



# The Effect of Mindfulness-Based Cognitive Therapy on the Clinical Efficacy and Psychological State in Patients with Functional Dyspepsia

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## Abstract

**Background and Aim:** To observe the clinical therapeutic effect and mental state of Mindfulness-Based Cognitive Therapy (MBCT) in patients with Functional Dyspepsia (FD).

**Methods:** In this study, 80 patients suffering from FD in outpatient clinic were enrolled from January to December 2020, they were randomly divided into conventional treatment group (control group) and MBCT treatment group (observation group). Patients in control group were prescribed rabeprazole and Mosapride, and patients in observation group were given MBCT therapy in addition to above drugs. After eight weeks of treatment, changes in gastrointestinal symptom score, anxiety, depression, mindfulness scale and sleep quality score, and gastric emptying testing were compared between these two groups.

**Results:** The observation group had strikingly lower gastrointestinal symptom scores, SAS, SDS, PSQI and SCL-90 scale scores than the control group, higher Five Facet Mindfulness Questionnaire (FFMQ) scale scores than the control group ( $P < 0.05$ ). No conspicuous changes in gastric emptying monitoring ( $P > 0.05$ ).

**Conclusions:** MBCT therapy can improve patients' gastrointestinal symptoms, lessen anxiety and depression levels and ameliorate sleep quality.

**Keywords:** Functional dyspepsia; Mindfulness-based cognitive therapy; Anxiety and depression; Gastrointestinal motility

## Introduction

FD (Functional Dyspepsia) is a common disease in digestive medicine with high incidence rate and unknown etiology, which is clinically characterized by satiety after meals, early satiety, epigastric pain, and epigastric burning sensation [1]. The majority of patients have concomitant mental and psychological disorders, which seriously affect their quality of life. Its pathogenesis has not yet been fully understood. The treatment measures are predominantly proton pump inhibitors, gastrointestinal motility drugs and others associating with symptomatic treatment, but the overall treatment effect is far from satisfaction [2].

In 1979, Professor Kabat Zinn [3] opened a mindfulness decompression clinic at the Massachusetts Institute of Technology School of Medicine, where mindfulness meditation training was adopted to lessen individual stress and actively manage emotions. Subsequently, psychologists John Teasdale and others integrated cognitive behavioral therapy and mindfulness decompression courses and designed an eight-week Mindfulness Based Cognitive Therapy (MBCT) course. As evidently demonstrated by a multitude of domestic and international empirical results, 8-week MBCT treatment exerts a satisfactory effect on improving symptoms of various psychosomatic diseases [4]. This research combines conventional drug therapy with MBCT treatment to explore the clinical efficacy and psychological status of MBCT in FD patients.

This study is intended to probe into the effect of MBCT on insomnia symptoms and dialysis effect in peritoneal dialysis patients.

## Methods

### Basic information

Eighty FD patients admitted to our hospital from January to December 2020 were selected

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**Table 1:** Comparison of general information between two groups (n=74).

Index	Control group (n=40)	Observation group (n=34)	$t/\chi^2$ value	P value
Gender (Male/Female)	17/23	16/18	0.374	0.541
Age (Years)	44.78 ± 8.00	45.79 ± 8.30	0.532	0.596
Course of disease (Year)	2.95 ± 0.99	3.24 ± 0.91	1.303	0.197
<b>Education level</b>				
Junior high school and below	2	3	0.435	0.804
High school	7	6		
College degree or above	31	25		
<b>Employment situation</b>				
Full-time	25	21	0.703	0.872
Individual business	8	5		
Not working	3	4		
Retire	4	4		

as the research objects. The patients were randomly divided into a conventional treatment group (control group) and an MBCT treatment group (observation group) with 40 cases each using a random number table method. Six people in the observation group failed to complete eight weeks of mindfulness cognitive training, four of whom gave up in the fifth week of training, and two of them dropped out owing to the addition of anti-anxiety drugs. The six people were deemed to have dropped out halfway and were not included in this study. The actual number of people in the observation group was 34, with a completion rate of 85%. There was no statistically striking difference in gender, age, course of disease, education level, and employment status between these two groups of patients (all  $P > 0.05$ , as exhibited in Table 1).

