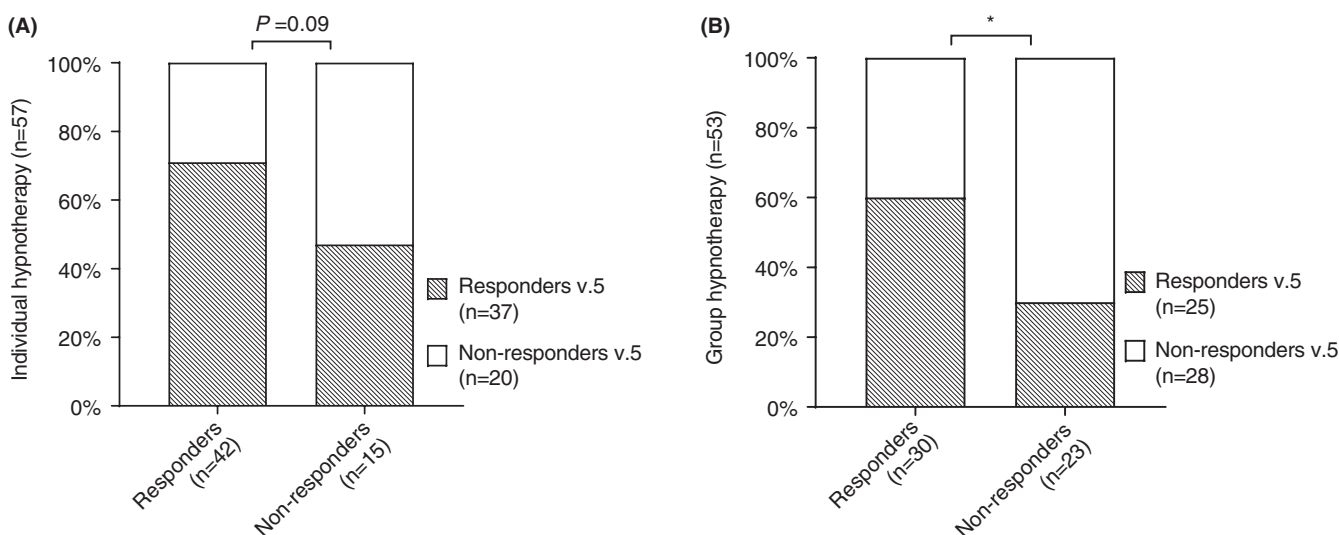


FIGURE 6 Proportion of responders and non-responders after hypnotherapy (visit 8), who were responders and non-responders at mid-treatment (visit 5). Responder = ≥ 50 p reduction in IBS-SSS at visit 8 vs baseline. * $p < 0.05$

hypnotherapy directly after the treatment, but this difference was not evident at follow-up. This further strengthens our interpretation of a good efficacy for both treatment options and with a durable effect over time. Furthermore, group hypnotherapy patients also showed similar results to those of the individual hypnotherapy regarding improvements of extracolonic symptoms, psychological symptoms and quality of life. This clearly suggests that nurse-administered group hypnotherapy could serve as an effective treatment option in IBS in order to increase availability and reduce cost, without losing efficacy.

The IBS symptom improvement and the proportion of responders to the treatment are in line with reports from previous studies of gut-directed hypnotherapy for IBS patients in tertiary care settings, with respect to individual hypnotherapy,^{19,36} as well as group hypnotherapy.^{27,28} However, there are so far a limited number of published reports on the efficacy of group hypnotherapy for IBS, and only two studies have performed direct comparisons between individual and group hypnotherapy.

Harvey et al.²⁶ conducted a randomised study comparing individual and group hypnotherapy and reported that group hypnotherapy showed similar IBS symptom improvement in both groups. However, the study group was relatively small ($n = 33$), and the patients received only four sessions of hypnotherapy during a 7-week period, which is half the number of sessions in our study and delivered in a shorter period of time. The results of the two studies are, therefore, difficult to compare. Given the fact that the study was conducted in 1989 and much has developed since then, regarding medical and other treatment options for patients with IBS, one could argue that the result from the study is difficult to apply fully to present times.

