

# Effectiveness of gestalt therapy, behavioral activation and placebo on symptoms of anxiety in women suffering multiple sclerosis: A randomized controlled trial study



Farnia Javadi Larijani<sup>1</sup>, Mina mojtabaie<sup>2\*</sup>, Mehdi Moghaddasi<sup>3</sup>, Mohammad Hatami<sup>4</sup>

<sup>1</sup> Ph.D. Student of Clinical Psychology, Department of Clinical Psychology, Roudehen Branch, Islamic Azad University, Roudehen, Iran.

<sup>2</sup> Associate Professor of Clinical Psychology, Department of Clinical Psychology, Roudehen Branch, Islamic Azad University, Roudehen, Iran.

<sup>3</sup> Professor of Neurology, Department of Neurology, School of Medicine, Iran University of Medical Sciences, Tehran, Iran.

<sup>4</sup> Associate Professor of Psychology, Department of Clinical Psychology, Kharazmi University, Tehran, Iran.

**Corresponding Author:** Mina mojtabaie, Associate Professor of Clinical Psychology, Department of Clinical Psychology, Roudehen Branch, Islamic Azad University, Roudehen, Iran. Email: mojtabaie\_in@yahoo.com

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## Abstract

**Introduction:** Recently, psychological therapies increasingly used as complementary treatment along with medication to help patients with multiple sclerosis (MS). This present study compared the effectiveness of gestalt therapy (GT) behavioral activation (BA) and placebo on the anxiety in women with MS.

**Methods:** This study was a clinical trial (pre/posttest with control group and 3-month follow-up). Using the inclusion criteria and implementation of Beck's anxiety inventory (BAI), 60 women with MS who had an active case in MS clinic of Rasool Hospital in Tehran, were randomly blocked and assigned into four equal groups including 3 interventional groups and a control group. The psychotherapy groups were received GT and BA intervention for 8 weekly sessions. During this period, in the placebo group, capsules containing rice flour were used once a day. The control group was placed on the waiting list. Again, at the end of interventions, all of participants were retested with BAI and 3-month after the post-test, follow-up test was performed. Data was analyzed using SPSS25 and the repeated measures ANOVA and Bonferroni's post hoc test. P-value less than 0.05 was considered statistically significant.

**Results:** The results showed GT and BA in comparison with placebo and control groups decreased anxiety mean scores in post-test and follow-up stages ( $p=0.001$ ). GT and BA had no significant difference.

**Conclusion:** GT and BA are equally effective on anxiety reduction in women with MS. Placebo had no effect on reducing the anxiety of these women.

**Keywords:** Psychotherapy, Behavior Therapy, Placebos, Emotions, Demyelinating Autoimmune Diseases, Clinical study

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## Introduction

Multiple sclerosis (MS) is a chronic and progressive disease with widely known physical and psychological complications, and it is considered as the most common, progressive neurological disease in adults with frequent relapses and an undeniable burden. predominantly affects patients aged 20 to 40 years.<sup>1</sup> The female-to-male ratio varies between 2:1 and 3:1.<sup>2</sup> it is the most common form is relapsing-remitting multiple sclerosis (RR-MS) with a prevalence of 85% at the onset of the disease.<sup>3</sup> The

estimated number of people with MS reaching 2.8 million affected individuals according to the latest atlas published by the Multiple Sclerosis International Federation (MSIF) and this trend is increasing.<sup>4</sup> Iran is not exempt from this issue, with the prevalence rate of 148.06 per 100,000, it has the highest prevalence rate in the Middle East.<sup>5</sup> In most cases, this disease has a chronic and recurrent nature and involves different parts of the central nervous system. It creates many challenges regarding physical problems and psychological adaptation in affected people. Studies

