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A randomized controlled trial of group cognitive behavioral therapy for Chinese breast cancer patients with major depression

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Abstract

Background: This study aims to evaluate the effects of Group Cognitive Behavioral Therapy (GCBT) in treating major depression in Chinese women with breast cancer.
Methods: Sixty-two breast cancer patients diagnosed with major depression were randomly assigned to GCBT group ($N = 31$) or a waiting list control group provided with an educational booklet ($N = 31$). The primary outcome measure was the 17-Item Hamilton Depression Rating Scale (17-HAMD). The second outcome measures were Self-Rating Anxiety Scale, Functional Assessment of Cancer Therapy – Breast and Self-Esteem Scale (SES). Assessments were carried out at completion of the study and six-month afterwards.
Results: Patients in the GCBT group had a significant reduction in the 17-HAMD mean score by 9 points ($p < 0.001$), more than any reduction among patients in the control group from baseline to the end of therapy and a significant 7 points ($p < 0.001$) more reduction from baseline to six-month follow-up. GCBT also yielded significantly greater improvement than the control group with regard to quality of life (QoL; $p < 0.01$) and self-esteem ($p < 0.05$). No significant differences were found between groups on improving anxiety ($p > 0.05$).
Conclusion: The results of this trial suggest that GCBT is effective for treating major depression, as well as for improving QoL and self-esteem in breast cancer patients.
Trial Registration: Chictr.org ChiCTR-TRC-11001689

Keywords

Breast cancer, group cognitive behavioral therapy, major depression

History

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Introduction

Breast cancer is the most common malignancy among women in China and many other countries in the world [1–4]. Since both cancer diagnosis and disease-related treatments can be very stressful for women, co-morbidity of depression in breast cancer patients is very common. Studies over the years have revealed that 5–25% women may suffer from major depression at some point on the disease trajectory [5–8], while sub-clinical depression was even more prevalent in this population.

The complexity of the medical condition as well as breast cancer-related treatment (tamoxifen in particular) may sometimes limit the use of antidepressants [9]. Instead, psychotherapy has proven to be a useful treatment modality. Cognitive Behavioral Therapy (CBT) is an empirically supported treatment for depression. Numerous studies have shown that CBT is both effective in treating acute depression and in preventing subsequent relapse and recurrence after the end of active treatment [10,11]. The past 20 years saw a growing interest in providing therapy in group format to reduce psychological distress in patients with breast cancer [5,12–16]. It is expected that the Group CBT (GCBT) approach may be particularly beneficial to depressed women with breast cancer, since the therapeutic components of CBT such as cognitive reconstructing and behavioral modification can be amplified by integrating group process [5,12]. A number of studies have demonstrated the effectiveness of GCBT for reducing psychological distress, improving quality of life (QoL), as well as reducing fatigue, premature menopausal symptoms and insomnia secondary to cancer treatment in breast cancer patients [13–16]. However, randomized controlled studies that assess the efficacy of GCBT in treating major depression in breast cancer patients are scarce.

Most of the trials of GCBT were conducted in Western countries and it is unclear whether GCBT could be an equally efficacious treatment for major depression in Chinese women with breast cancer. Until now, there were only a few isolated

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studies that tested the effects of psychological interventions for depression in breast cancer patients in the Chinese population [17,18]. Furthermore, these studies had a number of methodological limitations. First, they lacked a specific model to be adhered to or a treatment manual to guide intervention. Second, they lacked a mechanism to monitor the therapist's adherence in treatment delivery, which is critical to ensure fidelity of the intervention. And more importantly, few of them were designed as randomized controlled trials. Therefore, a well-designed study to examine the effectiveness of GCBT for major depression in Chinese breast cancer women is needed.

Methods

The present study was conducted in Shanghai Mental Health Center, and the study protocol was approved by the hospital's institutional review board.

Objectives

This study aims to evaluate the effects of GCBT for major depression in Chinese breast cancer patients in a randomized controlled trial, in which a treatment protocol-guided short-term GCBT was compared to a waiting list controlled condition. Our primary hypothesis was that GCBT would produce a more favorable outcome than the control group for reducing depression. A secondary hypothesis was that the GCBT group would show superior effects in improvement of QoL and self-esteem than the control group.