Flik et al.²⁹ recently conducted a large ($n = 344$) multi-centre, randomised controlled study, comparing individual and group hypnotherapy, with educational supportive therapy as a control group. Responder rates in the different hypnotherapy groups were lower in this study compared with ours, although the responder criterion in the study (adequate relief for three or four times out of the last four consecutive weeks of treatment) could be considered a responder

TABLE 5 Potential predictors for treatment response, individual versus group hypnotherapy

Baseline variables	Individual hypnotherapy (n = 61)			Group hypnotherapy (n = 58)		
	Responders (n = 42)	Non-responders (n = 19)	p-value	Responders (n = 33)	Non-responders (n = 25)	p-value
Sex (females/males), n	31/11	13/6	0.66	27/6	16/9	0.13
Age, mean (range)	43 (20–67)	41 (22–67)	0.47	39 (21–62)	38 (20–67)	0.67
Predominant bowel habit Constipation/Diarrhoea/Mixed, n	12/13/17	5/3/11	0.36	3/18/12	9/11/5	0.04*
IBS-SSS, median (IQR)	322 (269–378)	340 (281–415)	0.19	337 (277–385)	280 (210–360)	0.20
IBS-SSS extracolonic score, median (IQR)	184 (140–252)	205 (159–309)	0.25	181 (125–262)	178 (135–242)	0.67
HAD anxiety, median (IQR)	9 (6–12)	10 (8–13)	0.26	12 (6–14)	9 (4–12)	0.42
HAD depression, median (IQR)	6 (3–9)	6 (2–8)	0.99	6 (4–9)	6 (3–11)	0.69
VSI, median (IQR)	43 (35–54)	53 (46–64)	0.38	52 (40–60)	38 (33–58)	0.16

Abbreviations: IBS-SSS, IBS Severity Scoring System; HAD, Hospital Anxiety and Depression scale; VSI, Visceral Sensitivity Index.

* $p < 0.05$.

criterion that is more difficult to reach compared with ours (IBS-SSS reduction ≥ 50 points relative to baseline). Patients were enrolled from primary or secondary care and since our study participants were recruited from a secondary/tertiary care setting, the results of the two studies might not be fully comparable. However, they²⁹ concluded that group hypnotherapy was not inferior to individual hypnotherapy in their study cohort, which is in line with our results. To our knowledge, there is no other randomised controlled trial of this relatively large size that compares individual and group hypnotherapy for IBS patients in tertiary care settings. Therefore, our results could be an important addition to what we know so far about the efficacy of group hypnotherapy for IBS.

In addition to the investigation of group hypnotherapy efficacy, our comparatively large study confirms previous reports of good effects of nurse-administered hypnotherapy for IBS patients.^{24,25} This could, as well as the group format, help to increase availability for the treatment, and is an important contribution to the few existing reports of nurse-administered, gut-directed hypnotherapy.

We also noted clear improvements in psychological and extracolonic symptoms, as well as quality of life in both treatment groups, further strengthening the clinical relevance. Some minor differences were noted regarding treatment effects between the study groups in these aspects. The trend noted was that patients who received individual gut-directed hypnotherapy had greater improvements regarding psychological factors, in particular for GI-specific anxiety, where a significant difference between the groups was observed. These differences between the two treatment groups suggest that individual gut-directed hypnotherapy may have a somewhat bigger impact when it comes to improving anxiety and depression for IBS patients. However, higher baseline scores for psychological symptoms did not predict treatment response in group treatment, indicating that group hypnotherapy might still be as efficacious as individual hypnotherapy when it comes to improving GI symptoms, also for patients who report a higher degree of psychological symptoms before treatment.

