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The Effects of Cognitive Behavioral Therapy with Biofeedback Therapy on the Quality of Life, Anxiety, Depression and Somatic Symptoms in Patients with Dyssynergic Defecation: A Randomized Controlled Trial

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Abstract

Background: Dyssynergic defecation (DD) is a major cause of chronic functional constipation. Patients with DD have greater psychological distress and impaired health-related quality of life compared with the general population. This study aimed to evaluate the effectiveness of cognitive-behavioral therapy (CBT) combined with biofeedback therapy (BFT) on the quality of life, anxiety, depression and physical symptoms in patients with DD.

Methods: This randomized controlled trial (IRCT20141115019957N2) was conducted on 45DD patients who were referred to the Rehabilitation Clinic of Iran University of Medical Sciences in 2017. The convenience sampling method was used to select the participants and then they were randomly allocated into three equal groups using RANDBETWEEN function in Excel. The first group received a combination of BFT&CBT and also standard-of-care therapy (SoCT). The second group was treated with BFT and SoCT, and the third group received only SoCT. The patients were assessed by digital rectal examination and the Short Form-36, Spielberger Anxiety, Beck Depression and Constipation Scoring System questionnaires before and after the treatment.The data were analyzed by SPSS-22, ANOVA, ANCOVA and Chi-Square tests.

Results: Patients who received both CBT&BFT had significant improvement in symptoms of constipation, depression, and anxiety.Furthermore, BFT and CBT&BFT groups are valued equivalent only on the mental component of SF36 and the total SF36 questionnaire. But the physical component was significantly different, favoring CBT&BFT ($p< 0.001$). In CBT&BFT group,67%of patients reached the relaxed stage. In contrast, no patient reached the relaxed neither in BFT nor in SoCT.

Conclusion: According to our study, patients with unfavorable responses to BFT may become better if CBT is added to their treatment plan.

Keywords: Anxiety, Cognitive Behavioral Therapy, Depression, Dyssynergic Defecation

Conflicts of Interest: None declared
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Introduction

Chronic constipation (CC) is one of t he most common problems of the digestive system (1). Healthcare resources

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↑What is "already known" in this topic:
Chronic constipation (CC) is one of the most common digestive system disorders, which can negatively affect quality of life (QoL). One-third of patients with CC are reported to have dyssynergic defecation (DD) which has both psychological and physiological causes. According to the studies, although, biofeedback is an effective treatment for pelvic floor dyssynergia, it has not been helpful in DD patients with high grades of stress, anxiety or depression.

→What this article adds:
This study suggests the use of biofeedback therapy in combination with cognitive behavioural therapy, as an applicable effective therapeutic protocol, for patients with an unfavorable response to BFT alone. This combination can reconstruct the process of thought and cognition about the disease and improve the psychological state through increasing self-monitoring and self-awareness.

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consider CC as a substantial burden, which can negatively affect the quality of life (QoL) (2). These patients often have psychological distress (1). The prevalence rate of defecation dysfunction is 36.5% in Iran (3), compared with 16% in the US (4). One-third of patients with CC are reported to have dyssynergic defecation (DD) (5). Patients suffering from dyssynergic pattern of defecation fulfill the Rome III criteria for functional constipation (6). Digital rectal examination shows a lack of pelvic floor relaxation, paradoxical contraction of the external sphincter and puborectalis on pushing (7). DD often occurs as a result of inappropriate toilet habits, obstetric and back injuries and brain-gut axis dysfunction. Another possible cause is that the proper process of defecation has never been learned during childhood (2).

DD, as a functional disorder, has both psychological and physiological causes (1). It is hypothesized that the limbic system is activated by such stimulating factors as irritations or threatening situations. Consequently, pelvic musculature will undergo tonic contraction as a result of limbic efferent stimulation and react with an increase in activity. A correlation between changes in muscle activity and experienced threat in the absence of awareness of such changes has been reported, which can form possible support for the “conditioning hypothesis” as a mechanism of involuntary pelvic floor muscle activity (8).Therefore, DD can possibly be improved by supplementing the treatment plan with the management of limbic dysfunction (9). If DD is not treated properly, it can lead to critical bowel problems such as incontinence, bowel perforations and fecal impaction with subsequent problems of QoL and healthcare costs in these people (4, 10).

The impact of chronic constipation on the mental and physical aspects of a patient’s QoL is great and analogous to other common chronic conditions (11). On the other hand, a history of physical and sexual abuse and their psychological consequences are reported by a lot of DD patients (12). The incidence of anxiety and depression in patients with DD is also much greater than in the general population (4). Therefore, behavioral techniques such as habit training and biofeedback therapy (BFT) should be included in their treatment protocols.