indicate that neuropsychological changes occur in 40 to 65 percent of patients.<sup>6</sup> So far, no definitive cure has been found for MS, and its course is vague and variable, this uncertainty and unpredictability in the course of the disease and the person facing many complications and the disease often occurs in the years when the person Since those years, the expectation of health makes patients highly susceptible to anxiety.<sup>7</sup> so that 36%-54% of these patients suffer from anxiety problems. Also, anxiety causes inappropriate and ineffective responses and exacerbation and relapsing of attacks.<sup>8</sup> Therefore, it is important to pay attention to psychological states and appropriate treatment methods because of the significant impact it has on the course and prognosis of the disease. Despite the documentation that exists in the field of the effectiveness of standard and common treatments such as cognitive behavioral therapy (CBT).<sup>9</sup> Some of studies have shown that CBT is less effective than other interventions in MS.<sup>10</sup> Gestalt therapy (GT) is one of the experimental approaches that emphasizes emotions and body.<sup>11</sup> Experimental treatments are recommended to improve emotional and anxiety problems.<sup>12</sup> According to the pathological theory of GT, lack of presence in the present and fear of the future are the fundamental factors in anxiety problems, therefore increasing the awareness and ability of a person to experience his inner experiences in here and now and living in the present are effective factors in the management of anxiety.<sup>13</sup> Many studies have shown that behavioral activation (BA), which is a behavioral, structured and cost-effective approach as an inter-diagnostic intervention, can be effective in reducing anxiety symptoms.<sup>14</sup> Because in this view, dealing with behavioral or situational avoidance patterns; which, as a perpetuating factor, plays a very important role in emotional disorders; It is one of the important goals of treatment and can help reduce anxiety.<sup>15</sup> On the other hand, some of studies have shown the effects of placebo in reducing psychological symptoms, which can be considered due to minor side effects and low cost.<sup>16</sup> In general, considering the increasing trend of people with multiple sclerosis (PWMS) in Iran and the reciprocal effects of the individual's psychological conditions with the severity and recurrence of the disease, choosing the appropriate treatment approach is of particular importance. Considering that no clinical trial has been conducted in this field, so, this study aimed to compare the effectiveness of GT, BA and placebo on reducing anxiety in women with MS.

## Materials and methods

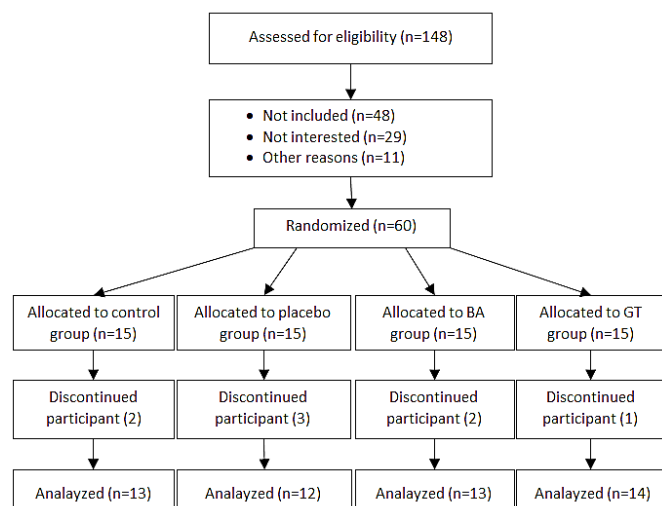
This study was a clinical trial (pre-test post-test with a control group and 3-month follow up). The study protocol

has been approved by the Ethical Committee and registered in the Iranian Registry of Clinical Trials (IRCT). GT, BA and placebo were considered independent variables and the Change in mean anxiety scores as a dependent variable.

## Participants

The study population included PWMS referred to the MS clinic of Rasool Hospital in Tehran between 22 June -22 November of 2019. The study sample was selected from among these people, applying the inclusion criteria. Inclusion criteria were: Completion of informed consent, suffering from RR-MS according to The Mc Donald diagnostic 2017 criteria with the confirmation of a neurologist, that at least 6 months have passed since the its definitive diagnosis, being in clinically inactive phase, moderate or severe anxiety (subclinical) based on the psychiatric records of the patients and have a score of 16 and greater on Beck's anxiety inventory (BAI), Age of 18-50 years and living in Tehran. The non-inclusion criteria included: serious psychological and psychiatric disorders; including psychotic, cognitive and personality disorders; and active substance and drug abuse (as assessed by the psychiatric record), use psychotropic drugs three months before and during the study. Exclusion criteria included: new attack, new severe diseases that have treatment priority, simultaneous initiation of other psychotherapy and absence of more than two sessions.