Another aim of our study was to identify potential predictors for a positive treatment response, but we failed to identify any clear

predictors from our baseline data. There are some indications in the literature that age, gender, severity of IBS and psychological symptoms may influence the chances of a positive response to hypnotherapy treatment,^{19,23,28,34} but these data have been inconsistent across studies. In our study, we noted a tendency towards differences regarding responder rates between groups for the patients with IBS with constipation, who were less likely to respond favourably to group relative to individual hypnotherapy. However, due to the small number of patients with constipation receiving group hypnotherapy ($n = 12$), it is difficult to draw any firm conclusions from this observation. Three of the other four published studies of group hypnotherapy have not reported such a tendency,^{26,28,29} whilst the fourth study even presented a more favourable effect regarding bowel habit improvements for constipation and not diarrhoea at the 1-year follow-up.²⁷

We have previously reported that an early response to gut-directed hypnotherapy after six of 12 weeks could predict the treatment outcome at the end of the treatment period.²³ The relationship between responder status halfway through the treatment period in the current study versus after the treatment period was not as pronounced as in our previous study, even though the same pattern was noted in those receiving group hypnotherapy, where a significant relationship was observed between an early response and a positive treatment outcome, with the same tendency seen, but not statistically significant in the individual hypnotherapy group. Hence, an early and positive IBS symptom response seems to be an indicator of a favourable treatment outcome of hypnotherapy.

There are of course limitations with our study. One potential limitation is that we did not have a control group in addition to the two hypnotherapy groups. However, the primary aim of our study was to compare these two hypnotherapy formats and not to show that hypnotherapy is effective in IBS, which is well established from many previously published controlled studies.²¹ Another potential limitation is that we performed a single-centre study, and the hypnotherapy treatment was given by only one therapist. This has, of course, implications for reproducibility. On the other hand, we believe that it

could also be an advantage that the treatment has been delivered to the study participants in a uniform way, with the same hypnotherapist for all patients in both study groups. Moreover, our use of standardised scripts for the entire treatment course that are widely used elsewhere ensured that the treatment was given in the same way for all patients in our study, differing only regarding the individual or group format, and makes it easy for others to reproduce the exact treatment that we tested. Despite a randomisation procedure, the distribution of the subtypes of IBS differed somewhat between our two study groups, with the largest proportion of patients reporting diarrhoea as their predominant bowel habit in the group hypnotherapy arm. However, we do not consider it likely that this had any substantial impact on treatment response rates between groups since the proportion of responders of patients who had diarrhoea as the predominant bowel habit did not differ between groups.

To conclude, our study, together with previous studies, indicates that group hypnotherapy is an efficient and safe treatment form for patients with IBS without any reported side effects, which not only reduces gastrointestinal symptoms for patients but also improves psychological symptoms and quality of life. The use of nurse-administered group hypnotherapy can increase availability of this treatment option. However, more studies of this treatment form are needed in order to further establish the efficacy of group hypnotherapy and investigate the reproducibility of existing studies. In addition, other ways to increase availability of this efficacious treatment form for IBS patients further, such as online therapy and use of apps, need to be considered.

ACKNOWLEDGEMENT

Declaration of personal interests: None.

Declaration of funding interests: None.

AUTHOR CONTRIBUTIONS

Jenny Lövdahl: Study concept and design; administered the hypnotherapy treatment; acquisition of data; analysis and interpretation of data; drafting of the manuscript; obtained funding. **Hans Törnblom:** Study concept and design; referred patients to the study; analysis and interpretation of the data; critical revision of the manuscript for important intellectual content. **Gisela Ringström:** Analysis and interpretation of data; critical revision of the manuscript for important intellectual content. **Olafur S Palssson:** Developed the hypnotherapy protocol; critical revision of the manuscript for important intellectual content. **Magnus Simren:** Study concept and design; referred patients to the study; analysis and interpretation of data; critical revision of the manuscript for important intellectual content; study supervision; obtained funding.

AUTHORSHIP

Guarantor of the article: Jenny Lövdahl.

