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# **Is Gut-Directed Hypnotherapy An Effective Treatment For Refractory IBS?**

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies  
Philadelphia College of Osteopathic Medicine  
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## ABSTRACT

OBJECTIVE: The objective of this selective EBM review is to determine whether or not “Is gut-directed hypnotherapy an effective treatment for refractory IBS?”

STUDY DESIGN: Review of three English language primary studies, one of which was published in 2012 and two in 2013.

DATA SOURCES: Two randomized controlled trials (RCTs) and one case study published in peer-reviewed journals analyzing the effects of gut-directed hypnotherapy (GHT) on irritable bowel syndrome (IBS) symptoms were found via PubMed and Cochrane databases.

OUTCOMES MEASURED: IBS symptoms including abdominal pain, abdominal distention, more or less frequent stools, looser or harder stools, diarrhea, and constipation were measured through the GI Symptom Questionnaire. Five domains including fatigue, impact on daily activities, sleep disturbance, emotional distress, and eating habits were measured through the IBS Impact Scale. Both the GI symptom questionnaire and the IBS-IS are measured on a seven-graded Likert Scale.

RESULTS: The two RCTs by Moser, et al. and Lindfors, Unge, et al. showed a statistically significant improvement in IBS symptoms at the primary endpoint of intervention (3 months) ( $p=0.046$  and  $p<0.01$  respectively) and again at the 1-year follow-up ( $p=0.04$  and  $p<0.01$  respectively). The case study by Lindfors, Ljotsson, et al. also had a statistically significant improvement from baseline to 3 months ( $p=0.005$ ).

CONCLUSION: The RCTs by Moser, et al. and Lindfors, Unge, et al. gave adequate evidence that gut-directed hypnotherapy is an effective treatment for refractory IBS. The unclear and inconclusive results in Lindfors, Ljotsson, et al. reduces this confidence due to the poorly explained methods and statistical analysis. Further investigation is warranted to confidently determine the effectiveness of gut-directed hypnotherapy on IBS symptoms.

KEY WORDS: IBS, Hypnotherapy.

## INTRODUCTION

Irritable Bowel Syndrome (IBS) is a common chronic disorder that affects the large intestine with symptoms including cramping, abdominal pain, bloating, gas, diarrhea, or constipation. Upon examining the patient, there is no visible signs of damage or disease of the digestive tract. IBS is considered to be a functional gastrointestinal (GI) disorder, which is related to defects in how the brain and gut work together.<sup>1</sup> This can lead to increased gut sensitivity and affects the contraction of the muscles in the bowel, which ultimately causes diarrhea and constipation.<sup>1</sup> With this increase in sensitivity, the patient may feel more abdominal symptoms related to IBS than the typical person. There are three types of IBS based on the patterns of bowel movements: IBS with constipation (IBS-C), IBS with diarrhea (IBS-D), and IBS with mixed bowel habits (IBS-M). There are numerous treatments used for IBS, but like many other diseases, there will often be patients refractory to the first, second, and even third line treatments. This paper evaluates two randomized controlled trials (RCTs) and a case study comparing the efficacy of hypnotherapy for the treatment of IBS.

The estimated prevalence of IBS globally is roughly 11%, and ranges from 3% to 20% in the US.<sup>2</sup> The incidence of patients who experience IBS symptoms is 6.7%, and 30% of these patients will consult physicians for their symptoms, which makes the prevalence of IBS difficult to measure.<sup>2</sup> Those who seek out physicians have a greater level of anxiety and lower quality of life.<sup>2</sup> Females more commonly experience IBS than males and the majority are diagnosed younger than 50 years old.<sup>2</sup> IBS accounts for 12% of healthcare visits and 28% of gastroenterology referrals, which results in 2.4 to 3.5 million provider visits per year in the US.<sup>3</sup> Annual healthcare costs for IBS-C (constipation predominant) averages \$11,182.<sup>4</sup> Annual cost for IBS-D (diarrhea predominant) averages \$13,038.<sup>5</sup> Given the high costs and missed diagnoses,

immediate and correct treatment for IBS is of value to the patient, the provider and the healthcare system. The knowledge of non-pharmaceutical treatments, such as hypnotherapy, can minimize time, costs, and symptoms for the patients.