The sample size needed to address the major aim of the study was calculated using the Cohen's table with a statistical power of (0.90), significance level (0.05) and an average effect size of (0.5), 15 participants for each group and totally 60 patients.<sup>17</sup> Then, using randomized 4-block design, a random chain was generated by <http://www.sealedenvelope.com>. simultaneously encrypted codes for each group was assigned by the same site. In order to, concealing the allocation of treatment, the treatments list, were placed in the enclosed and numbered (to maintain order of sequences) envelopes. These codes were inserted in 60 consecutive, separate and sealed envelopes based on random sequence and placed at the MS clinic, so that each patient took one of the envelopes after entering the study. Finally, 60 patients who had the conditions to participate in the study were assigned in four equal groups (n=15); including three experimental groups and one control group. During the implementation, we encountered a drop of 8 people, so that finally the number of participants were reduced to 14 people in GT group, 13 people in BA group, 12 people in placebo group and 13 people in control group, and their data entered the final analysis. (Figure 1). Blinding was not performed in our study.



**Figure 1.** Clinical trial flow

## Research tools

### 1. Demographic information questionnaire

it included age, sex, marital status, education level, city of residence, history of receiving psychotherapy services and psychotropic drugs.

### 2. Beck Anxiety Inventory (BAI)

is a 21-item self-report measure that assesses cognitive, somatic, and affective anxiety symptom severity. Each item is rated on a Likert scale from 0 to 3, and the total BAI score can range from 0 to 63, where higher scores are indicative of higher levels of anxiety. Scores of 16 to 25 indicate moderate anxiety and 26 to 63 indicate severe anxiety. (Beck et al., 1988) reported the internal consistency of this scale as 0.92 and its one-week retest reliability as 0.75.<sup>18</sup> The Persian version of this inventory in the Iranian population had validity of 0.72, reliability

of 0.83, and internal consistency of 0.92.<sup>19</sup> The reliability of the BAI in the present study was 0.83.

After obtaining the necessary permits to conduct the research and selecting the participants according to the inclusion criteria, First, we were explained to the participants about the research process Then, as a pre-test, BAI was performed in all of four groups. Next, for the first experimental group (GT), sessions based on the integration of Gestalt's methods and techniques from Joyce & Sills and Brownell with the framework of eight weekly 90-minute sessions during 8 consecutive weeks and once a week were performed.<sup>13,20</sup> In the second experimental group (BA) based on the therapeutic guidelines of Gollan et al. and Martell et al. developed according to the conditions of the patients and implemented in 8 sessions of 90-minute with a therapeutic framework of one session per week and for eight consecutive weeks became.<sup>15,21</sup> In the placebo group, one capsule containing 250 mg rice flour was used daily for 8 weeks. During this period, the control group did not receive any intervention. At the end of the interventions, the groups completed the BAI in the post-test and three months later in the follow-up stages. The summary of the sessions is given in [Table 1](#).

In order to comply with ethical considerations, the participants were assured that entering the research will not have an effect on the medical treatment of their MS disease. The possibility of withdrawing from the study and the confidentiality of personal information were also taken into consideration. SPSS-25 software and the repeated measures ANOVA and Bonferroni's post hoc test were used for data analysis. The significance level in this study was considered  $P < 0.05$ .

**Table 1.** Summary of Gestalt therapy and behavioral activation sessions

Sessions	Gestalt therapy
1	"Focusing and scanning the body" and pay attention to specific emotions that a person is involved in
2	Staying in the present to create balance by bringing avoidant behaviors to the level of awareness. Familiarity with polarities, boundaries, and defenses with respect to feelings and perceptions
3	Accepting responsibility for your choices, including your thoughts, feelings, and actions
4	The "empty chair" technique and the release of suppressed emotions
5	"Reversal" to replace self-limiting thoughts with positive thoughts
6	"Dream exploration" in order to discover the missing parts of the person
7	Use of "symbolic games" for greater transparency through the dialogue of hidden parts
8	Reviewing the maintenance program and post-test
Sessions	Behavioral activation
1	Acquaintance with negative emotions: anxiety and depression
2	The role of negative events, avoidance of situations and people, and rumination in maintaining negative emotions.
3	Grading pleasure-success and creating a pleasurable activity program
4	"ACTION" skill
5	"TRAP and TRAC" skill
6	Stress, depression, anxiety
7	assertiveness skill
8	Reviewing the maintenance program and post-test