ORCID

Jenny Lövdahl  <https://orcid.org/0000-0001-9732-0606>

Hans Törnblom  <https://orcid.org/0000-0003-2117-9874>

REFERENCES

1. Sperber AD, Bangdiwala SI, Drossman DA, Ghoshal UC, Simren M, Tack J, et al. Worldwide prevalence and burden of functional gastrointestinal disorders, results of Rome foundation global study. *Gastroenterology*. 2021;160(1):99–114.e113.
2. Sperber AD, Dumitrascu D, Fukudo S, Gerson C, Ghoshal UC, Gwee KA, et al. The global prevalence of IBS in adults remains elusive due to the heterogeneity of studies: a Rome foundation working team literature review. *Gut*. 2017;66(6):1075–82.
3. Oka P, Parr H, Barberio B, Black CJ, Savarino EV, Ford AC. Global prevalence of irritable bowel syndrome according to Rome III or IV criteria: a systematic review and meta-analysis. *Lancet Gastroenterol Hepatol*. 2020;5(10):908–17.
4. Longstreth GF, Thompson WG, Chey WD, Houghton LA, Mearin F, Spiller RC. Functional bowel disorders. *Gastroenterology*. 2006;130(5):1480–91.
5. Mearin F, Lacy BE, Chang L, et al. Bowel disorders. *Gastroenterology*. 2016;150:1393–407.
6. Drossman DA. Presidential address: gastrointestinal illness and the biopsychosocial model. *Psychosom Med*. 1998;60(3):258–67.
7. Hillila MT, Siivola MT, Farkkila MA. Comorbidity and use of health-care services among irritable bowel syndrome sufferers. *Scand J Gastroenterol*. 2007;42(7):799–806.
8. Schneider MA, Fletcher PC. 'I feel as if my IBS is keeping me hostage!' exploring the negative impact of irritable bowel syndrome (IBS) and inflammatory bowel disease (IBD) upon university-aged women. *Int J Nurs Pract*. 2008;14(2):135–48.
9. Ringstrom G, Abrahamsson H, Strid H, Simren M. Why do subjects with irritable bowel syndrome seek health care for their symptoms? *Scand J Gastroenterol*. 2007;42(10):1194–203.
10. Simren M, Tornblom H, Palssson OS, Whitehead WE. Management of the multiple symptoms of irritable bowel syndrome. *Lancet Gastroenterol Hepatol*. 2017;2(2):112–22.
11. Shepherd SJ, Parker FC, Muir JG, Gibson PR. Dietary triggers of abdominal symptoms in patients with irritable bowel syndrome: randomized placebo-controlled evidence. *Clin Gastroenterol Hepatol*. 2008;6(7):765–71.
12. Halmos EP, Power VA, Shepherd SJ, Gibson PR, Muir JG. A diet low in FODMAPs reduces symptoms of irritable bowel syndrome. *Gastroenterology*. 2014;146(1):67–75.e65.
13. Bohn L, Storsrud S, Liljebo T, et al. Diet low in FODMAPs reduces symptoms of irritable bowel syndrome as well as traditional dietary advice: a randomized controlled trial. *Gastroenterology*. 2015;149(6):1399–1407.e1392.
14. Krogsgaard LR, Lyngesen M, Bytzer P. Systematic review: quality of trials on the symptomatic effects of the low FODMAP diet for irritable bowel syndrome. *Aliment Pharmacol Ther*. 2017;45(12):1506–13.
15. Ringstrom G, Storsrud S, Posserud I, Lundqvist S, Westman B, Simren M. Structured patient education is superior to written information in the management of patients with irritable bowel syndrome: a randomized controlled study. *Eur J Gastroenterol Hepatol*. 2010;22(4):420–8.
16. Palssson OS, Whitehead WE. Psychological treatments in functional gastrointestinal disorders: a primer for the gastroenterologist. *Clin Gastroenterol Hepatol* 2013;11(3):208–216; quiz e222–203.
17. Whorwell PJ, Prior A, Faragher EB. Controlled trial of hypnotherapy in the treatment of severe refractory irritable-bowel syndrome. *Lancet*. 1984;2(8414):1232–4.
18. Gonsalkorale WM, Miller V, Afzal A, Whorwell PJ. Long term benefits of hypnotherapy for irritable bowel syndrome. *Gut*. 2003;52(11):1623–9.
19. Miller V, Carruthers HR, Morris J, Hasan SS, Archbold S, Whorwell PJ. Hypnotherapy for irritable bowel syndrome: an audit of one thousand adult patients. *Aliment Pharmacol Ther*. 2015;41(9):844–55.