Unfortunately, the exact cause of IBS is unknown. A variety of factors may play a role and different factors may cause IBS in different people. The brain-gut interaction discussed previously seems to be the main cause of bowel abnormalities in IBS patients. Certain situations appear to be a commonality among IBS patients. These situations include stressful or difficult early life events, mental disorders, such as depression, anxiety, and somatic symptom disorder, bacterial infections, small intestinal bacterial overgrowth, and food intolerances or sensitivities.<sup>1</sup> Research also suggests that genes may make some people more susceptible to the development of IBS.

The treatment of IBS typically begins with a trial elimination diet in which the patient will eliminate high-gas foods, gluten, and FODMAPs (fermentable oligosaccharides, disaccharides, monosaccharides and polyols).<sup>6</sup> Providers will often recommend fiber supplements, such as psyllium or methylcellulose, or probiotics in attempts to regulate the GI system.<sup>6</sup> Pharmaceutical options include anti-diarrheal medications (loperamide, cholestyramine), anticholinergic and antispasmodic medications (hyoscyamine, dicyclomine), antidepressants (SSRIs or tricyclics), and IBS-specific medications (alosetron, lubiprostone).<sup>6</sup> Non-pharmaceutical options include psychotherapy, acupuncture, herbs, meditation, and regular exercise.<sup>6</sup> The method being analyzed in this study is a non-pharmaceutical approach for those who want relief of symptoms, but have failed pharmaceutical treatment or choose not to use the pharmaceutical route. Hypnotherapy is a form of psychotherapy used to create change in a patient while in a state of sleep or unconsciousness. It has been used to treat a wide range of

conditions such as phobias, sleep disorder, anxiety, depression, PTSD, smoking cessations, weight loss, etc.

## OBJECTIVE

The objective of this selective EBM review is to determine whether or not “Is gut-directed hypnotherapy an effective treatment for refractory IBS?”

## METHODS

The studies utilized in this review include two randomized control trials, one double-blinded and one single-blinded, and one case study. The population consists of male and female patients between the ages of 18 and 70 who suffer from IBS related symptoms. The intervention used was gut-directed hypnotherapy (GHT), and the control group received supportive and educational therapy. The outcome measured in all three studies was improvement in IBS symptoms.

Key words used to discover the literature included hypnotherapy and irritable bowel syndrome (IBS). All articles were published in the English language and in peer-reviewed journals. The articles were searched via PubMed and Cochrane Library and selected based on their relevance to the clinical question and the presence of patient oriented outcomes (POEMs). Inclusion criteria for this study necessitated that these studies be published after 2006. The patients had to have IBS refractory to standard treatment, confirmed IBS diagnosis through Rome II/III Criteria, and suffered from IBS for at least 5 years. Participants were excluded if they had any organic GI disorders or psychiatric disease, were currently on antidepressants, or had any severe co-existing diseases. Summary of statistics used include p-values, mean change from baseline, mean difference, Fisher’s exact test, two-sample *t*-tests, Mann-Whitney *U*-test, ANOVA, Wilcoxon signed-rank tests, RRR, ARR, and NNT.

**Table 1 – Demographics & Characteristics of Included Studies**

Study	Type	# Pts	Age (yrs)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Moser, 2013 (7)	RCT	164	18-70	- Severe IBS symptoms without response to IBS therapies (medication, psychotherapies) - Confirmed IBS diagnosis (Rome III criteria). - Medications according to patients' symptoms (spasmolytic, antidiarrheal) were allowed and controlled	- Pregnancy, bowel surgery, mental retardation, insufficient knowledge of German, a severe organic/psychiatric disease - Recent treatment with antidepressants - Started on psychotherapies or antidepressants in the last 3 months - >1hr travel from hospital - No relaxation techniques in control	3 mo. 10  1 year 10	Gut-directed hypnotherapy vs. supportive talks with medical treatment (SMT)
Lindfors, Unge, 2012 (8)	RCT	90	21-68	- IBS refractory to standard treatment - Meet the Rome II criteria for IBS - Medications according to patients' symptoms (spasmolytic and antidiarrheal)	- Any organic GI disorders - Patients with other GI conditions explaining their symptoms, or other severe co-existing disease. - The use of psychotropic drugs or antidepressants.	3	Gut-Directed hypnotherapy vs. supportive and educational therapy
Ljndfors, Ljotsson, 2013 (9)	Case Study	83	21-68	- IBS refractory to standard treatment - Meet the Rome II criteria for IBS - Must have completed the RCT by Lindfors, Unge, et al.	- Any organic GI disorders or other severe co-existing diseases. - The use of psychotropic drugs or antidepressants was not allowed.	7	Gut-directed hypnotherapy