Participants

From June 2008 to January 2010, research participants were recruited from an epidemiological study in a sample of post-surgery outpatients, aimed to investigate the 1-month prevalence rate of major depressive disorder according to the Diagnostic and Statistical Manual, Fourth Edition (DSM-IV) [19]. In this study, participants with stages 0–IV breast cancer were selected 6–36 months after surgery, who had completed radiation therapy and/or chemotherapy and had no other active treatment except for hormonal therapy. Details of the study have been described elsewhere [20]. A total of 95 patients were diagnosed with Major Depressive Disorder. Among them, 64 patients agreed to participate in the trial. Thirty patients declined. There were no significant differences between patients who participated and those who refused in terms of age ($t_{93} = 0.65$, $p = 0.5$), clinical stage of cancer ($\chi^2_2 = 2.99$, $p = 0.22$), time of surgery ($\chi^2_2 = 2.38$, $p = 0.30$), education ($\chi^2_{22} = 0.55$, $p = 0.91$), past psychiatric history ($\chi^2_2 ? > = 3.30$, $p = 0.07$) and severity of depression by scores on the 17-Item Hamilton Depression Rating Scale (17-HAMD) [21] ($t_{93} = 1.41$, $p = 0.16$). In addition, none of them had the experience of GCBT.

All 64 patients consecutively attended for a detailed clinical assessment. The Mini International Neuropsychiatric Interview [22,23] and 17-HAMD were administered to confirm the diagnosis and assess the severity of depression. The inclusion criteria required subjects to meet the DSM-IV criteria for major depressive disorder, and the score on 17-HAMD ≥ 17 [20]. The following exclusion criteria were applied: (1) any acute, unstable or severe medical disorder that might interfere with the successful completion of treatment, (2) any current or past history of schizophrenic disorder, bipolar disorder and severe antisocial personality disorder, (3) any current or past neurological disorder, (4) current concomitant psychotherapeutic or psychopharmacological treatment. After the assessment, a total of 62 patients fulfilled the inclusion criteria and did not meet any of the exclusion criteria. These 62 patients were subsequently randomized to GCBT and waiting list control groups according to 1:1 ratio based on a computerized randomization sequence. After a complete description of the study was provided to these patients, written informed consent was obtained. In order to shorten the waiting time for intervention, once at least five patients had been randomized to each arm, the intervention started. Allocation of patients was performed by a staff member independent of the study.

Thirty-one patients in the GCBT group and 31 in the control group completed the intervention and waiting list condition, respectively. They received the assessment at the end of therapy and at six-month follow-up. During the follow-up period, except for one maintenance session provided to GCBT participants one month after the end of therapy, patients in the trial received no other psychotherapeutic or psychopharmacological treatment. At the six-month follow-up assessment, two patients from the treatment condition and six from the control group dropped out. The difference on drop-out rate between the two groups was no more than by chance ($\chi^2_1 = 2.30$, $p = 0.13$). Flow of patients through the study is depicted in Figure 1.