BFT is a non-invasive treatment that has no side effects and can correct inappropriate dyssynergic contractions of the anal sphincter and puborectalis during defecation (6).The aim of treatment in these patients is not only to relieve symptoms but also to combat the physiological, psychological, emotional and social components (11).

Cognitive-behavioral therapy (CBT) is a psychosocial intervention for the management of mental health (13, 14). CBT concentrates on both changing maladaptive thoughts and unhelpful patterns in cognition such as thoughts, beliefs, behaviors and emotional states. It also helps create healthy behavioral patterns (14). CBT has been used to treat psychological disorders such as depression, anxiety, and also post-traumatic stress disorder, insomnia, obsessive-compulsive disorder, and substance abuse. The aim of this therapy is to help patients identify maladaptive thoughts and "self-defeating" behavioral patterns that seriously affect QoL and mental health. Tasks of therapy often make the patient conscious of the relationship between symptoms, stressors, and thoughts, modify illogical beliefs and confront the automatic negative thoughts. In addition, tasks of therapy identify the factors that make symptoms worse, find better solutions and also detect effective coping methods to combat the symptoms (14).

CBT is mainly based on the theory that "maladaptive thoughts" are the causes of psychological symptoms such as anxiety and depression, which can be the source of the physical symptoms or aggravate them. Avoiding defecation when there is a feeling of need to pass stools weakens the defecation reflex. Therefore, the individual will have to strain for evacuation. For example, fear of getting sick in public toilets may lead to postponing defecation. Such maladaptive thoughts would disturb one’s defecation (DD syndrome) and make it necessary to use CBT in the treatment of such patients. These patients become anxious when participating in social interactions, which may lead them to evade such interactions altogether (self-defeating behavior). The anxiety and autonomic arousal caused by this maladaptive thought may lead to somatization disorders. So, there is a need for supplemental interventions to reduce the psychological symptoms by focusing on changing thought patterns or learning and practicing healthy behavioral patterns (14). Previous randomized clinical trials and controlled studies have shown that BFT is an effective treatment for pelvic floor dyssynergia (6, 15-19). However, improvement of symptoms after BFT varies in studies ranging from 44% to 100% (4). Also, anxiety and depression are shown to be relative to poorer treatment outcomes in these patients (14).

CBT and BFT, based on multiple randomized controlled trials, are two effective psychological treatments that can improve functional gastrointestinal disorders (FGID) (14). Using BFT in patients with paradoxical contraction of pelvic floor muscles during defecation teaches them how to relax the pelvic floor muscles instead of contracting them. BFT acts differently from the other forms of psychological treatments for FGIDs because BFT couldn’t change thoughts or feelings, and it rather teaches the patient how to control physiological dysfunctions, so the type of biofeedback mostly used in the treatment of gastrointestinal disorders is not helpful in reducing autonomic arousal in confrontation with stress and anxiety (14). According to findings by Ting Yu and colleagues, high-grade depression is a poor predictor of BFT efficacy (4).

There is a lot of evidence on the efficacy of CBT in reducing gastrointestinal symptoms and psychological distress (14, 20, 21). But to the best of our knowledge, this is the first study that has sought to identify the effects of CBT combined with BFT on the psychological and physiological symptoms in DD patients. The aim of this randomized controlled study was to evaluate and compare the effects of CBT with BFT on the quality of life, anxiety and physical symptoms in patients with dyssynergic defecation.

Methods

This randomized controlled trial (RCT) study was car-

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ried out on Dyssynergic defecation patients who, were referred to the Rehabilitation Clinic of Iran University of Medical Sciences between April 2016 and December 2017. The sample size for each group was calculated using R software version R-3.3.5 (β=0.8, α=0.05, number of categories; k= 3, (Cohen's d) Medium effect size; f = 0.5; sample size; n=15 per group).

70 patients diagnosed with chronic constipation according to Rome III criteria were referred to our pelvic floor physiotherapy clinic by medical specialists. 45 individuals met the inclusion criteria through evaluation by a specialized physiotherapist; a patient must have experienced at least two of the following symptoms over the preceding 3 months (12):

- Fewer than three spontaneous bowel movements per week
- Straining for more than 25% of defecation attempts
- Lumpy or hard stools for at least 25% of defecation attempts
- Incomplete evacuation and digital manipulation in more than 25% of bowel movements
- Paradoxical contraction of puborectalis and external anal sphincter (EAS) during straining is diagnosed by digital rectal examination (DRE) and diagnostic tests such as anorectal manometry, defecography or balloon expulsion test (18).

The exclusion criteria included a history of anorectal surgery, anorectal tumors, structural anorectal disorders leading to surgery, endocrine and metabolic diseases, and severe cardiovascular, respiratory, neurologic, or psychological problems (5).

