

Comparison of Hypnotherapy and Standard Medical Treatment Alone on Quality of Life in Patients with Irritable Bowel Syndrome: A Randomized Controlled Trial

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ABSTRACT

Introduction: Irritable bowel syndrome (IBS) is one of the most prevalent gastroenterological disorders. IBS is characterized by abdominal pain, cramping, diarrhea, constipation, bloating and flatulence. Complementary therapy is a group of diverse therapeutic and health care systems products that are used in treatment of IBS. Hypnotherapy helps to alleviate the symptoms of a broad range of diseases and conditions. It can be used independently or along with other treatments.

Aim: This study was conducted to compare therapeutic effect of hypnotherapy plus standard medical treatment and standard medical treatment alone on quality of life in patients with IBS.

Materials and Methods: This study is a clinical trial investigating 60 patients who were enrolled according to Rome-III criteria. The sample size was determined per statistical advice, previous studies, and the formula of sample size calculation. The participants were randomly assigned to two groups of hypnotherapy plus standard

medical treatment group (n: 30), and standard medical treatment group (30). The study consisted of three steps; prior to treatment, after treatment and six months after the last intervention (follow-up). The instruments of data gathering were a questionnaire of demographic characteristics and standard questionnaire of quality of life for IBS patients (Quality of Life IBS-34). The data were analysed by analysis of co-variance, Levene's test and descriptive statistics in SPSS-18.

Results: There were significant differences between the two groups of study in post-treatment and follow-up stage with regards to quality of life ($p < 0.05$).

Conclusion: Psychological intervention, particularly hypnotherapy, alongside standard medical therapy could contribute to improving quality of life, pain and fatigue, and psychological disorder in IBS patients resistant to treatment. Also, therapeutic costs, hospital stay and days lost from work could be decreased and patients' efficiency could be increased.

Keywords: Inflammatory bowel disease(HBD), Complementary medicine, Quality of life

INTRODUCTION

Irritable Bowel Syndrome (IBS) is the most prevalent dysfunction of gastrointestinal tract developed for unknown reasons and characterized by gastric pain in defecation and variations in bowel habits [1]. By the standard diagnostic criteria of IBS, its prevalence depends on numerous variables, but it has been reported as ranging 5-20% [2]. IBS affects approximately 7-15% of the population in North America, 11.5% in the Europe and 5.8% in Iran [2,3].

IBS causes a significant economic burden on community through reduced work productivity and increased use of health-related resources [4] and imposes a large burden on family and community so that most patients abandon treatment because of failure to afford it. Quality of life in chronic patients is one of the indicators of effective healthcare. It is clear that quality of life is influenced by the individual's beliefs, life experiences, personality and expectations. Some studies are being done to investigate the effect of quality of life on the differences among patients, the prediction of disease, and evaluation of interventions [5-10].

IBS affects the patients' quality of life greatly, so that it occasionally disturbs occupational function, traveling and interpersonal relationships and prevents the patients from enjoying life [11]. Study of the quality of life in the IBS patients for gastrointestinal dysfunction is particularly important to determine the rate of recovery and therapeutic progress in terms of physical, psychological and mental domains because of lack of specific tangible and clinical symptoms [12].

Hypnosis is a psychotherapeutic approach which helps to address or apply the process of hypnotherapy through variations in consciousness and a complicated process in the brain with three components; concentration, segregation and reduction of environmental awareness and empathy [13]. This approach was first introduced by Mesmer, a Vienna physician in the 18th century, under the theory of animal magnetic and process of energy transmission, later known as Mesmerism [14,15]. Hypnosis contributes to treatment of gastrointestinal diseases including gastric and duodenal ulcers, IBS, Crohn's disease, reflux, bloat, nausea, vomiting and abdominal neuralgia [8].

Hypnotherapy exerts therapeutic effects on IBS symptoms. Few studies have already reported long term effects of hypnotherapy [9]. Quality of life and symptoms decreased significantly in 63% of the participants after military training [16]. Pain was relieved in patients after 7-12 sessions of hypnotherapy [17]. The symptoms of IBS changed in follow-up period [18]. Rectal sensitivity was reduced after hypnotherapy [15,19]. Hypnotherapy contributed to the symptoms management and control [4]. Many studies have demonstrated the efficacy of psychological intervention such as relaxation, cognitive and behavioral therapy and meditation on improvement of quality of life and decrease in the symptoms in IBS patients [20,21]. These studies have indicated that psychological intervention alongside pharmacologic treatments could help the signs improve in IBS patients [18]. Since no similar study has been yet conducted in Iran and similar studies have been done mainly outside Iran, which is greatly different from Iran in terms of lifestyle

and cultural specifications, such as excessive use of sour, acidic, carbonated, and spicy foods with many spices, additives and preservatives, lately absorbed foods like red meat, fast food, fat, and raw foods such as fruits and vegetables, the present study was conducted to compare therapeutic effect of hypnotherapy plus standard medical treatment and standard medical treatment alone on quality of life in the patients with IBS.