### Inclusion and Exclusion criteria

The enrolled patients are diagnosed in accordance with the Rome IV diagnostic criteria:

- They have one or more of the following clinical symptoms, including postprandial fullness and discomfort, early satiety, pain in the upper and middle abdomen, and burning sensation in the upper and middle abdomen.
- A chronic process of continuous or recurrent onset, with symptoms occurring for at least 6 months and symptoms meeting the diagnostic criteria mentioned above in the past three months.
- All enrolled patients underwent C13 urea breath inspection testing, and those who were HP positive were treated with standard quadruple therapy for eradication. The final HP test was negative before enrollment.
- It is essential to exclude organic diseases that can explain symptoms, including undergoing gastroscopy, abdominal imaging examination, etc.
- Other diseases are excluded, such as various gastrointestinal diseases, hepatobiliary and pancreatic diseases, kidney diseases, diabetes, rheumatic diseases, etc. [5].

### Exclusion criteria

- Combined organic diseases such as peptic ulcer and gastrointestinal tumor;
- Patients with severe cardiopulmonary cerebral dysfunction;

- Individuals with mental disorders who are unable to communicate effectively and complete scale tests;
- Pregnant and lactating women and children under 12 years old;
- Those who cannot complete eight weeks of mindfulness training or withdraw midway.

### Implementation methods

The conventional treatment group (set as the control group) was treated with Rabeprazole (Jiangsu Haosen Pharmaceutical, 10 mg/time, twice a day), Mosapride citrate (Fujian Haixi New Pharmaceutical, 5 mg/time, three times a day) and other drugs. The MBCT treatment group (set as the observation group) was treated with MBCT on the basis of conventional drug treatment. After eight weeks of treatment, the scores of gastrointestinal symptoms, anxiety, depression, mindfulness levels, sleep quality scores, and gastric emptying tests were compared between these two groups of patients. MBCT treatment is led by a mindfulness therapist with over 3 years of mindfulness practice and over 1 year of group therapy experience. This includes formal group therapy once a week (2.5 hours/time) and daily homework. Each group treatment consists of 16 to 20 people, and homework includes 30 min of mindfulness practice per day (recorded in line with the instructions), as well as exercises to integrate mindfulness into daily life, such as walking, talking, and eating, recorded in self-report form. Part of the content should be adjusted appropriately on the basis of the patient's cognitive characteristics. If antidepressant need to be increased remarkably owing to the fluctuation of the condition, it shall be deemed as dropping.

### Observation items and efficacy evaluation criteria

**Gastrointestinal symptom score:** This index was primarily adopted to assess the severity of indigestion related symptoms, using the 7-point Global Overall Symptom Scale (GOSS) and Gastrointestinal Symptom Score (GIS) [6]. Efficacy evaluation: ① GOSS consists of 10 items: Upper abdominal pain, upper abdominal discomfort, acid reflux, heartburn, upper abdominal fullness, belching, nausea, early satiety, and postprandial fullness, each item is divided into seven grades: One is asymptomatic, and seven is seriously affected. ② GIS was funded and developed by Steigerwald Company, and includes 10 items for gastrointestinal symptoms such as nausea, vomiting, abdominal distension, spasmodic upper

abdominal pain, early satiety, heartburn, loss of appetite, discomfort behind the sternum, upper abdominal pain, and stomach discomfort. Likert 5-point rating method (0~4 points) was used, and 0 point was asymptomatic.