The patients were randomly allocated into three groups using RANDBETWEEN function in Excel; each group included 15 patients. The first group received BFT combined with CBT. The second group was treated with BFT, and the third group only received standard-of-care therapy (SoCT). The standard protocol was used for all the three groups to receive similar instructions for managing constipation.

This study was approved by the Ethics Committee of Iran University of Medical Sciences (ethical code: 1394.94-01-32-19397) and registered in the Iranian Registry of Controlled Trials (IRCT) (registration number: IRCT20141115019957N2).

Measures

At first, the patients were assessed by DRE, and the pattern of defecation was evaluated as paradoxical (the worst condition), non-relaxed, partially-relaxed and relaxed (the best or normal condition) based on the severity of paradoxical contraction of puborectalis and EAS. Then the culturally-adapted version of Short Form-36 (SF-36) and its two subscales i.e. physical and mental components (22), Spielberger State-Trait Anxiety Inventory (STAI-Y) (23), and Beck Depression Inventory (BDI-II) (24) questionnaires were completed by patients before and after treatment. Furthermore, the severity of constipation symptoms was assessed by the Agachan questionnaire, i.e., Constipation Scoring System (CSS). Obtaining a higher score on the CSS questionnaire represented the severity of constipation (minimum score 0, and maximum score 30) (25).

The SF36 questionnaire assesses patients from different aspects of general health status, including physical and mental health. In this study, all items of SF36 were asked from the patients and were calculated to measure the total SF36 and its physical and mental subscales. SF36 scores and its physical and mental subscales vary from 0 (poor health) to 100 (good health) (22). The reliability and validity of the SF-36 were confirmed by Bunevicius (26). In translated version into Persian, 100 patients with myocardial infarction took part in the study. The criterion validity demonstrated a high and significant correlation between most of the SF-36 scores. The Cronbach's alpha for the scale ranged from 0.74 to 0.887 and test-retest reliability (ICC) within two weeks in all dimensions was greater than 0. 90 (27).

The State-Trait Anxiety Inventory (STAI) is a commonly used measure of trait and state anxiety. Form Y, its most current revision, has 20 items for assessing trait anxiety and 20 for state anxiety. Scores range from 20 to 80, with higher scores correlating with greater anxiety (23). Balsamo approved the reliability and validity of the Spielberger State-Trait Anxiety Inventory questionnaire(28). In Gholami Booreng's study, 55 subjects responded to the Spielberger State-Trait Anxiety Inventory. It was found that the correlation of Anxiety scale research with Spiel-Berger was equal to 0.65 and the correlation with Self-Esteem Test was -0.63. To study the questionnaire, validity was calculated by factor analysis, convergent and divergent validity and judgment of experts. In the judgment of experts were included validity by 5 Counseling center consultant. The reliability of the instrument through Cronbach's alpha was equal to 0.87, and its stability using the test-retest method on 22 subjects within a one-week interval from the first pilot study was 0.76. Totally the reliability coefficient of the research anxiety test was at the optimal level for the entire sample (23). The BDI-II questionnaire is composed of 21 questions related to symptoms of depression. The selected cut-offs differed from 0-13 (minimal depression), 14-19 (mild depression), 20-28 (moderate depression) and 29-63 (severe depression). Higher total scores indicated more severe depressive symptoms (24). And, Reliability and validity of the Beck Depression Inventory questionnaire were confirmed by Loosman (29). Persian version of BDI-II was performed on 233 subjects over the age of 60 sampled by stratified random sampling in Qom City, Iran. The BDI was examined at about a two-month interval. Twenty-four elders were withdrawn during the retest of BDI-II; therefore, the retest conducts on 209 subjects. The BDI represented significant positive internal consistency (Alpha=0.92) and test–retest reliability (r=0.64), Intra-class Correlation Coefficient (ICC=0.81) (30). All of the questionnaires mentioned above alongside DRE, were measured as primary outcomes.

Treatment and Therapy Setting

Standard of Care Treatment: The patients in SoCT group were trained to attempt to have a bowel movement

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twice a day, usually 30 minutes after meals or walking (timed toilet training). During attempted defecation, they should not strain for more than 5 minutes. The patients were advised not to use digital maneuvers to impact the feces. They were educated on appropriate positioning and diaphragmatic breathing during defecation in order to increase intra-abdominal pressure and facilitate the defecation process. They were also encouraged to take sufficient fiber, drink adequate amounts of water and take part in daily exercises. The SoCT duration was three months, and patients were followed-up by phone calls once a week (5).

Biofeedback Therapy: It is an "instrument-based" technique and a form of "operant conditioning". The goals are to correct the pattern of defecation or to coordinate the abdominal and pelvic floor muscle contractions during straining and enhance the perception of "rectal filling" if the rectal sensation is impaired (15).