**Note:** ACTION: A= Access; C= Choose; T= Try; I= Integrate; O= Observe; R=Result; N=Never Give Up; TRAP: (T= Trigger; R= Response; AP= Avoidance Pattern)  
TRAC: (T= Trigger; R= Response; A= Alternative Coping)

**Results**

According to [Table 2](#), there were 14 people in the GT group, 13 people in the BA group, 13 people in the control group, and 12 people in the placebo group. The use of one-way analysis of variance (ANOVA) test showed that there is no significant difference between the groups in terms of average age. Also, the use of Pearson's chi-square test showed that there is no significant difference between the four groups in terms of education level and marital status. [Table 3](#) shows the mean (standard deviation) and Shapiro-Wilk values (significance level) of anxiety in four groups and in pre-test, post-test and follow-up stages.

**Table 2.** Participant characteristics

property	Statistical index/level	GT	BA	Placebo	Control
Age	Mean	32.79	37.31	35.08	37.69
	Standard deviation	6.76	5.59	5.33	6.50
Education level	diploma	2	3	4	4
	Associate degree	5	3	2	1
	Bachelor and higher	7	7	6	8
Marital status	single	4	4	4	5
	married	6	3	7	2
	Divorce/widow	4	6	1	6
<b>Total</b>		<b>14</b>	<b>13</b>	<b>12</b>	<b>13</b>

Abbreviation: GT= gestalt therapy; BA= behavioral activation

**Table 3.** Mean (standard deviation) and Shapiro-Wilk values (significance level) of anxiety in three stages

variable	group	Mean (standard deviation)			Shapiro-wilk (significance level)		
		Pre-test	Post-test	f/u*	Pre-test	Post-test	f/u*
anxiety	GT	28.08 (4.75)	17.14 (5.13)	20.57 (4.67)	0.949 (0.545)	0.916 (0.196)	0.902 (0.120)
	BA	27.92 (3.38)	19.38 (4.75)	22.77 (4.30)	0.956 (0.694)	0.935 (0.393)	0.886 (0.086)
	Placebo	27.50 (3.45)	27.23 (3.91)	29.75 (4.23)	0.978 (0.976)	0.977 (0.970)	0.874 (0.074)
	Control	27.54 (4.12)	29.38 (4.54)	29.62 (4.70)	0.935 (0.401)	0.963 (0.806)	0.965 (0.831)

Note: \*= follow up; GT= gestalt therapy; BA= behavioral activation

According to [Table 3](#), Shapiro-Wilk values of anxiety variable in four groups and in three stages of pre-test, post-test and follow-up is non-significant at 0.05 level. This shows that the distribution of the data related to the dependent variable is normal. In the present study, the assumptions of homogeneity of error variances were checked using Leven's test, the equality of variance-covariance matrices using the Box's M test, and the equality of error covariance matrix using the Mauchly's sphericity Test, and the results demonstrate they are met assumptions the mentioned data is valid.

[Table 4](#) shows that the interaction effect of group × time for anxiety ( $\eta^2=0.520$ ,  $P=0.001$ ,  $F=17.33$ ) is significant at the 0.001 level. These findings indicate that at least the difference in the effect of implementing one of the independent variables compared to the other independent variable or the control group on anxiety is significant at the 0.001 level. [Table 5](#) shows the results of the Bonferroni's test of scores related to anxiety in four groups and three stages of implementation.

**Table 4.** Results of repeated measure analysis of variance (repeated measure ANOVA) in explaining independent effects on anxiety

Variable	Effects	SS	MSE	F	P	$\eta^2$
Anxiety	Group effect	1406.85	1881.17	11.97	0.001	0.428
	Time effect	112.34	420.18	12.83	0.001	0.211
	Interaction effect of group × time	866.64	798.93	17.33	0.001	0.520

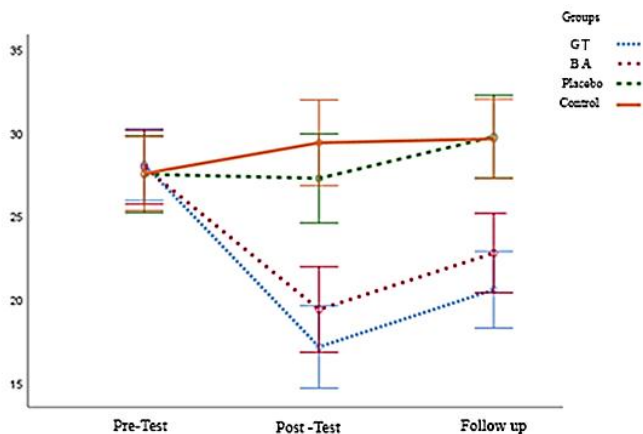
Note: SS= Sum of Squares; MSE= Mean Squared Error

