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Is cognitive behavioral therapy effective in alleviating IBS-related symptoms experienced by patients with irritable bowel syndrome?

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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 Suwanee, Georgia

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ABSTRACT

OBJECTIVE: The objective of this selective EBM review is to determine whether or not cognitive behavioral therapy is effective in alleviating IBS-related symptoms experienced by patients with irritable bowel syndrome.

STUDY DESIGN: A systematic review of three randomized controlled trials (RCTs) that were published in peer-reviewed journals in 2009, 2010, and 2018, all in the English language. **DATA SOURCES:** All three studies discussed in this systematic review were found and

accessed using PubMed.

OUTCOME MEASURED: Reduction of IBS symptoms as measured by the IBS-SSS questionnaire and the IBS symptom score analysis.

RESULTS: All three studies yielded a statistically significant reduction (p<.05) in IBS symptoms through sessions of cognitive behavioral therapy.

CONCLUSIONS: CBT is an effective treatment option that can reduce anxiety and internal conflict, which may be a contributory or causative agent in IBS patients. The evidence presented within each of the three studies analyzed in this review suggests that cognitive behavioral therapy is an effective intervention to alleviate discomfort in patients with irritable bowel syndrome.

KEY WORDS: Cognitive therapy, CBT, cognitive behavioral therapy, cognitive behavioural therapy, behavioral therapy, behavioural therapy, irritable bowel syndrome, IBS

INTRODUCTION

Irritable bowel syndrome (IBS) is a common condition that affects the large intestine. The typical patient may experience symptoms such as abdominal pain, nausea, flatus, diarrhea, and/or constipation. Patients with this disorder may experience some or all of these symptoms. with severity ranging from mild to debilitating. This disorder is more common amongst females, and affects approximately 25-45 million people in the United States. Additionally, IBS is known to affect the younger population more significantly, and may be influenced by genetics and environmental disposition. It is estimated that there are 3.5 million healthcare visits annually attributable to IBS.² Therefore, providers of all specialties will likely encounter IBS at some point within their careers. The workup for this diagnosis can be quite extensive, as there is no specific test for IBS, and thus it is a diagnosis of exclusion. A typical GI workup for IBS will include obtaining a complete history and physical exam, stool testing, gluten intolerance testing, flexible sigmoidoscopy or colonoscopy, x-ray or CT scanning. Due to this extensive testing, the cost associated with IBS medications and indirect costs have been estimated at 21 billion dollars annually in the United States alone.³ After a provider rules out other potential diagnoses such as ulcerative colitis, crohns disease, bowel obstruction, or other potentially serious conditions, a diagnosis of IBS may be appropriate.

There is much yet to learn about this diagnosis. For example, the exact pathophysiology of this common disorder has perplexed researchers for centuries. The reason for this is in part due to the complex physiology associated with the enteric nervous system, and how it may be influenced by external factors such as emotion, diet, and genetics. Furthermore, the gut microbiota of an individual is responsible for producing a variety of neuroactive molecules, which communicate with the brain to execute physiologic functions. This communication

between the gut and the brain is bidirectional. The brain affects the gut primarily through the central nervous system and endocrine system. Consequentially, the gut is significantly affected by factors that impact the brain, and dynamics within the brain. Therefore, ones mental health may have a profound degree of influence on their guts functioning.

Gastrointestinal disturbances are a common complaint amongst patients experiencing increased levels of anxiety. The specific cause remains unknown, but it may be due in part to the fact that this population has a colon that is hypersensitive to stress. Research has shown that 50 to 90 percent of IBS patients who seek treatment have a comorbid psychiatric condition such as anxiety or depression.⁴ Therefore, mental health conditions may predispose one to an increased chance of developing irritable bowel syndrome. Conversely, IBS may also increase anxiety or depression, as it can significantly impair ones daily activities and overall quality of life.

There currently is no cure for this disorder, but there are a number of ways one can manage this condition. Perhaps the most obvious and initial treatment one should employ, is avoidance of the dietary factors that are known to cause one distress. Additionally, other lifestyle changes such as a high fiber diet, adequate hydration, a regular exercise schedule, as well as a healthy sleep schedule can contribute to the reduction of symptoms.⁵ As far as pharmalogical treatment of IBS is concerned, there are a number of different options available. The most appropriate treatment will correlate with the specific symptoms and severity that one is experiencing. These classes of medications include laxatives, anticholinergic medications, tricyclic antidepressants, SSRI antidepressants, pain medications, Alosetron, Eluxadoline, Rifaximin, Lubiprostone and Linactolide.⁵ Researchers continue to work tirelessly to develop new medications to combat this syndrome. For instance, researchers speculate that future treatments may involve serum-derived bovine immunoglobulin/protein isolate (SBI) and enteric