**Assessment of psychological measurement related scales:** ① Zung Anxiety Self Rating Scale (SAS) and Zung Depression Self Rating Scale (SDS); ② The Five Facet Mindfulness Questionnaire (FFMQ) includes 39 items to assess the patient's mindfulness level. ③ The Pittsburgh Sleep Quality Index (PSQI, total score >5 is considered as sleep disorder) measures the changes of sleep quality before and after treatment. ④ The self-reporting Inventory (SCL-90) test consists of 90 self-evaluation items, a 5-level scoring system, and 90 self-evaluation items. The nine factors tested are: Somatization, obsessive-compulsive symptoms, interpersonal sensitivity, depression, anxiety, hostility, terror, paranoia, and psychosis. Subsequently, this research observed the changes in scores of SAS, SDS, FFMQ, PSQI, and SCL-90 scales before and after treatment.

**Detection of gastric emptying function:** The barium strip method was adopted to detect gastric emptying function. It should be noted that the participants should fast the night before the examination and swallow a capsule containing 20 barium bars during their meals the next morning. After 4 h, a film is snapped and the number of residual barium strips in the stomach of participants is observed. After 4 h of treatment, if the residual rate of barium strips in the stomach is less than or equal to 50%, it is considered markedly effective. If the residual rate of barium strips is greater than 50%, but less than 75%, it is considered ineffective; Failure to meet the above standards is considered ineffective.

Effective rate (%) = (number of markedly effective cases + number of effective cases)/total number of cases × 100%

### Statistical methods

SPSS 21.0 software was used for statistical analysis of the observation group and the control group. The measurement data obeying the normal distribution was expressed as mean ± standard deviation ( $\bar{x} \pm s$ ), the inter group comparison was performed with independent samples by *t* test, the intra group comparison before and after treatment was performed with paired samples *t* test, and

the non-normal distribution was expressed as median and Quartile (M (P25, P75)). The inter group and intra group comparison before and after treatment were performed with non-parametric rank sum test; The counting data was expressed with regard to percentage or composition ratio (%), and inter group comparisons were made using  $\chi^2$  test, non-parametric rank sum test was used for inter group comparison of grade data, with  $P < 0.05$  as the statistically conspicuous difference.

## Results

### Comparison of gastrointestinal symptom scores between two groups before and after treatment

Before treatment, there was no remarkable difference in gastrointestinal symptom scores between these two groups of patients ( $P > 0.05$ ); after treatment, the GOSS and GIS of these two groups of patients were remarkably lower than those of the same group before treatment. Aside from that, the GOSS and GIS of the observation group were noticeably lower than those of the control group (both  $P < 0.05$ ) (Table 2).

### Changes in FFMQ before and after treatment in two groups of patients

In some sense, the FFMQ scale reflects the patient's level of mindfulness. There was no marked difference in the FFMQ scale scores between these two groups before treatment ( $P > 0.05$ ), and there was no remarkable change in the control group after treatment ( $P > 0.05$ ). The observation group exhibited a remarkable increase in scores in comparison with the treatment group and the control group ( $P < 0.05$ ) (Table 3).

### Comparison of SAS and SDS scale scores before and after treatment between two groups

Before treatment, there was no striking difference in SAS and SDS scores between these two groups of patients ( $P > 0.05$ ). After treatment, the SAS and SDS scores of these two groups of patients decreased strikingly in comparison with before treatment ( $P < 0.05$ ). After treatment, the observation group displayed a more dramatic decrease compared to the control group ( $P < 0.05$ ) (Table 4).

**Table 2:** GOSS and GIS scores before and after treatment in two groups (mean ± standard deviation, scoring).

Variables	Group	Before treatment	After treatment	$f_{\text{intra group}}$ value	<i>P</i> value
GOSS	Control group (n=40)	19.83 ± 6.02	17.15 ± 5.10	8.181	<0.001
	Observation group (n=34)	22.15 ± 6.72	14.82 ± 3.28	9.083	<0.001
	$t_{\text{inter group}}$ value	1.567	2.367		
	<i>P</i> value	0.122	0.021		
GIS	Control group (n=40)	16.02 ± 6.31	14.10 ± 5.44	7.16	<0.001
	Observation group (n=34)	17.91 ± 6.39	11.15 ± 4.35	9.232	<0.001
	$t_{\text{inter group}}$ value	0.426	2.484		
	<i>P</i> value	0.671	0.015		