MATERIALS AND METHODS

This study was a clinical trial. The patients were enrolled according to Rome-III criteria, definite diagnosis of IBS by a gastroenterologist per the interview and clinical examination. A sample size determined as 60 individuals per statistical advice, previous studies, and the formula of sample size calculation. The samples were randomly assigned to two groups, 1 (hypnotherapy {n: 30}) and 2 (standard medical treatment {n: 30}). The study population consisted of all patients with gastrointestinal diseases referring a specialty clinic in Shahrekord, southwest Iran. In this study, 13 from group 1 and 13 from group 2 were excluded for no cooperation, migration, death, and severe psychological problems. The inclusion criteria were as follows: Meeting diagnostic criteria per Rome-III diagnostic criteria by a gastroenterologist; lack of taking psychiatric medicines within the last three months; failure to participate in psychological intervention within the last six months; and consent to participate in the study.

The hypnotherapy used in the present study has been developed by Wendy [22]. This method is applied for psychosomatic patients and its therapeutic design consists of five sessions, which is conducted on the patients within one or two sessions per the rate and intensity of the symptoms. The duration of each session lasted for 45 to 60 minutes. Hypnotherapy was conducted by a hypnotist. The first two sessions included hypnotic induction, usually with progressive relaxation and other techniques to deepen the hypnotic state, followed by suggestions for general self-assurance building, 'self-image rise' and improved happiness, that were related to the individual. The patient was given an audiotape, with content similar to the sessions, for daily use to practice autohypnosis. From the third session forwards, bowel directed hypnotic suggestions and techniques for normalizing and controlling bowel function were also used, including: (1) placing their hands on their abdomen and inducing a sense of warmth and relieve; and (2) imagery to symbolize the bowel which was then altered accordingly to represent normal function. For example, a patient with loose bowels might imagine the bowel as a rapidly flowing river and change it to a much slower smoothly flowing one. The patients were expected to practice these techniques daily with a second audiotape containing these bowel directed suggestions and to use them independently as necessary to relieve symptoms. The techniques were then reinforced and/or modified if necessary in following sessions when it was possible to include other interventions for any specific issues that triggered or exacerbated symptoms [22].

During the implementation of the study, both groups received standard medical treatment. The standard treatment included routine gastroenterological drugs for IBS patients predominantly with diarrhea that was prescribed by a gastroenterologist.

The study consisted of three steps; prior to treatment, after treatment and six months after the last intervention (follow-up). The instruments of data gathering were a questionnaire of demographic characteristics and standard questionnaire of quality of life for IBS patients (Quality of Life IBS-34). This was firstly developed by Drossman and Patrick in 1998 [23] and consists of 34 items and eight subscales; disphoria, interference with activity, body image, health worry, food avoidance, social relation, sexual problems and relationship.

The content validity of the questionnaire was confirmed by European and Asian academy. For reliability assessment, the questionnaires were simultaneously completed and the correlation coefficient was calculated as 0.91 [16]. The patients of both groups were asked to complete a validated quality of life questionnaire relating to their experiences over the preceding 6-month period. The obtained data were analysed by analysis of covariance, Levene's test and descriptive statistics in SPSS 18. The study protocol obtained the permission from the ethics committee of the university and was registered as IRCT20121026825N2 in Iranian Registry of Clinical Trials.

RESULTS

The findings indicated that the mean age was 38.04 years in the group 1 and 39.51 years in the group 2. In the group 1, 64.7% were men and 82.35% married, 41.17% had guidance and secondary education and mean history of IBS was derived 9.24 years [Table/Fig-1].

The findings indicated that score of quality of life in the group 1 increased significantly after the intervention compared to the group 2 (p<0.05). Coefficient was obtained 0.44. In other words, 0.44% of the variance in post-test (quality of life) was related to hypnotherapy [Table/Fig-2].

In addition, the findings indicated a significant difference in quality of life in IBS patients between group 1 and group 2 in follow-up (p<0.05). There was no statistically significant difference in psychophysical symptoms, abdominal pain, diarrhea and pathophysiological signs between the two groups. These findings indicated that hypnotherapy improved quality of life in the IBS patients [Table/Fig-3]. Further, hypnotherapy reduced somatic, mental symptoms, abdominal pain, diarrhea, depression, isolation, anxiety and psychopathological symptoms.