**Table 5.** bonferroni post hoc test results for pairwise comparisons of the effects of groups and times on anxiety

Variable	Times		MD	SE	Pvalue
	Anxiety	Pre-test	Post-test	4.47	0.82
Pre-test		Follow up	2.08	0.68	0.001
Post-test		Follow up	-2.39	0.87	0.134
Variable	Group differences		MD	SE	Pvalue
	Anxiety	GT	BA	-1.43	1.39
GT		Placebo	-6.24	1.42	0.001
GT		Control	-6.92	1.39	0.001
BA		Placebo	-4.81	1.45	0.001
BA		Control	-5.49	1.42	0.001
Placebo		Control	-0.68	1.45	1.00



The results of the Bonferroni's test in [Table 5](#) show that the implementation of GT and BA compared to the placebo and control groups led to reduction in the mean anxiety scores at the post-test and follow-up stages. Also, the results of [Table 5](#), in consistent with the diagram in [Figure 2](#), show that although, in follow-up stage, anxiety mean scores increased somewhat compared to the post-test stage, the difference between the mean scores in the post-test and follow-up stages are non-significant at the 0.05 level. This means that the changes caused by the implementation of GT and BA on anxiety in PWMS three months after the completion of the treatment were still maintained.



**Figure 2.** Diagram related to anxiety in research groups in three implementation stages

Also, the results of Bonferroni's post hoc test in [Table 5](#) show that the difference in the effect of GT on anxiety compared to BA is not significant at the 0.05 level. Therefore, it can be said that there is no significant difference between the effectiveness of GT and BA on anxiety reduction in the PWMS. [Figure 2](#) shows the diagram related to anxiety in the research groups in three stages: pre-test, post-test and follow-up.

## Discussion

The research results showed that GT and BA play a significant role in reducing anxiety in PWMS. So that the mean scores of the post-test anxiety of the patients were significantly reduced compared to the pre-test, while no significant change was observed in the placebo and control groups between the pre-test and the post-test. However, comparing the effectiveness of two types of psychotherapy used in the research did not show any significant difference. This means that both had a similar effect on the improvement of anxiety symptoms in PWMS and this similarity was evident in both the post-test and three-month follow-up phases. So far, no research has been done in order to compare the effectiveness of these interventions, so similar studies have been reported only in terms of the effectiveness of these methods on

reducing anxiety. Our findings are consistent with the results of Raffagnino<sup>11</sup>, Leung and Khor, Herrera et al., Singla et al., Kharaei and Azizi, Hirayama et al., Rezapour et al.<sup>22-27</sup>

In the possible explanation of the research findings regarding the effectiveness of GA on reducing anxiety, the following can be stated: GT believes that anxiety and unfavorable perception of events is because people abandon the present and become preoccupied with a possible uncertain future. Therefore, GT tries to manage anxiety by increasing the individual's capacity to experience in here and now, which is one of the effective factors in the treatment of anxiety.<sup>13</sup> Perls et al, (1989[1951]) describe anxiety excitement suppressed and deprived of oxygen.<sup>28</sup> Because anxious people prevent the proper passage of air flow in the body due to the contraction of their muscles. Focusing on physical processes such as mindful breathing is a main part of self-support, and considering that GT emphasizes promoting self-support to reduce mental distress. for this purpose, conditions were provided during the treatment for people to pay attention to their breathing and become aware of what type of breathing gives them a more relaxed feeling at this moment, so that they can cope with their anxiety better by practicing mindful breathing and increasing the organismic self-support.<sup>20</sup>

On the other hand, anxiety is associated with many physiological and physical signs and symptoms.<sup>29</sup> According to Gestalt therapists ideas, physical signs are a manifestation of person's unspoken inner world<sup>30</sup>, so according to this view, in PWMS where the level of physical anxiety is often high, expressing emotions and re-experiencing suppressed emotions and processing them properly is effective in reducing the anxiety symptoms of patients. It seems that a technique like the "empty chair" helped people by focusing on their physical symptoms release a lot of mental energy that they had spent to hide their physical symptoms and reduce their anxiety.