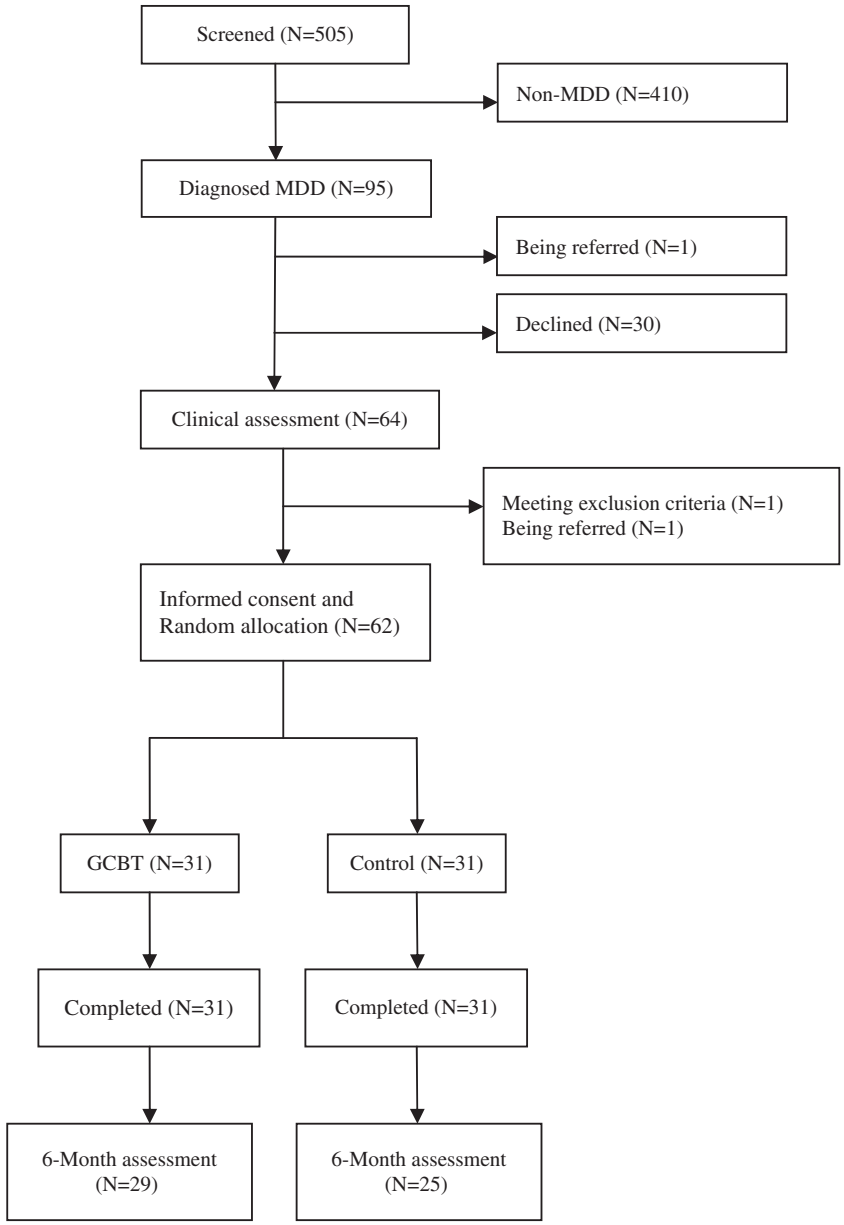
The mean age of the intention-to-treat study group ($n = 62$) was 50.63 years (standard deviation (SD) = 7.09, range 31–64). Fifty-four (87.1%) patients had 0–II stage breast cancer. The mean time after surgery was 16.95 months (SD = 8.68, range 6–36). Fifty-six (90%) patients married. Forty-four (71%) had junior or high middle school education level, while only 18 (22.6%) had college or higher education level. Fifty-two (83.9%) had a lower income ($\leq$RMB ¥2000). Nearly 56 (90%) received mastectomy.

Intervention

The intervention was a closed, treatment protocol-guided group intervention, in which patients met weekly for 10 two-hour sessions. One month following the end of the intervention, one booster session was provided.

Our intervention protocol was developed and modified based on the manual of Aron and Judith Beck [24,25]. We used the basic conceptual modal and treatment techniques from their manual, but the therapy was tailored to meet the specific needs of breast cancer patients in terms of pace and content. Our intervention protocol comprises three parts: first, the ''Cognitive Reconstructing'' part focuses on cognitive intervention; most of the existential concerns and themes caused by breast cancer diagnosis and treatment were incorporated into this part. Secondly, the ''Behavioral Activation'' component focuses on the importance of behavioral activation in improving depressive symptoms [26];

Figure 1. Breast cancer patients entering a trial of GCBT for major depression.



coping with side effects of cancer-related treatment and pursuing healthy behavior and life-style were explored in this part. In addition, the frequently presented behavioral patterns of avoidance and withdrawal in depressed breast cancer patients were particularly addressed. Finally, the ''Interpersonal Communication'' component examines the impact of positive and negative interpersonal relationship on one's mood. Patients were helped to identify the existing family and social resources, build new networks of social support and improve skills for interpersonal conflict resolution. Patients also learned assertiveness skills to facilitate emotional expression and communication with professional care providers, their partners and their families.

In the treatment group, each patient received three sessions for each treatment component. Since anxiety and physical symptoms were common in these patients, progressive muscle relaxation training [27] was provided within each session in the last 30 minutes, except for the last session which was spent on integration, wrapping-up and end-of-treatment celebration.

In the waiting list control group, each patient was provided an educational booklet. The booklet covered topics from facts on breast cancer, treatment and related side effects to the guidelines for rehabilitation. The psychological distress experienced by breast cancer patients was also mentioned, and coping strategies were recommended. In addition, during the waiting period (10-week GCBT intervention plus six-month follow-up), patients were reminded to call project staff for worsened mood symptoms or any problems related to mental well-being. They were also suggested to contact the medical doctors for any further medical problems. After the trial, patients in the control group were recommended to the GCBT, provided continuously.

