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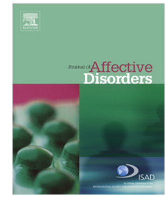

Research report

A comparison of cognitive-behavioral therapy, antidepressants, their combination and standard treatment for Chinese patients with moderate–severe major depressive disorders

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ABSTRACT

Background: No study has examined the effect of cognitive-behavioral therapy (CBT) on moderate–severe major depressive disorders (MDD) in China. The objective of this study was to evaluate the effect of CBT, antidepressants alone (MED), combined CBT and antidepressants (COMB) and standard treatment (ST; i.e., receiving psycho-educational intervention and/or medication treatment determined by treating psychiatrists) on depressive symptoms and social functioning in Chinese patients with moderate–severe MDD.
Method: A total of 180 patients diagnosed with MDD according to ICD-10 were randomly allocated to one of the four treatment regimens for a period of 6 months. Depressive symptoms were measured using the Hamilton Rating Scale for Depression (HAMD) and the Quick Inventory of Depressive Symptomatology-Self-Report (C-QIDS-SR). Remission threshold was defined as a C-QIDS-SR total score of <5. Social functioning was evaluated with the Work and Social Adjustment Scale (WSAS). All outcome measures were evaluated at entry, and at 3- and 6-months follow-up.
Results: At the 6-months assessment, the remission rates in the whole sample ($n=96$), the MED, the CBT, the COMB and the ST groups were 54.2%, 48%, 75%, 53.5% and 50%, respectively. Following the treatment periods, there was no significant difference in any of the study outcomes between the four groups. However, the CBT showed the greatest effect in the HAMD total score with the effect size=0.94, whereas the ST has only a moderate effect size in the WSAS total score (effect size=0.47).
Conclusions: The findings support the feasibility and effectiveness of CBT as a psychosocial intervention for Chinese patients with moderate–severe MDD. We also found that single treatment using MED or CBT performed equally well as the combined CBT-antidepressant treatment in controlling the remission. The study provided important knowledge to inform the mental health care planning in China.
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1. Introduction

In past decades, psychosocial interventions have been increasingly used to manage major depressive disorder (MDD). Cognitive and behavioral therapy (CBT) was developed by Beck in the 1960s, and focuses on patients' dysfunctional thinking, emotion and behavior (Beck et al., 1979). Since then, CBT has been widely adopted in clinical practice and there is compelling evidence that it is an effective treatment for MDD (Butler et al., 2006; Churchill et al., 2001; Clark and Beck, 2010; Epp et al., 2009). CBT can reduce symptoms of mild to moderate MDD (Compton et al., 2004) with remission rates ranging between 42% and 84% (Berking et al., 2013; Hollon et al., 1991). Most studies on CBT have been conducted in Western countries, and it is still unclear if their results could be applied to different socio-cultural contexts. Previous studies on CBT only focused on mild to moderate

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MDD and did not involve severely ill MDD patients, perhaps due to the concern that patients with more severe depression may not be able to fully engage in CBT. As an important outcome measure, social functioning was not included in the previous studies on CBT in MDD patients.

This study was conducted to determine whether CBT could be adopted in the provision of mental health care services in China. In particular, it aimed to examine the effects of CBT in Chinese patients with MDD with respect to changes in depressive symptoms, remission rate and social functioning. The research hypotheses were as follows:

1. The CBT would be more effective than the standard treatment (ST; psycho-educational intervention and/or medication determined by the treating psychiatrists) in improving the remission rate and social functioning of Chinese patients with MDD.
2. The antidepressant only (MED) would be more effective than the ST in improving the remission rate and social functioning of Chinese patients with MDD.
3. The combined treatment of CBT and MED would be more effective than the effects of the single treatment modality in improving the remission rate and social functioning of Chinese patients with MDD.