In this study, all of the treatments were performed by the same physical therapist who specialized in pelvic floor dysfunctions in all three groups of patients. At the beginning of the first treatment session, the physiology of defecation and the pathophysiology of dyssynergic defecation were explained to the patients. Biofeedback therapy was done during a simulated defecation attempt. The patients were trained to synchronize the increase of intra-abdominal pressure with the relaxation of the puborectalis and external anal sphincter muscles. This procedure involved the insertion of a pressure probe into the patient's rectum and the placement of a surface electrode on abdominal muscles to monitor muscular activity. While the patients were lying in a left lateral position and watching the EMG tracing on a computer monitor, they received visual and verbal feedback to correct dyssynergia and coordinate their abdominal push effort and concurrent relaxation of the EAS and the puborectalis which was depicted by decreased anal pressure on the monitor. The duration of the BFT session was 45 minutes twice a week for 12 sessions, then once a week for 6 sessions (7, 15, 31).

Cognitive Behavioral Therapy: The treatment consists of six sessions that focus more on the present situations in which the symptoms occur rather than the patient's history. The patient is helped with identifying the self-defeating behavioral patterns and maladaptive thoughts that have a harmful effect on mental well-being, quality of living, and experiencing symptoms. CBT consists of increasing awareness of the relation between tensions, automatic negative thoughts and symptoms; illogical beliefs are inspected and refined; destructive thoughts are combatted while distinguishing and accepting alternative coping strategies to deal with persecutory life situations and gastrointestinal symptoms (14).

In this study, a physical therapist who specialized in pelvic floor dysfunctions performed the standard care therapy and biofeedback treatments for all groups. This ensured a homogeneous treatment process be received by all patients. Cognitive-behavioral therapy was performed by a separate psychologist who was not aware of group distinction in the research process. Also, patients had no chance of contact neither within nor between groups with each other. These precautions were taken to reduce probable biases as much as possible.

Statistical Methods

Statistical analysis was performed in SPSS V. 22 software by using ANCOVA, ANOVA and chi-square test. The treatment effect is tested by either of three methods for comparing three groups: (1) analysis of covariance (ANCOVA) with the posttest as an outcome and pretest as covariate, or (2) analysis of variance (ANOVA) of the change from baseline, defined as posttest minus pretest, and (3) chi-square test for the ordinal variable. Assumptions for normality were met for the use of ANCOVA modeling including the normality of predictors in the model and homogeneity of both variance and regression coefficients (i.e., no relationship between groups and covariates).

Quantitative data were shown as mean ± standard deviation (SD) and frequencies and percentages were used to describe discrete variables. Sidak Post Hoc test was performed at $P \leq 0.05$ after testing the assumption of normality by the Kolmogorov-Smirnov test and the equality of variances by Levene's test. Paired sample t-tests were used for comparison between groups before and after supplementation and within groups for analysis of normal distribution variables. Wilcoxon test was used to analysis of non-normal distribution variables within and between groups.

Results

Forty-five patients had the diagnosed with chronic constipation according to Rome III criteria which divided into three equal groups. Homogeneity of age, gender and education distribution among the three groups were assessed. Based on the results, the distribution of all of them was the same (homogeneous) across groups. The demographic characteristics of the participants are shown in Table 1. There is no meaningful difference in demographic characteristics between the three groups. Also, there were no side effects during the trial and none of the patients withdrew from the study (Fig. 1). For ANCOVA analyses, the normality of data was confirmed by Kolmogorov–

Table 1. Comparison between the three studied groups according to demographic data

Variable		SoCT (n=15)	BFT (n=15)	CBT&BFT(n=15)	*P*-value
Age (yr)		38.07 ± 10.41	38.8 ± 13.41	36.93 ± 6.97	0.889*
Gender	Male	4 (26.7%)	4 (26.7%)	5 (33.3%)	0.897#
	Female	11(73.3%)	11(73.3%)	10 (66.7%)	
Education	high school	5 (33.3%)	4 (26.7%)	6 (40%)	0.540#
	diploma	3 (20%)	4 (26.7%)	8 (53.3%)	
	tertiary education	5 (33.3%)	4 (26.7%)	6 (40%)	