Therapist

All the interventions were conducted by one therapist. The therapist was a psychiatrist, who had eight years of experience working on women's mental health issues. The therapist was trained in CBT as well as group therapy.

Supervision

Implementation of the treatment protocol, including adherence to the protocol and competent delivery of the intervention was ensured by continuous supervision in this trial. The supervision was carried out by two registered supervisors for psychotherapy in China. The supervision included reading treatment protocol, reviewing the group process or special treatment situations and checking the fulfilled tasks. Each supervision session was audio-taped and reviewed periodically.

Assessment and measures

Individual face-to-face interviews were conducted by a psychiatrist. Patients were assessed at baseline and the end of treatment. Follow-up evaluation was carried out six months after the end of treatment. As the primary outcome measure, the 17-HAMD was first rated independently by two trained blinded raters, who were present during the interview. In the case of divergent ratings, the raters discussed about the findings until consensus was reached.

In addition, several self-report measures were administered to assess the secondary outcomes. Anxiety was assessed by the Chinese version of Self-Rating Anxiety Scale (SAS) [21,28]. QoL was measured by the Chinese version of Functional Assessment of Cancer Therapy – Breast (FACT-B) [29]. In addition, the Chinese version of Self-Esteem Scale (SES) [30,31] was administered to assess patients' self-esteem. An independent research assistant finished the outcome assessment of these scales.

Data analysis

Analyses were performed on an intention-to-treat basis. The statistician was blind to therapy allocation. The baseline clinical and demographic variables of the GCBT and the control groups were compared by *t*-tests for continuous variables such as HAMD, SAS, SES and FACT-B or by chi-square tests and Fisher's exact test (when frequencies were low) for dichotomous variables. Effect sizes (ESs) were assessed by dividing the mean difference between the two groups by the pooled SD [32]. PASW Statistics released version 17.0.3 (SPSS, Inc., 2009, Chicago, IL, USA) was used for the above analyses.

Given the nature of repeated measures in the outcomes, two-level linear modeling [33], controlling for age, education, marriage status, time after surgery, past psychiatric history, state of tumor-node metastasis (TNM), chemotherapy, radiation therapy and cancer recurrence, was used as the primary method to investigate the differences between intervention and control groups on total scores of 17-HAMD, FACT-B, SAS and SES, respectively. The model examined both time effects and intervention effects. Time effects were estimated by mean changes of outcome measures from the baseline to the end of the therapy, and to six-month follow-up for all patients. Intervention effects were estimated by interaction terms between time effects and treatment group, reflecting the mean differences in time effects between the two groups. A negative value of the mean difference indicates a greater deduction of the outcome measure in the GCBT group from the baseline to the end of the therapy or to six-month follow-up than that in the control group in the same period, hence possible intervention effects. We used a z score test to examine time and intervention effects. Intention-to-treat analysis ($N = 62$) was employed by using the last observation carried forward. In addition, we conducted a complete analysis of patients who finished the treatment and follow-up to cross check main findings. The package MLwiN v2.1 was used for the analysis.

Results

Comparison of baseline characteristics between groups

No significant differences were found in demographic or clinical characteristics such as months after surgery, educational level between the GCBT treatment and the waiting list control group at baseline (Table 1), which suggests that two groups were comparable in baseline depression and anxiety severity, as well as levels of QoL and self-esteem.

Comparison of raw mean scores of outcomes between groups

The raw outcomes of two groups were compared by a *t*-test. Between-group ESs were also estimated (Table 2). At the end of therapy, significant effects of the intervention were found for 17-HAMD with the ES of 2.19, and for SAS with an ES of 0.56. At six-month follow-up, the significant effects of the treatment continued for 17-HAMD with a slightly reduced ES of 1.51, and for SAS (ES = 0.66). The SES score showed a significant improvement at six-month follow-up ($p = 0.02$, ES = 0.63). No significant effects were found for FACT-B at both the end of therapy and six-month follow-up.

