



Objectives

- Provide brief history of gut-directed hypnotherapy for GI disorders
- Review efficacy and durability addressing the brain-gut axis
- · How to use gut-directed hypnosis in clinical practice
- Evolution to technology-based treatment
- · How to talk to patients about gut-directed hypnosis
 - For in-person treatment
 - For a digital therapeutic

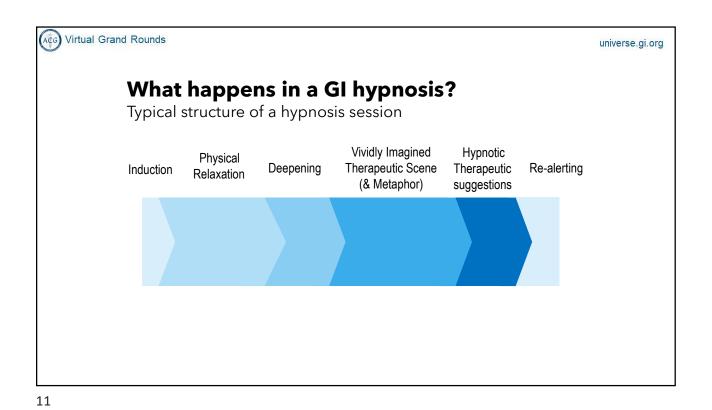
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The Nature of Clinical Hypnosis

- A form of psychological intervention that utilizes a special mental state of heightened receptivity or openness (the hypnotic state) to produce therapeutic physical, emotional and behavioral changes.
- The state of hypnosis is typically induced by verbally guiding the patient to narrow their focus of attention, physically relax, allow things to happen spontaneously, activate their imagination/visualization, and dissociate from the here-and-now.
- Therapeutic suggestions and imagery are the active ingredients in treatment.
- In treatment of GI disorders, a series of six or more sessions is generally required for a substantial lasting effect on the physical symptoms.



Virtual Grand Rounds universe.gi.org **History of gut-directed hypnosis** Whorwell et al. 1984 placebo-controlled IBS hypnosis tria Hypnotherapy vs. supportive therapy + placebo pills. 30 adults with severe treatment-refractory IBS. Seven sessions over 12 weeks. · First randomized controlled trial for IBS published in the mean general wellbeing scor Lancet in 1984. • Efficacy for IBS supported by p<0.001 more than a dozen other RCTs, and also by large consecutive case series. • GI hypnosis has been mostly tested for IBS, but individual mean weekly pain score RCTs also support its use for functional chest pain, functional dyspepsia, IBD, and weekly I pediatric abdominal pain.

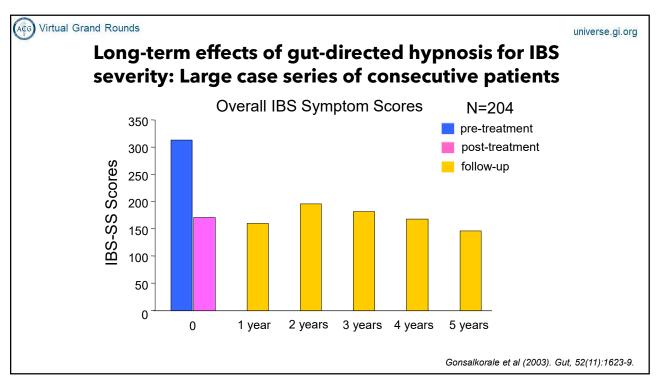
Whorwell, Prior & Faragher. The Lancet 1984, Dec 1;2(8414):1232-4.

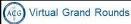


Efficacy and durability of therapeutic effects

- Two dozen RCTs and 40+ total clinical outcome trials published on hypnosis for GI disorders
- Most trials have shown significant therapeutic effect on symptoms, but the evidence is currently
 only sufficient for IBS. Recent systematic reviews generally conclude that hypnotherapy is an
 effective treatment for IBS.
- Efficacy reported in clinical trials for IBS hypnosis treatment varies greatly, depending in part on the GI expertise of the therapist, the treatment protocol, length of treatment, and the outcome measures.
- A three-month course of treatment conducted with structured hypnotherapy protocols for IBS
 has been shown in several trials to benefit at least 60-70% of patients unresponsive to the usual
 medical treatments for the disorder.
- Treatment generally improves all central symptoms of IBS.
- Treatment benefits are well-maintained at follow-up. The majority of patients remain improved at one, two, and up to five-year follow-up.
 Black et al. Gut. 2020 Aug;69(8):1441-1451.
 Ford et al. Am J Gastroenterol. 2019 Jan;114(1):21-39.
 Palsson OS. Am J Clin Hypn. 2015 Oct;58(2):134-58.

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Evolution of gut-directed hypnosis

- Originally applied exclusively as one-on-one in-person therapy.
- Fully scripted therapy courses aided validation of clinical effects and broad dissemination to therapists.
- GI psychologists at most top academic GI clinical centers in the U.S., as well as hundreds of therapists in the community, now offer gut-directed hypnotherapy for a variety of gastrointestinal problems.
- Group hypnosis formats have been found to be effective and a cost-effective option.
- Hypnosis treatment for IBS and other GI problems via video conferencing is now widely used, broadening the reach of this intervention.
- Digital therapeutics (automated hypnosis via mobile devices) are beginning to enable availability of GI hypnosis to any patients anywhere: Fully self-administered (no therapist involvement needed), convenient, inexpensive, and empirically validated.