coated peppermint oil for successful treatment of diarrhea in certain patients with IBS.⁵
Psychological interventions such as cognitive behavioral therapy, mindfulness exercises, hypnosis, and various forms of relaxation therapy may also be of benefit in the treatment of IBS. The primary focus of these interventions is to utilize the mind as a tool to reduce the negative effects that the brain produces on the gut. Cognitive behavioral therapy is a specific type of psychotherapy a therapist can employ to help a patient manage negative thinking or emotional challenges in a more constructive way. This can ultimately reduce anxiety by teaching one effective methods to manage their personal stressors. This paper serves to evaluate three randomized controlled trials (RCTs) to evaluate the potential efficacy of CBT in IBS patients.

OBJECTIVE

The objective of this selective EBM review is to determine whether or not cognitive behavioral therapy is effective in alleviating IBS-related symptoms experienced by patients with irritable bowel syndrome.

METHODS

Three RCTs were chosen based on their relevance and ability to answer the objective. The first RCT completed by Moss-Morris et al. investigates patients meeting Rome I and Rome II criteria between the ages of 18-72 who can read and write English.⁶ The intervention applied to the participants in this study was a seven week manualized program of CBT that is self-administered in conjunction with a one hour face to face therapy session, and two one hour phone sessions.⁶ These patients were compared to a control group of treatment as usual patients with IBS.⁶ The outcome that was measured in this study is IBS symptom relief as measured by the irritable bowel syndrome severity scoring system questionnaire or IBS-SSS.⁶

The second study done by Jarrett et al. is a three-arm randomized controlled trial, which

studied adults with IBS recruited through community advertisement.⁷ The intervention applied to this population is CBT through nine weekly in-person comprehensive self-management sessions.⁷ This population was compared to a control group of IBS patients that were receiving their usual care.⁷ The outcome measured in this study is the IBS symptom score, which consists of 26 IBS symptoms, that were rated on a scale of 0-4.⁷

The third study done by Lackner et al. is a randomized controlled parallel group trial studying individuals 18-70 years of age whom are diagnosed with Rome III criteria IBS who receive CBT.⁸ The intervention specifically is a group receiving standard-CBT with ten weekly sixty-minute sessions.⁸ They were compared against a control group of patients with IBS that received four information sessions about IBS and the role of lifestyle factors.⁸ The outcome of this study was measured by the irritable bowel syndrome symptom severity scale, or IBS-SSS.⁸

Each of the three articles chosen for this systematic review were personally discovered, and accessed from the PubMed database. They were all published within the last ten years, in English, and within peer-reviewed journals. 6,7,8 They were discovered by searching the following keywords: "Cognitive therapy, CBT, Cognitive behavioral therapy, cognitive behavioural therapy, behavioral therapy, behavioural therapy, irritable bowel syndrome, IBS." The articles were selected upon their relevance and ability to answer my proposed clinical question. The inclusion criteria used for my search consisted of studies published after 2009, randomized controlled trials, human study participants, and outcomes presented as patient oriented evidence that matters. The exclusion criteria used for my search consisted of animal study participants, and studies published earlier than 2009. The three studies all present non-dichotomous data, and the following statistics were reported and analyzed to make assumptions of treatment efficacy: mean change from baseline, p-values, CI's and OR's.

Table 1- Demographics & characteristics of included studies

Study	Туре	Number of patients	Age (years)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Moss- Morris ⁶ , 2010	Randomized controlled trial	64	18-72	Primary care patients between the ages of 18-72 meeting Rome criteria for IBS. Must be able to read and write English. Must live in geographic proximity of the study centre.	Patients were excluded if they have a comorbid illness that could affect their symptoms. Also, if they had bowel surgery, or a current mental disorder such as a psychotic disorder or substance abuse disorder.	1	7-week manualized program of CBT that is self- administered with an one hour face to face therapy session and two one hour phone sessions.
Jarrett ⁷ , 2009	Three-arm randomized controlled trial	188	≥18	Participants must be18 or older, have a previous diagnosis of IBS made by a healthcare provider. Additionally, they must have current IBS symptoms per Rome criteria.	Patients were excluded they had a history of GI, renal, or reproductive pathology. They were also excluded if they had GI surgery, or took medications or had comorbidities that could be potentially confounding to the study.	12	9-week comprehensive self - management course of cognitive behavioral therapy.
Lackner ⁸ , 2018	Randomized controlled parallel group trial	436	18-70	Participants must be between 18-70 years of age and suffering from IBS Rome III criteria. These patients must have moderately severe symptoms occurring at least twice weekly and causing some life interference.	Patients were excluded from the study if they had other primary GI disease or malignancy (other than skin cancer). Also, if they had received IBS-targeted psychotherapy, could not commit to follow up, had an unstable extra intestinal condition, major psychiatric disorder, current GI infection, or used a gut sensitive antibiotic 12 weeks before the assessment.	The study reports a 9% attrition rate amongst 436 participants. This correlates to ~40 people dropping from the study.	10-week standard cognitive behavioral therapy for 10 weekly 60 minute sessions.