*ANOVA test
#Pearson Chi-Square test

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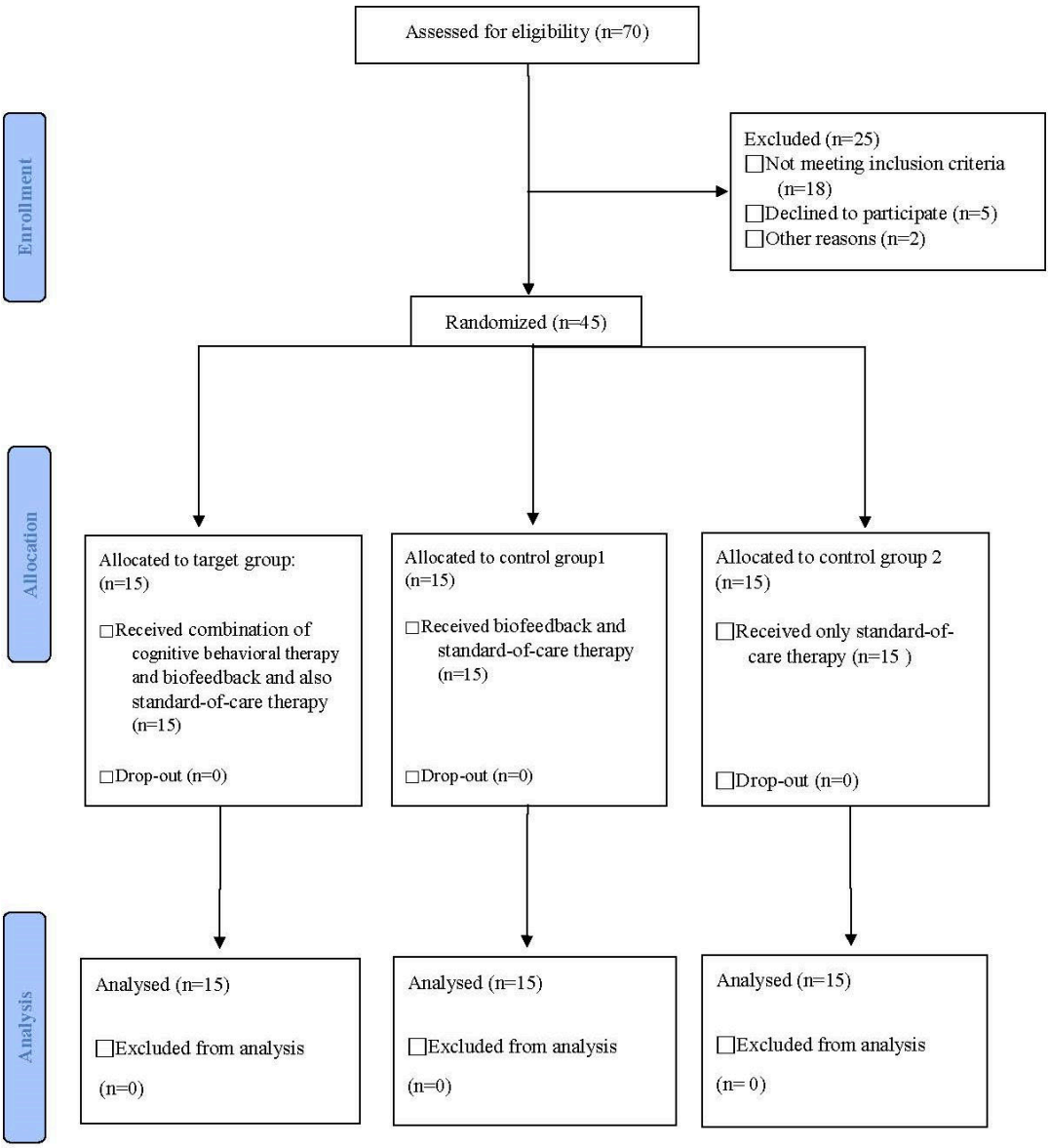

Fig. 1. Patient enrollment flow CONSORT table. This illustrates the flow of all patients screened, excluded, and randomized.

Smirnov test (p>0.05). Also, Pre-ANCOVA screening for homogeneity of regression analysis slopes indicated non-significant interaction between the independent variables and the covariate (p> 0.05).

Table 2 shows seven gain variables assessment in three groups at the beginning and at the end of the study with the comparison of within-groups changes and the between-groups changes. After removing the outlier data, there were no statistically significant differences in six gain variables at the beginning of the study between the three groups (p>0.05).

In the SCOCT group, there were significant changes in CSS, STAI, PCS, SF36, and MCS within groups at the beginning and at the end of the study (p<0.05). And also, there was a difference in BDI between the before and after treatment but this difference was not significant (p<0.05). On the other side, the CSS, STAI, PCS, SF36, BDI, MCS and DRE had significant changes between post-treatment and baseline values in both BFT and BFT&CBT groups (p<0.05).