Effects of time and comparison of changes over time between groups

Table 3 presents model estimates of time effects in the outcome measures and intervention effects by mean score changes in the GCBT group versus mean changes in the control group. This analysis was adjusted for difference in previous history of depression, education and occupation between the two groups of patients. Time effects suggested that for control group patients there were significant reductions of the mean scores at the end of the therapy and at six-month follow-up for both 17-HAMD and SAS, and a significant increase in mean scores over time for FACT-B. The findings indicate a marked improvement on these outcome measures over time in a course when no treatment was presented in this study. No changes over time on SES score were indicated.

For the intervention effects, our analysis indicated that patients in the GCBT group had a significant reduction of the 17-HAMD mean score by 9 points ($p < 0.001$) more than any reduction among patients in the control group from baseline to the end of therapy, and a significant 7 points ($p < 0.001$) more reduction from the baseline to six-month follow-up. However, further comparison in the mean change scores of the GCBT group between the two time periods suggested a rebound of the 17-HAMD score by 2 points ($\chi^2 = 5.47$, $p = 0.02$) at six-month follow-up. The GCBT intervention significantly improved the FACT-B outcome by about

Table 1. Baseline characteristics of GCBT and controlled groups.

	GCBT ($n=31$)	Control ($n=31$)	χ^2/t p
Age	51.68 ± 5.95	49.58 ± 8.03	1.17 (0.25)
HAMD	20.61 ± 2.68	20.68 ± 3.18	0.09 (0.93)
SAS	47.65 ± 7.74	50.19 ± 7.99	1.28 (0.21)
SES	26.39 ± 2.83	26.39 ± 2.40	0.00 (1.00)
FACT-B	77.42 ± 12.68	81.17 ± 16.66	1.00 (0.32)
Months after surgery			
>6, ≤12	17 (54.8)	10 (32.3)	4.25 (0.12)
>12, ≤24	11 (35.5)	13 (41.9)	
>24, ≤36	3 (9.7)	8 (25.8)	
Marriage status			
Married	29 (93.5)	27 (87.1)	0.74 (0.39)
Unmarried/Separated/ Divorced/Widowed	2 (6.5)	4 (12.9)	
Occupation status			
Unemployed	0 (0)	5 (16.1)	5.47 (0.07)
Retirement	15 (48.4)	12 (38.7)	
Employed	16 (51.6)	14 (45.2)	
Education			
Primary school	0 (0)	4 (12.9)	7.47 (0.06)
Junior middle school	8 (25.8)	12 (38.7)	
High middle school	16 (51.6)	8 (25.8)	
≥College	7 (22.6)	7 (22.6)	
Monthly income			
≤2000	25 (80.6)	27 (87.1)	1.19 (0.55)
>2000, ≤5000	5 (16.1)	4 (12.9)	
>5000	1 (3.2)	0 (0)	
Types of operation			
Mastectomy	28 (90.3)	29 (93.5)	0.22 (0.64)
Breast-conserving	3 (9.7)	2 (6.5)	
TNM stage			
0–I	21 (67.7)	15 (48.4)	2.39 (0.30)
II	7 (22.6)	11 (35.5)	
III–IV	3 (9.7)	5 (16.1)	
Radiation therapy			
No	20 (64.5)	20 (64.5)	0.00 (1.00)
Yes	11 (35.5)	11 (35.5)	
Chemotherapy			
No	2 (6.5)	1 (3.2)	0.35 (0.55)
Yes	29 (93.5)	30 (96.8)	
Immunotherapy			
No	19 (61.3)	21 (67.7)	0.28 (0.60)
Yes	12 (38.7)	10 (32.3)	
Recurrence or metastasis			
No	31 (100.0)	28 (90.3)	3.15 (0.08)
Yes	0 (0)	3 (9.7)	
Psychiatric history			
No	24 (77.4)	26 (83.9)	0.41 (0.52)
Yes	7 (22.6)	5 (16.1)	
Family history of mental illness			
No	29 (93.5)	31 (100.0)	2.07 (0.15)
Yes	2 (6.5)	0 (0)	

9 points ($p<0.01$) at the end of therapy and 11 points ($p<0.01$) at six-month of follow-up. The comparison in the improvement between the two periods found no significant difference ($\chi^2=0.63$, $p=0.43$), which suggested a sustainable intervention effect after six months of completion of the GCBT. Similarly, greater improvement was found in the GCBT group on the SES, which remained at the six-month follow-up period. The GCBT intervention did not show significant effects over time on SAS outcome.