OUTCOMES MEASURED

The outcome of interest in each of the three studies is reported as patient oriented evidence that matters (POEM). Many different outcomes were assessed throughout each of the three studies. However, the primary focus of this review will be on IBS symptom reduction reported through questionnaires. The study by Moss-Morris et al. utilized the IBS-SSS and had patients return questionnaires at baseline, end of treatment, three months post-treatment, and six months post-treatment. The study by Jarrett et al. utilized the IBS symptom score questionnaire at baseline, three months post treatment, six months post-treatment, and twelve months post-treatment. The study by Lackner et al. measured the outcome through the IBS-SSS at baseline, three months post treatment, and six months post-treatment.

RESULTS

The three studies analyzed in this systematic review present continuous data that is unable to be converted to dichotomous data. Though the RCTs are all focused on reduction of IBS symptoms through CBT, the experimental designs are slightly different in each study. Additionally, the data is analyzed with a variety of differing statistical analyses throughout each of the studies. The mean change from baseline in regard to symptomatic reduction in IBS symptom severity is the primary statistic utilized to report the data amongst the three studies.

The study conducted by Moss-Morris et al. was a randomized controlled trial with a relatively small number of participants, which consisted of IBS patients who had presented to a primary care office or general practitioner (n=64). The small sample size allowed strict monitoring of compliance to therapy. This was done by accounting for patient attendance and compliance with completing their questionnaires. Over 80% of the population at every point throughout this study attended their CBT therapy sessions, and completed the required

questionnaires. The results of this study reveal significantly lower severity of IBS symptoms occurred in the patients who received CBT, in comparison with the treatment as usual (TAU) group. Interestingly, these patients showed marked improvement immediately at the end of the study, and continued to improve at three and six months post-treatment. As depicted in Table 2 below, the mean change from baseline in the patient population receiving CBT was 109 points on the IBS-SSS, compared to 29.5 in the TAU group, when measured at six months post treatment. The study notes that a 50-point change on the IBS-SSS is clinically significant. 83% of the population receiving CBT had a clinically significant reduction in their symptoms at six months post treatment. Additionally, 49% of the population receiving TAU reported clinically significant reduction in their symptoms at six months post-treatment. Only four participants within the experimental group reported that the intervention was not very effective, and no members reported the treatment as ineffective.⁶ All in all, this study reports an odds ratio of 12.2 with an associated 95% confidence interval of 3.72-40.1.6 This odds ratio suggests a very strong likelihood that CBT as a treatment intervention leads to symptomatic reduction in patients with IBS.

Table 2- IBS symptom evaluation through the IBS-SSS questionnaire amongst patients receiving CBT versus TAU.

	Baseline	End of treatment	3 Months Post- Treatment	6 Months Post- Treatment
СВТ	228.5	156.7	135.4	119.4
TAU	222.8	195.0	190.5	193.3

The study done by Jarrett et al. was a three-arm randomized controlled trial that had a slightly larger number of subjects, consisting of IBS patients recruited through community advertisement (n=188). Though the reports were analyzed on a slightly different scale than the other studies previously discussed, the results of this study were similar. A significant reduction

of IBS symptoms as measured by the IBS symptom score questionnaire was noted at 3 months, 6 months, and 12 months. These results are further delineated below in Table 3. At 6 months after treatment initiation, patients receiving CBT reported a 26.6 decrease in their IBS symptom score questionnaire, compared with a 10.3 decrease in the usual care population. Odds ratio throughout the statistics within this study's analyses were all large (i.e., greater than 2.3). The patients within this study also reported a significant increase in their work productivity. The study reports a p-value less than .001 in regard to the IBS symptom score reduction, and improvement of quality of life amongst the patients receiving CBT. The 95% confidence interval reported within this study at 6 months after the initiation of treatment for group receiving CBT is -21 to -32, while the usual care group had a 95% confidence interval of -3 to -16.7 Interestingly, this study applied further analysis of IBS symptomatic reduction by logging recordings of the change from baseline in a variety of specific symptoms that patients were experiencing. The study yielded results that suggest the largest symptomatic reduction was in abdominal pain and intestinal gas. Thirty-seven percent of patients receiving CBT in this study reported greater than 50% improvement in their abdominal pain/discomfort. Additionally, these patients reported significant increases in their quality of life and less absence from work due to their illness after receiving CBT for at least three months. Compliance to therapy and the assigned homework questionnaires were monitored throughout the study. Eighty-seven percent of subjects received at least seven of nine sessions, and 91% of patients met the expectations for the amount of homework that was to be completed.⁷