Groups	Variable	Group 2 (n: 17)	Group 1 (n: 17)
Age (mean)		39.51±11.3	38.04±19.71
Sex	Male	7(41.17%)	11(64.7%)
	Female	12(70.5%)	14(82.3%)
Marital Status	Married	12 (70.5%)	14 (82.35%)
	Single	8 (29.5%)	3 (17.65%)
Educational level	Primary	8(47.05%)	6(35.3%)
	Guidance	6(35.3%)	7(41.17%)
	Secondary Diploma	11 (2.88%)	3 (17.46%)
	Associate degree and BSc/BA	1 (5.88%)	1 (5.88%)
Disease history (year)		8.40±5.75	9.24±5.07

[Table/Fig-1]: Demographic characteristics of the participants in the two groups.

Statistical indices → Sources of variation ↓	Mean	df	F	Level of significance	Eta ²	Statistical power
pretest	180.55	1	0.929	0.343	0.029	0.154
Group membership	4788.12	1	24.63	0.0001	0.44	0.998

[Table/Fig-2]: Covariance analysis of quality of life score in post-test. * p < 0.05 between group 1 group 2

Statistical indices → Sources of variation ↓	Mean	df	F	Level of significance	Eta ²	Statistical power
pretest	139.05	1	1.20	0.282	0.37	0.186
Group membership	866.04	1	7.47	0.01*	0.194	0.754

[Table/Fig-3]: Covariance analysis of quality of life score in follow-up. * p < 0.05 between group 1 and group 2.

DISCUSSION

Mean history of the disease in the present study was obtained 8-9 years which indicates the chronic nature of IBS. These patients

suffer from numerous mental disorders and psychological problems, so that most of them became depressed and isolated, encountered family difficulties, lived an anxious, troubled life, underwent pharmacologic treatment alone and paid no attention to psychological factors that exacerbated the symptoms within the disease. A study indicated that about 50-90% of the IBS patients adhering to their treatment reported previous psychiatric intervention [24]. Hypnosis can reduce anxiety. It is also effective for insomnia, particularly when the techniques are integrated into a package of cognitive therapy. Hypnosis enhances the effects of cognitive behavioral therapy for conditions such as phobia, obesity and anxiety. In the present study, the majority (55%) of the participants were male, which is not consistent with Hungin et al and Greenberg et al studies that found a higher prevalence of IBS in women [14, 25]. One of the reasons for this inconsistency could be the small sample size and/or exclusion of many female patients with exclusion criteria. Other findings indicated that the mean score of quality of life decreased significantly in the patients in the group 1 compared to the group 2 after hypnotherapeutic intervention. These findings are consistent with Lindfors et al., study. The findings demonstrated a significant difference between the two groups after the intervention and three months after the last intervention (follow-up). In addition, the quality of life improved notably in the hypnotherapy group for both quality of life and symptoms [18]. In another study, 53% decrease was seen in symptoms after six sessions of hypnotherapy [26], which is consistent with the present study. Hypnosis can sometimes exacerbate the psychological problems, for example in the patients with post-traumatic disorders or by inducing "false memories" in psychologically susceptible individuals. Its use should be avoided in patients with borderline personality disorder, dissociative disorders, or the patients who have previous profound abuse.

In Vlieger et al., study, hypnotherapy caused a decrease in susceptibility, gastric pain and symptoms in IBS patients in case group [27]. In another study, hypnotherapy reduced the severity of symptoms, improved the quality of life, reduced total scores of dissatisfaction and increased the satisfaction in IBS patients [16], which confirms the presents study. Wilson et al., Whorwell et al., and Hefner et al., have also confirmed the efficacy of this therapy on improvement of quality of life and decrease in IBS symptoms [4,17,19]. The evidence has shown that the combination of hypnotherapy plus standard medical treatment is superior to medical treatment alone for IBS treatment.

Other finding of the present study indicated that significant difference between the groups 1 and 2 was obtained six months after the last intervention (follow-up). This was consistent with another study [28]. As described by the biopsychosocial model of medicine, modulation of the stress response can result in a change in intestinal function and the symptom experience for the patient, so hypnotherapy is the most evidence-based psychophysical intervention for IBS.

LIMITATION

Small sample size was a limitation of the present study, which affects the generalization of the findings. The major barrier to the clinical use of hypnotherapy was its limited availability outside of the centers especially interested in hypnotherapy for IBS. Further study of group hypnotherapy as well as home hypnotherapy (by CD or other audio guides) is needed to expand the availability of this promising intervention.

CONCLUSION

Standard treatments of IBS remain unsatisfactory for many patients. Use of psychological intervention, particularly hypnotherapy, alongside standard medical therapy could contribute to improving quality of life in IBS patients resistant to treatment. Therefore, it

is recommended to have gastroenterologists, psychologists, nurses and psychiatrists co-operate in treating IBS patients and to develop the treatments as pharmacologic, counseling and psychotherapeutic packages.

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