**Table 3:** Scale scores of FFMQD before and after treatment in two groups (mean ± standard deviation, scoring).

Variable	Group	Before treatment	After treatment	$f_{\text{intra group}}$ value	<i>P</i> value
FFMQ	Control group (n=40)	128.43 ± 12.17	130.58 ± 9.08	2.624	0.012
	Observation group (n=34)	127.88 ± 16.07	141.65 ± 16.76	5.195	<0.001
	$t_{\text{inter group}}$ value	0.165	3.446		
	<i>P</i> value	0.869	0.001		

**Table 4:** Scoring of SAS and SDS scales before and after treatment in two groups (mean ± standard deviation, scoring).

Variables	Group	Before treatment	After treatment	$t_{intra\ group}$ value	P value
SAS	Control group (n=40)	47.50 ± 9.73	44.18 ± 9.68	7.16	<0.001
	Observation group (n=34)	47.94 ± 10.71	36.38 ± 6.85	9.232	<0.001
	$t_{inter\ group}$ value	0.186	4.038		
	P value	0.853	<0.001		
SDS	Control group(n=40)	48.68 ± 7.93	44.70 ± 5.77	8.333	<0.001
	Observation group(n=34)	49.18 ± 9.02	41.32 ± 4.06	6.605	<0.001
	$t_{inter\ group}$ value	0.254	2.804		
	P value	0.8	0.007		

**Table 5:** Comparison of PSQI scale scores between two groups before and after treatment (mean ± standard deviation, scoring).

Variable	Group	Before treatment	After treatment	$t_{intra\ group}$ value	P value
PSQI	Control group (n=40)	15.50 ± 5.97	12.73 ± 5.37	9.727	<0.001
	Observation group (n=34)	15.94 ± 8.46	7.85 ± 3.13	7.553	<0.001
	$t_{inter\ group}$ value	0.262	4.849		
	P value	0.794	<0.001		

**Table 6:** Comparison of SCL-90 scale scores between two groups before and after treatment (mean ± standard deviation, scoring).

Variable	Group	Before treatment	After treatment	$t_{intra\ group}$ value	P value
SCL-90	Control group (n=40)	147.55 ± 39.71	134.08 ± 27.84	3.953	<0.001
	Observation group (n=34)	144.79 ± 36.24	117.79 ± 20.46	6.121	<0.001
	$t_{inter\ group}$ value	0.31	2.893		
	P value	0.758	0.005		

**Table 7:** Gastric emptying status of two groups of patients (residual rate of barium strips, %).

Group	Markedly effective (%)	Effective (%)	Ineffective (%)	Total effective rate (%)
Control group (26 cases)	8 (30.8%)	15 (57.7%)	3 (11.5%)	23 (88.5%)
Observation group (28)	9 (32.1%)	17 (60.7%)	2 (7.1%)	26 (92.9%)
Z/ $\chi^2$ value	Z=0.308			$\chi^2 = 0.198$
P value	0.758			0.657

Note: P>0.05

### Comparison of sleep quality scores between two groups of patients before and after treatment

After treatment, the PSQI scale scores of both groups of patients noticeably decreased compared to before treatment ( $P<0.05$ ), and the observation group further decreased in comparison with the control group ( $P<0.05$ ) (Table 5).

### Comparison of SCL-90 scale scores between two groups before and after intervention

Before treatment, there was no statistically dramatic difference in the SCL-90 scale scores between these two groups of patients before treatment ( $P>0.05$ ). After treatment, the SCL-90 scale scores of both groups of patients decreased strikingly in comparison with before treatment. The observation group exhibited a more striking decrease compared to the control group ( $P<0.05$ ) (Table 6).