Table 3- IBS symptom evaluation through the IBS symptom score questionnaire amongst patients receiving CBT or usual care

	Baseline	3 Months	6 Months	12 Months
CBT	76	-28.5	-26.6	-25.6
Usual Care	64.9	-5.4	-10.3	-9.5

The study performed by Lackner et al. was a randomized controlled parallel group trial consisting of a larger sample size (n=436). Of these participants 9% dropped out from the study due to varying demographic, psychological, and IBS–related variables. This study also showed significant reduction in the symptoms of IBS with standard CBT. However, the control group in this study showed a significant reduction in symptoms as well. The study notes that CBT outperformed IBS education on the IBS-SSS and overall symptomatic improvement but failed to produce any significant between group difference. At six months after the initiation of treatment the standard CBT group reported a -103.5 +/- 17 point decrease on their IBS-SSS questionnaire, compared to a 97.93 +/- 15.4 point decrease in the IBS education only sample. All changes from baseline reported below in Table 4 are significant (p<.01). Eighty-nine percent of the participants within this study were compliant with the treatment regimen, as indicated by attending at least eight of the ten CBT sessions.

Table 4- IBS symptom evaluation through the IBS-SSS questionnaire amongst patients receiving CBT or IBS education alone.

	Immediate Post - Treatment	3 Months Post - Treatment	6 Months Post - Treatment
СВТ	-80.99 +/- 17.0	-103.2 +/-16.4	-103.5 +/- 17.7
IBS Education Only	-84.43 +/- 14.6	-88.53 +/- 14.6	-97.93 +/- 15.4

DISCUSSION

In summary, CBT is an effective treatment option for an array of mental health illnesses, as well as IBS. The results from all studies within this review show irrefutable evidence that CBT is a great treatment option to reduce the symptoms associated with IBS. Though CBT is a safe form of treatment with no black box warnings or long-term side effects, it may not be appropriate for every patient. For instance, individuals who have limited intellectual functioning

or cognitive impairment may not receive benefit from CBT as an intervention. One finding throughout these studies that raises concern over the true effect of CBT can be found within the Lackner et al study. The control group, which is patients receiving IBS education only, produced comparable findings to the CBT population. This suggests that a phenomenon other than CBT may be the causative agent in reducing one's symptoms. Throughout the three studies, patients showed continued symptomatic improvement at six months, and in two of the studies, even at one year. Therefore, CBT can help patients learn skills to independently manage their conditions appropriately to some degree. A potential drawback from CBT is that the cost may not be accessible to those without insurance. Approximately 27.6 million people under the age of 65 are uninsured and may be unable to afford this treatment option. Home therapy, or a cheaper alternative to treatment delivery may reduce this limitation.

Each of the three studies presents limitations that need to be accounted for when making analyses. For instance, all of these studies focused on CBT in the adult population. More research needs to be conducted to determine effectiveness of CBT in regards to treating the pediatric IBS population. In the study by Moss-Morris et al., the majority of participants had severe IBS symptoms and were less disabled, and depressed than cohorts of comparable studies.⁶ A lower baseline level of anxiety or depression amongst study participants is a large potential confounding variable. Within the study by Jarrett et al., the majority of participants were educated Caucasian females.⁷ The final study by Lackner et al. relied upon mostly volunteers, which coincidentally were comprised of mostly women as well.⁸ Perhaps the biggest drawback within this study as aforementioned, was that the control group produced similar results to the treatment population. This leads one to consider if CBT is truly the agent that is reducing IBS

symptoms. This study suggests that education alone may lead to significant improvement of their condition, without receiving any form of CBT.

CONCLUSION

In conclusion, CBT is a great option for those with insurance, and ample free time, as a means of treatment for IBS. Each study produced statistically significant results, which clearly answers the question of whether or not IBS can be effectively treated with CBT. Further studies need to be conducted that account for the limitations mentioned within this review. Gender differences, as well as a patients' baseline anxiety levels and other mental health illnesses, must be accounted for to appropriately establish the impact that CBT has on a cohort. The longevity of symptomatic relief that CBT can provide for these patients is a potential area of research to be expounded upon. Additionally, future studies can address the cost effectiveness of IBS treatment, as Americans have one of the highest rates of underinsured or uninsured individuals. It is well known that CBT can effectively help those with mental health illnesses. However, a future area of research could focus on how CBT affects those with IBS that have very low baseline levels of anxiety or other mental health issues. All in all, these studies have done an excellent job in portraying the many benefits which cognitive behavioral therapy can provide for those suffering from IBS.

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