As presented in Table 2, after adjusting for baseline value according to the ANCOVA model with the standard of care treatment, CSS, STAI and BDI were significantly increased while PCS, SF36, and MCS were significantly decreased (p<0.05). Similarly, after adjusting for baseline value according to the ANCOVA model with biofeedback therapy, CSS and BDI were significantly decreased while PCS, SF36, STAI and MCS were significantly increased

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Table 2. The assessment of gastrointestinal symptoms and psychological distress scales at the baseline and at the end of the study in three groups of patients with dyssynergic defecation

Treatment group			SOCT group (n=15)	BFT group (n=15)	BFT &CBT group (n=15)	*P*.value
CSS	Baseline		15.73 ± 4.38	13.73 ± 4.69	16.8 ± 5.53	0.231×
	Post-intervention		16.8 ± 4.91	10.47 ± 5.6	6.93 ± 4.43	<0.001*
	Difference		1.06 ± 1.43	-3.26 ± 2.5	-9.86 ± 1.92	<0.001×
	P.value#		0.012	<0.001	<0.001	
STAI	Baseline		95.4 ± 15.44	79.4 ± 25.82	81.0 ± 26.08	0.055×
	Post-intervention		100.27 ± 16.11	95.67 ± 25.78	116.8 ± 30.98	<0.001*
	Difference		4.86 ± 6.4	16.26 ± 4.86	35.8 ± 14.3	<0.001×
	P.value#		0.011	<0.001	<0.001	
PCS	Baseline		44.75 ± 9.17	45.7 ± 5.28	44.7 ± 6.38	0.916×
	Post-intervention		42.37 ± 8.92	49.43 ± 4.31	49.98 ± 6.08	<0.001*
	Difference		-2.38 ± 1.58	3.73 ± 1.45	5.22 ± 1.33	<0.001×
	P.value#		<0.001	<0.001	<0.001	
SF36	Baseline		80.26 ± 15.81	82.46 ± 6.48	80.6 ± 10.39	0.854×
	Post-intervention		75.83 ± 15.14	89.33 ± 5.85	89.05 ± 10.28	<0.001*
	Difference		-4.43 ± 3.15	6.86 ± 1.99	8.45 ± 3.68	<0.001×
	P.value#		<0.001	<0.001	<0.001	
BDI	Baseline		14.47± 4.76	16. 87 ± 3.22	18.53 ± 4.01	0.130×
	Post-intervention		15.13± 6.18	14.33 ± 3.08	9.6 ± 3.13	<0.001*
	Difference		0.67 ± 2.71	−2.53 ± 1.12	-8.93 ± 2.91	<0.001×
	P.value#		0.358	<0.001	<0.001	
MCS	Baseline		35.5 ± 7.43	36.76 ± 4.44	35.85 ± 5.83	0.840×
	Post-intervention		33.45 ± 7.03	39.9 ± 4.24	39.08 ± 5.74	<0.001*
	Difference		−2.04 ± 2.01	3.13 ± 0.92	3.22 ± 2.76	<0.001×
	P.value#		0.002	<0.001	<0.001	
DRE	Baseline	Paradox	10 (66.7%)	8 (53.3%)	11 (73.3%)	0.678×
		Non-relax	5 (33.3%)	7 (46.7%)	3 (20%)	
		Partial relax	-	-	1 (6.7%)	
	Post-intervention	Paradox	10 (66.7%)	-	-	<0.001**
		Non-relax	5 (33.3%)	8 (53.3%)	-	
		Partial relax	-	7 (46.7%)	5 (33.3%)	
		Relax			10 (66.7%)	
	P.value##		1	<0.001	<0.001	

Data are expressed as mean ± SE/ Frequency (%)
*difference between two groups adjusting for baseline value according to ANCOVA model
× ANOVA test
** Chi-Square test
#differences within the group (Paired sample t-test)
Wilcoxon test
Note. Abbreviations: Standard-of-care therapy (SoCT), biofeedback therapy (BFT), cognitive behavioral therapy (CBT), constipation Scoring System questionnaires (CSS), beck depression (BDI), Spielberger Anxiety (STAI), Mental Component Score (MCS), Physical Component Score (PCS), Short Form-36(SF36)

(p<0.05). Whereas, according to the ANCOVA model with biofeedback and standard of care therapy, PCS, STAI, SF36 and MCS were significantly increased while CSS and BDI were significantly decreased (p<0.05).

Table 3 below shows the results of a post hoc (Sidak) analysis for seven gain variables assessment, which shows there are significant differences in state scores between SCOT and both the BFT and BFT&CBT groups (p<0.05). Only for MCS, there was NOT any significant difference between BFT and BFT&CBT groups (p>0.05). And also, for MCS, there was no significant difference between BFT and BFT&CBT groups (p>0.05).