Also, GT believes that forcing a person to change; Paradoxically, it leads to more distress and loss of coherence. Gestalt seeks change through acceptance.<sup>20</sup> In fact, this acceptance is the opposite of avoiding experiencing.<sup>30,31</sup> Therefore, by adopting a holistic point of view, the therapist leaving space for figures to surface in the between of their relationship with the patients. Sometimes it is even necessary for the therapist to raise the tension in the clients. In fact, instead of looking for a solution to control anxiety, he should seek to find the meaning of the client's anxiety and use it as an important data for treatment.<sup>30</sup> During the intervention, using a technique such as "Please stay with this feeling" helps people cope with the bad feeling caused by anxiety and

experience the anxiety completely and without any escape. According to this view, staying with experiences in order to re processing them increases the connection with the present moment and the result of such experiences often reduces the level of anxiety.

On the other hand, in this approach, the symptoms of anxiety experienced in the body are defined as suffering at the contact boundaries.<sup>30</sup> People with healthy functioning have permeable and flexible boundaries that can manage contact with the environment for achievement and growth.<sup>30,31</sup> If the boundaries in people are too open and permeable, the restrictive and rigid social standards and values penetrate the person so that he gradually denies his real needs or distorts them, which is a kind of the problem is in the style of contact (introjection) and can lead to neurotic anxiety.<sup>20</sup> By increasing the awareness of this incorrect style, a person is able to solve his unfulfilled needs by using constructive creativity and appropriate flexibility here and now, and his anxiety is reduced.

In explaining the effectiveness BA on reducing the anxiety of these patients, it can be said that considering that MS has a chronic, debilitating and unpredictable nature, and often occurs in youth and at an age that one expects health from those years, creates many challenges in the lives of patients, which causes a lot of anxiety and tension in these people. On the other hand, the tendency to avoiding patterns when faced with negative feelings and annoying situations are common. Usually, these patients take an avoidance approach to reduce their anxiety. Thus, according to BA's point of view, this avoidance and passivity increases the intensity of their anxiety symptoms. Therefore, during the treatment, the avoidance patterns and their function are clarified for the patients, and the anxiety symptoms in these people are improved due to regular attention to the avoidance behaviors and facilitation of response-dependent positive reinforcement.<sup>14,33</sup> It seems that in our research, "TRAP and TRAC" as a psychotherapeutic technique to reduction of anxiety in PWMS was effective according to this argument.

Nonexistence difference between the effectiveness of various and psychologically active treatments on reducing anxiety is not unprecedented, and some of them are actually slightly different from each other. In explaining this sameness, it can be said that the contribution of effective common factors in treatments is probably involved in this matter. On the other hand, considering that the therapist was the same in both interventions, this may not affect the effectiveness of these two types of psychotherapy.

### Limitations of Study

One of the limitations of the current study was the purposeful sampling method. In addition, the results were limited to the community that participated in this study. Therefore, should be cautious in generalizing the results. For better generalization, it is suggested this type of study be done in MS associations across the country. Also, future research with a longer follow-up period can better define the differences between these two approaches.

### conclusion

Based on the results of this research, the implementation of GT and BA protocols compared to intervention in the placebo and control groups has caused a significant reduction in anxiety levels in women with MS at the post-test and follow-up stages .However, no difference was observed between GT and BA

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### Conflicts of interest

The author has no conflict of interest to declare.

### Ethical Approval

The protocol for this study was approved by the committee of Biomedical Research Ethics (IR.IAU.TMU.REC.1398.201).

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None received.

### Research Highlights

#### What Is Already Known?

MS is increasing in the world. Almost half of PWMS have anxiety problems, which cause the exacerbation and relapsing of the disease. no definitive drug treatment has been found for MS. Psychological treatments can help to reducing the symptoms of the disease. GT is an efficient approach in reducing anxiety symptoms

#### What Does This Study Add?

BA was as effective as GT in anxiety reduction and with lower cost and less complexity, it produced similar results as GT. also, BA had a good resistance to relapse. BA can be an alternative treatment in the absence of access to a trained expert in the gestalt field.

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