### Gastric emptying before and after treatment in two groups of patients

Before treatment, 26 patients in the control group (26/40) and 28 patients in the observation group (28/34) had delayed gastric emptying, and there was no statistically striking difference in the residual rate of barium strips in the stomach between these two

groups of patients ( $\chi^2=2.806$ ,  $P=0.094$ ). After 8 weeks of treatment, the residual rate of gastric barium strips in both groups of patients strikingly decreased. Nonetheless, there was no statistically remarkable difference in efficacy evaluation and total effective rate comparison between these two groups (both  $P>0.05$ ) (Table 7).

## Discussion

In general, FD refers to a series of digestive disorders after excluding organic diseases, including postprandial discomfort in the stomach, bloating, feeling full, and acid reflux [7]. It should be pointed out that the pathogenesis of FD remains unclear and may be associated with various factors such as gastrointestinal motility disorders, abnormal brain gut interaction [8,9], visceral hypersensitivity, and psychological factors [10]. The incidence rate of this disease is high, and it usually accounts for more than 1/3 of the patients in the outpatient department of gastrointestinal specialty. Owing to the recurrence of the disease, some patients are accompanied with a certain degree of anxiety, depression and sleep disorder, which further affects the quality of life and work of patients, and has become a medical problem of great concern in modern society [10]. As a result, psychological intervention conducts a paramount role in the treatment of FD [11,12].

Negative thinking is a pivotal reason for this. To be specific, the mind and body are interconnected, and when symptoms of indigestion occur and persist, psychological activities inevitably change accordingly. FD patients face recurrent symptoms, erroneous cognition of the severity and development of the disease. Moreover, the generation of negative emotions is inevitable, which in turn gives rise to the activation of automatic thinking. MBCT is the third wave of cognitive behavioral therapy. The so-called mindfulness is "a purposeful and non-judgmental method to focus on the moment" [13]. There is evidence that it has a marked effect on alleviating the mental psychological stress resulted from chronic diseases [14].

In this study, the FFMQ scale reflected the patient's level of mindfulness. After treatment, there was no striking change in the control group compared to before treatment ( $P>0.05$ ), while the observation group exhibited a remarkable increase in scores compared to after treatment and the control group ( $P<0.05$ ). As the level of mindfulness increased, the gastrointestinal symptom scores of these two groups of patients were markedly lower than those of the same group before treatment. Aside from that, the symptom scores of the observation group were strikingly lower than those of the control group ( $P<0.05$ ). With regard to sleep quality, the PSQI scale scores of both groups of patients after treatment displayed a noticeable reduction in comparison with before treatment ( $P<0.05$ ), while the scores of the observation group further decreased compared to the control group ( $P<0.05$ ). In reference to overall evaluation of anxiety, depression, and psychological status, we found that the SAS, SDS, and SCL-90 scores of these two groups of patients decreased strikingly after treatment in comparison with before treatment ( $P<0.05$ ), and the observation group displayed a more marked decrease in comparison with the control group after treatment. As illustrated by the experimental results, routine PPI combined with Prokinetic agent can ameliorate gastrointestinal symptoms in some degree, and after increasing MBCT treatment, the anxiety, depression, sleep quality and other aspects of patients are conspicuously ameliorated in comparison with the control group.

The reason may reside in that through mindfulness practice, patients' perspectives on observing their internal and external experiences have undergone striking changes, gradually learning to perceive and accept their physical and mental perceptual experiences, not making automated habitual reactions, concentrating on everything that is happening now, and gradually experiencing the beauty of life itself. Negative thinking is no longer automatically activated.

In reference to improving gastric emptying, the total effective rate of barium strip emptying in both groups after treatment was higher than before treatment. Nonetheless, there was no remarkable difference between these two groups after treatment. The reason is correlated with the small sample size and poor sensitivity of barium strip test for gastric emptying examination. Aside from gastrointestinal motility disorders, FD is also bound up with various factors such as visceral hypersensitivity and abnormal brain gut interaction.

Altogether, the combination of MBCT and medication can conspicuously ameliorate patients' gastrointestinal symptoms, lessen anxiety and depression levels, and better sleep quality, which is worthy of clinical promotion and application.

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