20. Lee HH, Choi YY, Choi MG. The efficacy of hypnotherapy in the treatment of irritable bowel syndrome: a systematic review and meta-analysis. *J Neurogastroenterol Motil.* 2014;20(2):152–62.
21. Palsos OS. Hypnosis treatment of gastrointestinal disorders: a comprehensive review of the empirical evidence. *Am J Clin Hypn.* 2015;58(2):134–58.
22. Palsos OS. Standardized hypnosis treatment for irritable bowel syndrome: the North Carolina protocol. *Int J Clin Exp Hypn.* 2006;54(1):51–64.
23. Lovdahl J, Ringstrom G, Agerforz P, Tornblom H, Simren M. Nurse-administered, gut-directed hypnotherapy in IBS: efficacy and factors predicting a positive response. *Am J Clin Hypn.* 2015;58(1):100–14.
24. Smith GD. Effect of nurse-led gut-directed hypnotherapy upon health-related quality of life in patients with irritable bowel syndrome. *J Clin Nurs.* 2006;15(6):678–84.
25. Bremner H. Nurse-led hypnotherapy: an innovative approach to irritable bowel syndrome. *Complement Ther Clin Pract.* 2013;19(3):147–52.
26. Harvey RF, Hinton RA, Gunary RM, Barry RE. Individual and group hypnotherapy in treatment of refractory irritable bowel syndrome. *Lancet.* 1989;1(8635):424–5.
27. Moser G, Tragner S, Gajowniczek EE, Mikulits A, Michalski M, Kazemi-Shirazi L, et al. Long-term success of GUT-directed group hypnosis for patients with refractory irritable bowel syndrome: a randomized controlled trial. *Am J Gastroenterol.* 2013;108(4):602–9.
28. Gerson CD, Gerson J, Gerson MJ. Group hypnotherapy for irritable bowel syndrome with long-term follow-up. *Int J Clin Exp Hypn.* 2013;61(1):38–54.
29. Flik CE, Laan W, Zuithoff NPA, van Rood YR, Smout AJPM, Weusten BLAM, et al. Efficacy of individual and group hypnotherapy in irritable bowel syndrome (IMAGINE): a multicentre randomised controlled trial. *Lancet Gastroenterol Hepatol.* 2019;4(1):20–31.
30. Francis CY, Morris J, Whorwell PJ. The irritable bowel severity scoring system: a simple method of monitoring irritable bowel syndrome and its progress. *Aliment Pharmacol Ther.* 1997;11(2):395–402.
31. Labus JS, Mayer EA, Chang L, Bolus R, Naliboff BD. The central role of gastrointestinal-specific anxiety in irritable bowel syndrome: further validation of the visceral sensitivity index. *Psychosom Med.* 2007;69(1):89–98.
32. Zigmund AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand.* 1983;67(6):361–70.
33. Hahn BA, Kirchdoerfer LJ, Fullerton S, Mayer E. Evaluation of a new quality of life questionnaire for patients with irritable bowel syndrome. *Aliment Pharm Ther.* 1997;11(3):547–52.
34. Gonsalkorale WM, Houghton LA, Whorwell PJ. Hypnotherapy in irritable bowel syndrome: a large-scale audit of a clinical service with examination of factors influencing responsiveness. *Am J Gastroenterol.* 2002;97(4):954–61.
35. Labus JS, Bolus R, Chang L, Wiklund I, Naesdal J, Mayer EA, Naliboff BD, et al. The visceral sensitivity index: development and validation of a gastrointestinal symptom-specific anxiety scale. *Aliment Pharmacol Ther.* 2004;20(1):89–97.
36. Palsos OS, van Tilburg M. Hypnosis and guided imagery treatment for gastrointestinal disorders: experience with scripted protocols developed at the University of North Carolina. *Am J Clin Hypn.* 2015;58(1):5–21.

SUPPORTING INFORMATION

Additional supporting information will be found online in the Supporting Information section.

How to cite this article: Lövdahl J, Törnblom H, Ringström G, Palsos OS, Simrén M. Randomised clinical trial: individual versus group hypnotherapy for irritable bowel syndrome. *Aliment Pharmacol Ther.* 2022;55:1501–1511. <https://doi.org/10.1111/apt.16934>