Discussion

To the best of our knowledge, this is the first randomized controlled trial to examine a short-term GCBT for treating major depression among breast cancer patients in China. In this trial, there were few drop-outs, and 62 (100%) participants completed the assessment at the end of therapy, with 54 (87.1%) participants completing the six-month follow-up. The attrition rate was comparable to that in previous similar studies [5,34]. Regarding the severity of depression at baseline, patients' mean score on 17-HAMD was 20.65 (SD = 2.92, range: 17–28), which was comparable to other psychotherapy or pharmacological intervention studies [26,35].

For the primary outcome, the 17-HAMD scores for both the GCBT group and the control group decreased significantly over time, but patients in the GCBT group achieved significantly greater improvement than those in the control group. The ESs were comparable to, or even larger than, what was reported in other studies. Osborn et al. [36] undertook a meta-analysis for CBT (including individual and group) treating depression in cancer patients, and the ES of 1.2 (95% CI: 0.22–2.19) was reported.

It is widely acknowledged that psychotherapy and antidepressants are equally effective for treating mild to moderate depression in the general medical population. For severe depression, antidepressant therapy combined with psychotherapy may be better than psychotherapy alone. As for breast cancer patients, the unique complexity and constraints in cancer care may often make clinical decisions more challenging [37]. Therefore, a number of group psychological interventions have been developed in the past 20 years for reducing overall psychological distress and improving QoL for patients with cancer. But in a handful studies conducted in recent years, evidence for the effectiveness of CBT-oriented group psychological interventions were mainly based on the heterogeneous sample with diagnosis of breast cancer, where often less depressed patients were recruited [38,39]. Therefore, the results from our trial directly suggested that GCBT is effective for major depression in breast cancer patients.

It should be noted that patients in the waiting list control group also attained significant improvement on HAMD in our trial, however greater improvement was seen in the GCBT group. Several reasons for this are plausible. First, some degree of spontaneous recovery from depression could occur due to various reasons, including psychological adjustment made in a supportive social-family environment. Secondly, and maybe more importantly, the patients in the current trial were in great need of psychological help in terms of the numerous stresses encountered after cancer diagnosis and treatment, as well as the major depression they were suffering. Studies already showed that psychotherapy would make its greatest impact on the subjects who were more distressed and thus in greatest need [38,40]. We speculate that the psychoeducational content in our study booklet (even a small dosage of intervention) could have made a remarkable reduction in depression in the control group. Another noteworthy finding in this trial is that the superiority of GCBT to the control group at the end of therapy was slightly elapsed at six-month follow-up, based on the primary outcome. There might be some bias in participants' immediate reports at the end of therapy when they tended to provide desirable responses to the evaluator. In addition, this result also raises the question of

Table 2. Outcomes by therapy in the intention-to-treat sample.

Variable and time point	GCBT ($N=31$) Mean SD	Control ($N=31$) Mean SD	t, p	Between-group ES*
HAMD				
Baseline	20.61 ± 2.68	20.68 ± 3.18	0.09 (0.93)	
End of therapy	6.03 ± 2.82	15.06 ± 5.09	8.65 (0.00)	2.19
6-Month follow-up	7.51 ± 3.71	14.35 ± 5.21	5.95 (0.00)	1.51
SAS				
Baseline	47.65 ± 7.74	50.19 ± 7.99	1.28 (0.21)	
End of therapy	40.23 ± 6.40	45.39 ± 11.42	2.20 (0.03)	0.56
6-Month follow-up	37.74 ± 5.20	43.10 ± 10.09	2.63 (0.01)	0.66
SES				
Baseline	26.39 ± 2.83	26.39 ± 2.40	0.00 (1.00)	
End of therapy	27.61 ± 2.83	26.23 ± 2.72	1.97 (0.053)	0.5
6-Month follow-up	28.42 ± 1.91	27.00 ± 2.57	2.47 (0.02)	0.63
FACT-B				
Baseline	77.42 ± 12.68	81.17 ± 16.66	1.00 (0.32)	
End of therapy	91.17 ± 13.35	86.13 ± 16.40	1.33 (0.19)	0.34
6-Month follow-up	97.17 ± 12.18	89.85 ± 16.54	1.99 (0.052)	0.53

*Pool SD between the two groups was used for calculating ES.

Table 3. Time effect by mean score changes over time for control group patients and intervention effects by difference of time effect between the GCBT and the control group, adjusted for previous history, education and occupation.