**OUTCOMES MEASURED**

All outcomes measured in the trials were based on POEMs that assessed the efficacy of GHT and clinical improvement of IBS symptoms. Both articles by Lindfors et al. examined abdominal pain, abdominal distention, more or less frequent stools, lower or harder stools, diarrhea, and constipation by utilizing the GI Symptom Questionnaire. Moser, et al. used the IBS Impact Scale (IBS-IS), which is a disease-specific documentation of the impact of IBS on patients' lives. It consists of 26 items/questions and represents five domains including fatigue, impact on daily activities, sleep disturbance, emotional distress, and eating habits. Both GI Symptom Questionnaire and IBS-IS are measured on a seven-graded Likert Scale.

## RESULTS

Moser, et al.<sup>7</sup> studied 164 adults between the ages of 18 to 70 and only 100 of which were randomized after assessment for eligibility and only 90 received the allocated intervention (46 GHT and 44 supportive talks with medical treatments (SMT)). These patients were recruited from the University of Vienna, from primary and secondary care physicians from the Austrian IBS patient's organization. This study was a single-blinded RCT; the patients were aware of which group they were in after randomization, but the investigator remained blind throughout the duration of the study. The intervention addressed in this study was GHT, and the comparison group received SMT. The results of the study were converted to dichotomous data. The GHT protocol used the Manchester protocol and consisted of 10 weekly 45-minute sessions over a 12-week treatment period and the same duration of SMT was given to the control patients. Experimental subjects were also given a compact disk for practicing at home on a daily basis, which was documented by the patients themselves.

In order to convert to dichotomous data, a minimal clinically important difference was represented by mean change in score of approximately 0.5 per item on the seven-point Likert scale. Therefore, an increase in total IBS-IS score of  $\geq 1$  unit was estimated as being clinically important improvement (treatment response). Change over time was modeled via repeated ANOVA models with GHT vs. SMT as the between subject factor. Comparisons between the two groups were made using the Fisher's exact test, two-sample *t*-tests and the Mann-Whitney *U*-test. All of these analyses contributed to the discovery of the *p*-value. There was no significant difference between the two groups at baseline. After the 12-week treatment period, 28 out of 46 GHT (60.8%) and 18 out of 44 controls (40.9%) responded to the intervention with significant improvement (95% CI 0-40.2%; *P*=0.046). A follow-up of patients was done at 12 months and



11% of participants did not complete the 12-month assessment (8 dropouts from GHT, 2 dropouts from control). These were included in analysis based on achieving baseline data analysis of all patients with intention to treat. Twenty-five out of 46 GHT patients (54.3%) and 11 out of 44 SMT (25%) showed clinically significant improvement in IBS symptoms (95% CI 10.1-48.6%;  $P=0.004$ ). RRR, ARR, and NNT are calculated in Table 2. The IBS-IS scores distinctly increased for the GHT group, whereas patients in the control group remained stable with slight improvement, giving us a statistically significant improvement in IBS symptoms at both 3 months and 12 months. According to the participants, GHT was without adverse effects.

Lindfors, Unge et al.'s<sup>8</sup> double-blinded RCT studied 90 (45 experimental, 45 control) adults between the ages 21 to 68 with IBS refractory to standard management and met the Rome II criteria. Ninety-seven were originally screened, but 7 of these patients were not included in the study. A study nurse randomized patients in blocks of four using numbered containers. The nurse was otherwise not involved in the study. All patients were told they would receive GHT in order to keep the groups blinded. The control group was informed that they would receive GHT after 6 months, which was recommended by the local ethics committee. The patients included were referred to the gastroenterology departments at the two units for IBS symptoms refractory to standard dietary and pharmacological therapies. The study was performed at Sahlgrenska University Hospital, Gothenburg, Sweden, at a highly specialized unit for functional GI disorders. The hypnotherapy took place in psychology private practices outside the hospital. The intervention addressed in this study was GHT, and the comparison group received supportive and educational therapy (e.g. dietary advice from a dietician, information about relaxation training with a physiotherapist, GI physiology/pathophysiology education with a gastroenterologist). The GHT protocol used was the Manchester protocol and consisted of 12 weekly 60-minute sessions