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GI hypnosis via mobile phone apps: The new era of fully self-administered hypnosis treatment

Regulora© - delivers the North Carolina IBS hypnosis protocol

- Is the first FDA-cleared prescription-only digital therapeutic.
- Seven 30-min. sessions over a 3-month period, with optional shorter sessions in between.
- In the pivotal RCT for FDA clearance, 63% had adequate relief of their IBS symptoms overall, but superiority compared to muscle relaxation treatment only seen in improvement of abdominal pain.

Nerva™ - delivers an IBS hypnosis protocol developed at Monash University, Australia

- Daily 15-min. hypnosis sessions for 6 weeks.
- 64% responder rate in an uncontrolled observational study of 190 IBS patients; broad symptom improvement.
- An RCT is under way.
- Not cleared by the FDA for use for IBS in the U.S.

Saleh, Chey & Berry, 2023. Behavioral Health Digital Therapeutics for Patients With Irritable Bowel Syndrome: A Primer for Gastroenterologists. Am J Gastroenterol. https://doi.org/10.14309/ajg.0000000000002220



The ideal patient for treatment

- Research has concluded that there are no conclusive predictors (e.g. gender, bowel habit subtype, age, personality traits, imaginative ability) of response in routine practice.
- Patient characteristics to consider:
 - Psychiatric co-morbidities do not require more comprehensive mental health treatment
 - Patient is not experiencing significant psychopathology, trauma or dissociative symptoms
 - · Openness and motivation to engage in treatment
 - Experiences hypervigilance and visceral sensitivity which exacerbates symptoms
 - Experiences stress-induced symptoms

Peters SL, Muir JG, Gibson PR. Review article: gut-directed hypnotherapy in the management of irritable bowel syndrome and inflammatory bowel disease. Aliment Pharmacol Ther. 2015. doi: 10.1111/apt.13202.

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Clinical practice

- Patient receives a definitive diagnosis of IBS
- Psychoeducation with patient regarding how gut-directed hypnosis will fit into their treatment plan
- Patient is not responded to medication or diet therapy
 - Hypnosis should be considered for patients with a history of eating disorder
- In-person, virtual, group are effective
- Treatment takes place over the course of 3 months with home practice

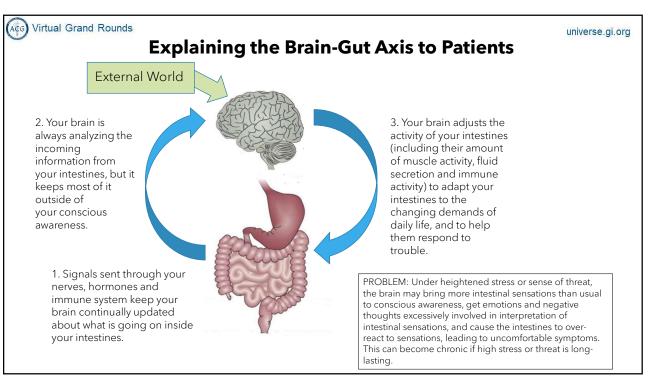


How to discuss hypnosis with your patient

- Setting the stage by explaining the important role of the brain-gut axis in their GI problem.
- Explaining that there are two psychological treatments with best evidence of improving IBS symptoms: CBT and hypnosis. Both with numerous published studies showing them to often improve symptoms even for those who have not responded to other treatment.
- Explain how these psychological treatments are ways to help improve or restore the brain's everyday regulation of the GI tract, thereby reducing symptoms.

Keefer L, Palsson OS, Pandolfino JE. Best Practice Update: Incorporating Psychogastroenterology Into Management of Digestive Disorders. Gastroenterology. 2018. doi: 10.1053/j.gastro.2018.01.045.

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Script for in-person consult

- Don't refer specifically for hypnosis.
- The patient will undergo a consultation with a mental health provider who will assess and determine appropriate treatment.
- You can discuss hypnosis as a potential treatment offered.
- "I would like to refer you for a consultation with a GI psychologist. They will discuss
 how brain-gut behavioral therapies, such as GI-specific cognitive behavioral
 therapy or gut-directed hypnotherapy may collaboratively fit into our treatment
 plan. They may also provide additional suggestions to support the management
 of your health."

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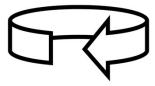


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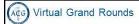
Script for technology-based treatment

"In the treatment of IBS, I find that some patients benefit from using technologyenable solutions (such as this App or this Digital Program) to supplement their care with me. There are some out of pocket costs, but this Product uses evidence-based interventions that are comparable to in-person GI behavioral therapy that I believe may be helpful for you based on our conversation today."

"I look forward to talking with you in our next appointment about your experience with this treatment."



Riehl ME. Limited Access to Integral Care: Digital Therapeutics Show Promise of Scalable Solutions to Behavioral Interventions. Clin Transl Gastroenterol. 2022. doi: 10.14309/ctg.0000000000000444.



Patient characteristics for different treatment options

General mental health

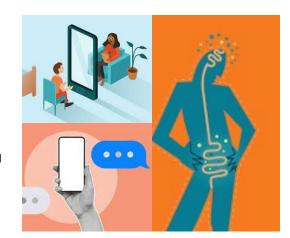
• Psychiatric co-morbidities require comprehensive mental health treatment.

GI psychologist

• Patient prefers option of tailored treatment.

Technology-based solution

- · Access to a GI psychologist is limited
- Patient would be appropriate for working with a GI psychologist
- Patient is highly motivated.
- Patient has no active trauma history or significant psychopathology.



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Take Aways

- Gut-directed hypnotherapy is safe and effective in the management of IBS.
- Access to evidence-based brain-gut behavioral treatment is limited.
- Digital therapeutics for IBS offer a scalable solution.