Discussion

In this nonblinded, randomized controlled trial, we studied the efficacy of BFT and CBT in 45 DD patients. No side effects were seen during the trial and none of the patients withdrew from the study (Fig. 1). The results of the study demonstrated that patients who fulfilled the Rome III criteria for chronic constipation & DD and received both CBT&BFT had significant improvement in symptoms of constipation, depression and anxiety. Furthermore, we have observed that BFT and CBT&BFT groups are valued equivalent on the mental component of SF36, MCS and also the total SF36 questionnaire. But the physical component was significantly different, favoring CBT&BFT. Also, in the CBT & BFT group, 67% of patients reached the relaxed stage and 33% the partially-relaxed i.e. the last two stages of the DRE scale. In contrast, no patient reached the relaxed stage neither in BFT nor in SoCT. This is remarkable evidence of our treatment efficacy. Besides, all patients' conditions have improved substantially. In the BFT group, 53% of patients were in the non-relaxed stage and 43% in the partially-relaxed stage i.e. the middle two stages of the DRE scale.

In the SoCT group, one person's condition shifted one stage back i.e. from non-relaxed to paradoxical. Another patient had one stage improvement i.e. from paradoxical to non-relaxed. That is in this group only 6.5% of patients had one stage improvement, 87% remained in the same stage (60% in paradoxical and 27% in the non-relaxed stage) and 6.5% degraded one stage.

Our findings emphasize the importance and the need for performing neuromuscular conditioning training in conjunction with CBT to get better results in correcting dys-

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Table 3. Comparison of gastrointestinal symptoms and psychological distress scales into the three groups with dyssynergic defecation patients using Sidak: post-hoc test.

Dependent Variable	(I) Therapy Groups	(J) Therapy Groups	Mean Difference (I-J)	Std. Error	*P*.value
Constipation Scoring System	SoCT	BFT	4.455*	0.745	0.001
		CBT&BFT	10.868*	0.738	0.001
	BFT	SoCT	-4.455*	0.745	0.001
		CBT&BFT	6.413*	0.760	0.001
	CBT&BFT	SoCT	-10.868*	0.738	0.001
		BFT	-6.413*	0.760	0.001
State Trait Anxiety Inventory	SoCT	BFT	21.096*	3.248	0.001
		CBT&BFT	37.650*	3.456	0.001
	BFT	SoCT	-21.096*	3.248	0.001
		CBT&BFT	16.554*	3.451	0.001
	CBT&BFT	SoCT	-37.650*	3.456	0.001
		BFT	-16.554*	3.451	0.001
Physical Component Summary	SoCT	BFT	-6.184*	0.500	0.001
		CBT&BFT	-7.606*	0.499	0.001
	BFT	SoCT	6.184*	0.500	0.001
		CBT&BFT	-1.422*	0.500	0.001
	CBT&BFT	SoCT	7.606*	0.499	0.001
		BFT	1.422*	0.500	0.020
Mental Component Summary	SoCT	BFT	-5.308*	0.728	0.001
		CBT&BFT	-5.307*	0.725	0.001
	BFT	SoCT	5.308*	0.728	0.001
		CBT&BFT	0.001	0.726	1.000
	CBT&BFT	SoCT	5.307*	0.725	0.001
		BFT	-0.001	0.726	1.000
SF36	SoCT	BFT	-11.460*	1.077	0.001
		CBT&BFT	-12.908*	1.074	0.001
	BFT	SoCT	11.460*	1.077	0.001
		CBT&BFT	-1.449	1.076	0.460
	CBT&BFT	SoCT	12.908*	1.074	0.001
		BFT	1.449	1.076	0.460
Beck Depression Inventory	SoCT	BFT	2.987*	0.900	0.006
		CBT&BFT	9.238*	0.949	0.001
	BFT	SoCT	-2.987*	0.900	0.006
		CBT&BFT	6.252*	0.886	0.001
	CBT&BFT	SoCT	-9.238*	0.949	0.001
		BFT	-6.252*	0.886	0.001

synergia and improving bowel function.

Our results were in agreement with and confirmed previous studies that reported BFT could significantly improve the clinical symptoms and psychological state of patients with DD (11, 12, 14-18, 32). Several randomized clinical trials have shown that BFT is an effective treatment for pelvic floor dyssynergia, and it is superior to laxatives, sham BFT, SoCT, placebo and diazepam, with improvement being maintained over a long-term follow up (4, 33, 34).

In this study, DRE showed the effectiveness of BFT in conditioning therapy for correcting dyssynergic pattern of defecation in DD patients, which is consistent with the previous studies (11, 12, 14-18). Moreover, we found that BFT combined with CBT can substantially improve the paradoxical defecation of patients to a relaxed state.