over a 12-week treatment period. Patients were told to practice their hypnotic skills at home between sessions. Results were recorded at baseline and 3 months after intervention using the GI symptom questionnaire. Three dropped out of the control group after completing the baseline questionnaires, but were included in the analysis based on the intention-to-treat principle. For dropouts, the authors used the principle of last observation carried forward technique and the data missing post-treatment were imputed from baseline assessments and included in the final analyses. Analyses of the results from the questionnaires were made with *t*-tests for paired samples. The mean difference of GI symptom severity change from baseline to 3 months between the two groups was also used (mean difference 3.7; 95% CI 0.3-7.2;  $P=0.03$ ). Mean change from baseline to 3 months of each group separately resulted in statistically significant improvement from GHT (2.2;  $P<0.05$ ), whereas no significant improvement of GI symptoms was seen in the control group (1.6;  $P=0.7$ ). Upon further breakdown of GI symptoms, mean difference for sensory symptoms was statistically significant ( $P=0.01$ ) and no statistical significance was found for bowel habits ( $P=0.15$ ). The results at 3 months were sustained up to 1 year ( $P<0.01$ ). Dichotomous data was obtained by using the responder definition, "Reduction of the total symptom score  $\geq 25\%$  on the GI-symptom questionnaire". According to this definition, there were 5 responders in the control group (11%) compared to 17 responders in the experimental group (38%) ( $P<0.01$ ). At the one-year follow-up, there were 19 responders in the gut-directed hypnotherapy group (42%), but no follow up was done on the control group for comparison. According to the *p*-values, the amount of responders from GHT shows a significant reduction in IBS symptoms. Calculations for RRR, ARR and NNT are presented in Table 2. No adverse events from the interventions were noted.

Table 2: Calculations for treatment from Moser, et al. and Lindfors, Unge, et al.<sup>7,8</sup>

Study	CER	EER	RRR	ARR	NNT	P-value
Moser, et al. (12 weeks)	40.9%	60.8%	0.47	19.9%	6 patients	0.046
Moser, et al. (12 months)	25%	54.3%	1.17	29.3%	4 patients	0.004
Linfors, et al.	11%	38%	2.45	27%	4 patients	<0.01

Linfors, Ljotsson, et al.<sup>9</sup> studied 83 patients ages 21 to 68 with IBS refractory to standard management in a case study. Seven patients from the control group of the previous study done by Lindfors, Unge, et al. were lost to follow-up and were therefore not included in the study due to the fact that no intention to treat was established. In this case study, Lindfors, Ljotsson, et al. used 38 patients from the control group in the previous study and crossed them over after 6 months of supportive therapy to then receive the experimental intervention (GHT) for 3 months. The crossover study was performed in the same conditions and the same location as the Lindfors, Unge, et al. study, except no control group was established. Continuous data were measured using mean change from baseline to three months and determined a statistically significant reduction in overall IBS symptom severity in the GHT experimental group (P<0.005) (Table 3). This statistical significance from pre to post-treatment changes was assessed using the Wilcoxon signed-rank tests. Directly after treatment, patients were also evaluated on their satisfaction of the results of GHT. Although this review does not focus on patient satisfaction with GHT, it is still important to note that 52% of the IBS symptoms responders’ and 31% of the IBS symptom nonresponders’ from their previous study were very satisfied with GHT (P=0.007). “Very satisfied” is observed as receiving a 5 out of 5 on the patient satisfaction questionnaire, which involves quality of life and GI symptom aspects of IBS after GHT. According to the participants, gut-directed hypnotherapy was without adverse effects.

Table 3. Comparison of total IBS symptom severity before (baseline) versus after gut-directed hypnotherapy (12 weeks)<sup>9</sup>

Questionnaire item/domain	Baseline	12 weeks	P-value
Total IBS symptoms	27.5 (20.3-34.7)	24.6 (16.8-32.4)	0.005

## DISCUSSION

Moser, et al. and Lindfors, Unge, et al. elicited a statistically significant improvement in IBS symptoms at the primary endpoint of 3 months, then at follow up at 12 months. Given this information, we have some evidence of adequate long-term effects of hypnotherapy, but more trials would be needed to confirm this theory. Lindfors, Unge, et al. also mentions that sensory symptoms were significantly improved, while bowel habits had no statistically significant improvement. Fortunately, there were no reports of adverse effects in all three studies.