	HAMD Est. diff. (SE)	SAS Est. diff. (SE)	FACT-B Est. diff. (SE)	SES Est. diff. (SE)
Time effect				
Baseline to end of therapy (t1)	−5.61 (0.65)***	−4.81 (1.26)**	4.94 (2.03)*	−0.16 (0.45)
Baseline to 6-month follow-up (t2)	−6.32 (0.65)***	−7.10 (1.26)***	8.68 (2.03)**	0.61 (0.45)
Intervention effect				
GCBT × Baseline	0.19 (1.05)	−3.09 (2.18)	−-1.79 (3.84)	−0.11 (0.75)
GCBT × t1	−8.97 (0.92)***	−2.61 (1.78)	8.79 (2.87)**	1.39 (0.64)*
GCBT × t2	−6.77 (0.98)***	−2.81 (1.78)	11.07 (2.87)**	1.42 (0.64)*
Chi-square (P)†	5.74 (0.02)*	0.01 (0.91)	0.63 (0.43)	0.003 (0.96)

***$p<0.001$; **$p<0.01$; *$p<0.05$.
†Chi-square test to compare difference of intervention effects between end of therapy (t1) and 6-month follow-up (t2).

long-term efficacy for GCBT. Osborn et al. [32] in their meta-analyses found that the efficacy of CBT for treating depression in breast cancer was only short term. We think that such an important question warrants further research.

Unsurprisingly, our study demonstrated that GCBT group significantly outperformed the waiting list control group for improving overall QoL in breast cancer patients. This finding was consistent with some previous studies, although various instruments were used [34]. Furthermore, our results showed that the GCBT intervention significantly improved the self-esteem in breast cancer patients. Sebastian and her colleagues [41] also found the positive effects of psychological intervention for self-esteem. To sustain self-esteem, breast cancer patients have to cope with the challenge of self-reconstruction. This effort involves rediscovering a new sense of health and self-efficacy, and psychological intervention may facilitate this process.

The unexpected finding in this study is that GCBT failed to demonstrate significant treatment effects on SAS, although anxiety levels improved remarkably in both groups. This result was inconsistent with the previous findings [34,36]. Certainly, depression is the primary focus for strategies designed in our intervention. For example, the behavioral strategies we used mainly focused on behavioral activation instead of techniques such as worry exposure. But we anticipated that the progressive relaxation training in our trial would reduce anxiety, as it was reported in some previous studies [34,42]. The different results here might suggest the specificity of worrying and anxiety in breast cancer patients. Further study with more homogeneous groups with anxiety disorder from breast cancer patients is needed.

This study has a number of strengths, including the recruitment of a homogeneous group with diagnostic assessments; rater blinding to treatment assignment; the utilization of psychometrically sound and comparable outcome measures; and the use of structured protocol-guided treatments. Based on the raw ESs observed at the end of therapy and at six months after the therapy on 17-HAMD outcome, the sample size of 62 patients in total gave us over 95% power to conclude the GCBT effects for the patients. In addition, the tolerability of GCBT (i.e. drop-out and attendance rates) was comparable to or better than other recent studies of CBT-based group intervention for breast cancer [5,34].

However this study also had a number of limitations. First, as a single-center trial, together with the highly qualified therapist and supervisor team in this trial, this study may constrain the generalization of the findings to other settings. Second, this study lacked the independent ratings of the therapist's competence.

In sum, this is the first randomized controlled and protocol-guided trial to test the efficacy of short-term GCBT for treating major depression in breast cancer patients in China. The results of this trial suggest GCBT is efficacious in treating major depression, as well as in improving QoL and self-esteem in breast cancer patients. In addition, GCBT is feasible and well accepted by Chinese breast cancer patients. The results in our trial highlight the importance of integrating psychological care into the cancer service, and particularly GCBT as a promising treatment.

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Declaration of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this article.

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➤ Current knowledge on this subject

- The co-morbidity of depression in breast cancer patients is very common. Some studies have showed that GCBT approach was particularly beneficial to the depressed women with breast cancer. But it is unclear whether GCBT could be an equally effective treatment for major depression in Chinese breast cancer women.

➤ What this study adds

- In this study we will evaluate the effects of GCBT for major depression in Chinese breast cancer patients in a rigorous analysis. The results of this trial suggest that GCBT is effective for treating major depression. The study also highlights the importance for integrating psychological care into the cancer service, and particularly, GCBT as a promising treatment.