The motility and sensation in the gut can be affected by the brain through the hypothalamic-hypophysial axis and brain-gut axis. Depression can increase pelvic floor muscle tension and consequently reduce rectal sensitivity (4). Furthermore, patients with depression have dysfunction in the autonomic nervous system, which can decrease gastrointestinal motility (35). Also, depression is associated with chronic diseases and leads to poor treatment outcomes. Previous studies suggested that this fact may be an important factor in the failure of BFT in some patients (36, 37). On the other hand, it has been shown that BFT has no effect on autonomic function (4, 38). Lestar et al. (1991) showed that the effects of therapy on dyssynergic patients were not due to psychotherapy because one-half of the patients immediately recovered after the first session of BFT (39), in contrast with the results of our study that suggest depression and anxiety could be affected by BFT&CBT in dyssynergic constipation patients. Also, in a study done by Turnbull and Ritvo, BFT and psychotherapy were in their treatment protocol for DD patients. They did not observe any obvious changes in the success rate compared with the previous studies (40).

In Palsson and Whitehead's study (2013), psychological treatments have been studied for patients with functional gastrointestinal disorders who have moderate or severe symptoms after 3-6 months of medical care. They propose BFT as an effective psychological treatment for dyssynergic constipation patients (14). In our study, we found that the patients with DD should be assessed for psychological aspects such as depression and anxiety and it is better to give patients with moderate to severe depression and anxiety both BFT and CBT concomitantly.

Pavlov applied a useful model of conditioning of interoception which is based on the effect of physiological func-

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tions according to conditioning anywhere in the afferent pathways. Stimuli by internal organs can act as a conditioned stimulus (41). A misconception of an individual's internal state or a misregulation in interoception processing can cause maladaptive behaviors. Accordingly, Paulus and colleagues have demonstrated that people with depression and anxiety have altered interoceptive processing (42). The gut and the brain are bidirectional communication systems. Any disruption in these systems due to negative external sensory events can have a detrimental effect on patients. Some of these negative impacts are dyssynergic function of defecation, colitis, irritable bowel syndrome and greed for eating.

It seems that the interoceptive memories of unpleasant experiences of defecation (conditioning interoception) interfere with the defecation process and incur negative results on it. Therefore, therapeutic procedures which can help alter the negative effects of behavioral patterns and maladaptive thoughts are suggested to correct defecation function.

Since individuals process all information selectively, patients are prone to take a bias in this concern and process the chronic disability or health-threatening condition repeatedly. The most important challenges of people with chronic illness are the rumination and cognitive conflicts regarding the cause and consequences of the illness and negative automatic thoughts regarding the threatening condition posed by disease on their physical and mental wellbeing (43).

CBT is a method that can stop rumination and reorganize the patient's beliefs regarding life and disease. Cognitive reconstruction can create a new behavioral pattern and lifestyle (usually the anxiety provoked by consequences of the disease such as possible disabilities and the patient's tendency towards social avoidance). Also, it ends the depressive mood and negative self-talk about the treatment and its effectiveness. CBT can improve thoughts and emotions regarding the disease and its consequences and also helps the patients to reconstruct their beliefs in this regard and ultimately adopt the behaviors towards a healthy lifestyle. In general, CBT can be used to reconstruct thoughts and appropriate lifestyles and help the patients decide on practical steps to follow treatment guidelines (44). The combination of CBT and BFT can enhance self-effectiveness in overcoming the disease and following the therapeutic conditions through the remodeling of cognitive and physical patterns. The improved perception of self-effectiveness creates a new behavioral pattern and improves the quality of life and finally decreases depression and anxiety (44).

In this study, patients in groups BF and BF&CBT have achieved a better life quality in physical and mental aspects, and the total SF36 is improved after the treatment. But only the QoL improvement in physical aspects (g.PCS) was significantly better in the BFT&CBT group. In this study, the patients were able to manage their feelings, and subsequently, their behavior and the pattern of their defecation were also improved. But for altering mental aspects of QoL, there are many other factors involved (such as economic, occupational, family and social factors also individual inner conflicts rooted in childhood, other physical illnesses and emotional relations between individuals) that need more sessions to control and manage. The QoL has widespread dimensions and a variety of factors that may affect the individual's mental health. It is obvious that mastering all variables affecting the mental aspects involved needs more sessions of CBT treatment.

Some limitations may have affected the results of our study, such as small sample size and a short-term assessment of BFT&CBT. The predictors of the long-term efficacy of BFT&CBT are not clear. Further studies should be done to obtain the optimal number of CBT sessions.

Conclusion

In patients with dyssynergic defecation as a chronic disease, rumination, and failure of treatment can often lead to depression and anxiety, which result in a decrease in quality of life. A combination of CBT and BFT can reconstruct the process of thought and cognition about the disease and also decrease anxiety through increasing self-monitoring and self-awareness. Accordingly, having CBT in combination with BFT may lead to better results in patients with an unfavorable response to BFT.

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Conflict of Interests

The authors declare that they have no competing interests.

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