Hypnotherapy can be time-consuming and costly if approached as a short-term resolution.<sup>10</sup> However, the sustained benefits has been calculated to be cost effective within 2 years when compared to conventional approaches.<sup>10</sup> Many major health insurance plans in the US reimburse GHT as treatment for IBS when it is billed as a psychological treatment under the mental health portion of plans since they will typically view it as “medically necessary”.<sup>10</sup> Some plans may not reimburse due to their view of hypnosis being “experimental”. Also, the patient must be certain they see only a state-licensed health professional who has more than 50 hours of certified workshop training in hypnosis to use GHT for their IBS symptoms.<sup>10</sup> If they are not state-licensed, a certified hypnotherapist does not have the necessary clinical qualifications and therefore may not be reimbursed by health insurance.<sup>10</sup> GHT has primarily been used for IBS treatment, but there are also some trials seen with other GI disorders such as irritable bowel disease (IBD). There have been no known risks specifically associated with GHT and there are no contraindications for GHT, as long as the patient has an accurate diagnosis of IBS.

A limitation in Moser, et al. was that despite randomization, control-group patients were older and therefore had longer disease duration. However, age and disease duration did not have

an influence on the long-term success of GHT. Another issue was the large amount of dropouts at the 12-month assessment, however, the proportions and reasons for dropouts were similar between the two groups. GHT was not compared with a group intervention, which could have added benefits such as social support and decreasing stigma. The use of at-home compact disks could also be a limitation since an investigator didn't oversee this. Furthermore, the large difference between groups at the 12-month follow-up may be attributed to the ongoing self-hypnosis of patients with GHT and the lack of supportive talks for controls. Lastly, with the study being single-blinded, there could be bias associated with the fact that patients were aware of which group they were being placed in.

A limitation in Lindfors, Unge, et al. was the fact that the bowel habit scores included the severity of constipation and diarrhea, which may have prevented the possibility to detect improvement in diarrhea and constipation separately. Results at the one-year follow-up had no control group to compare to; this makes it difficult to evaluate proper effectiveness. An added limitation is the lack of specialization and experience with GHT in the psychologists used. Subjects were also instructed to practice their skills at home regularly, but investigators did not oversee this. Moreover, since GHT was given at highly specialized centers, there may be a more pronounced placebo effect due to unspecific psychological effects such as higher treatment expectation.

After analyzing the data presented by Lindfors, Ljotsson, et al., much of it was misleading and unreliable. Recruitment, methods, procedures and questionnaires were mostly taken directly from the study performed by Lindfors, Unge, et al. The crossover of the controls after 6 months of supportive therapy to then receive GHT makes the data appear tarnished since half of the experimental group had already received the control. Not only is this a confusing

aspect, but the case study also failed to remark on this crossover and explain the shortcomings. This also makes the “patient satisfaction” arm of the study unreliable since they are utilizing the same patients for the satisfaction questionnaire. The authors explain that patient satisfaction is “incompletely understood”, “relatively complex”, and “only modestly associated with GI symptoms and IBS-related quality of life”. Since the authors themselves did not have the best grasp on patient satisfaction, the GI symptom questionnaire aspect was the main focus according to the crossover study. According to their mean change from baseline results GHT still gave a statistically significant reduction in IBS symptoms, but with all of the misleading information, it is difficult to have confidence in this study and the results.

## CONCLUSION

Based on the two RCTs reviewed, there is convincing data supporting the benefits and efficacy of gut-directed hypnotherapy for IBS patients. Their symptoms had significantly improved and remained improved for up to a year after. Future studies would be needed to determine if this improvement could be maintained for years after, or even a lifetime. The case study shared conflicting evidence of GHT efficacy. While the outcome of IBS symptom reduction was clinically significant, the investigators were not forthcoming in their analysis and the crossover aspect made their results questionable. A future study could benefit from the exclusion of at-home GHT practice done by the experimental group. Each therapy should be overseen in order to assure all interventions are accounted for. There also needs to be a study performed in the United States to be certain that this therapy applies to all demographics and cultures. With all of these factors considered, future studies are warranted to confidently conclude whether gut-directed hypnotherapy is an effective treatment for refractory IBS patients.

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