2. Method

2.1. Patients and setting

The study was a randomized controlled trial conducted between June 2009 and October 2011 in a university-affiliated teaching hospital in Beijing. This hospital has 800 beds, receives 1100 outpatient visits daily and serves approximately 19 million people. This study was part of an ongoing, multicenter project comparing the effects of only CBT with combined CBT and psychotropic medications and standard clinical management on MDD, anxiety and psychotic disorders in China.

Outpatients were consecutively screened and enrolled if they fulfilled the following inclusion criteria: (1) a diagnosis of non-psychotic DSM-IV MDD ascertained by the Mini International Neuropsychiatric Interview (MINI) (Sheehan et al., 1998; Si et al., 2009); (2) age between 17 and 60 years; (3) length of illness less than 1 year; (4) total score of the 17-item Hamilton Rating Scale for Depression (HAMD) – Chinese version (Hamilton, 1960; Xie and Shen, 1984) ≥ 17 (moderate–severe depression); (5) Ability to communicate and provide a written consent form; and (6) having at least one family member cohabitating with the patient. Due to the lack of community-based rehabilitation or day-care facilities in most areas of China (Xiang et al., 2012), psychiatric patients frequently live with their families. Psychosocial interventions are more effective if patients are supported by their families (Xiang et al., 2007). Exclusion criteria included (1) current or past history of any other psychiatric disorders including drug and alcoholic dependence; (2) ongoing acute medical and neurological conditions; (3) lack of response to citalopram, sertraline, or paroxetine and CBT in the past; (4) taking an antipsychotic medication or mood stabilizer; and (5) having suicidal ideation, suicide plan or attempt in the current depressive episode.

The study protocol was approved by the Human Research and Ethics Committee of Beijing Anding Hospital.

A total of 180 patients satisfied the study criteria and were randomly assigned to the MED group, CBT group, COMB group and the ST group with a 2:1:2:1 ratio based on a table of random numbers. More patients were assigned to the MED and COMB groups because they were also involved in other studies of the parent project. The sample size in each group in all study sites of the parent project were calculated on the basis of the power analysis theory (Cohen, 1988) with a power of 0.8 and the significance level set as 0.05 (two sided). Further details of the power analysis will be given in the main report of the project that is in preparation.

2.2. Interventions

Patients in the MED and the COMB groups received either citalopram (20–60 mg/day), escitalopram (10–20 mg/day), paroxetine (20–60 mg/day) or sertraline (25–100 mg/day) within the therapeutic dose ranges recommended by the Guidelines for the Prevention and Treatment of Major Depression in China (Chinese Medical Association, 2003). The prescription decision was made by the treating psychiatrist based on their preference. For patients in the MED and COMB groups, doses of antidepressants were increased to the recommended therapeutic dose range by week 2; the optimal dose was determined by the treating psychiatrist, but it had to be within the above-recommended dose ranges. Patients who had been receiving a different antidepressant at study entry had their previous medications tapered off during the first week while the assigned study medication was gradually introduced. No other psychotropic medications were prescribed with the exception of short-acting benzodiazepines for agitation, anxiety and insomnia. Benzodiazepines were used as sparingly as possible. Other medications not affecting the central nervous system were also allowed.

Patients in both the CBT and the COMB groups received a 24-week individual CBT program that consisted of 20 sessions with each session lasting 1 h: Sessions 1–2: introduction to the CBT Program and the therapeutic setting. Session 3: establishment of the therapeutic goal and plan (Rector et al., 1999); Session 4: understanding patterns of automatic thoughts and behaviors. Session 5: understanding and controlling anxious symptoms. Sessions 6–8: restructure of automatic thoughts (Beck et al., 1979; Overholser, 1995). Sessions 9–13: recognizing, challenging and remedying the schema (Beck et al., 1979). Sessions 14–16: identifying warning signs of relapse and keeping track of warning signs (Hollon et al., 1992; Persons, 1993). Sessions 17–19: consolidate stage of the treatment effect (Teasdale et al., 1995). Session 20: review of the treatment process, gains and shortcoming of the therapy. Sessions 1–3 taking place in week 1, sessions 4–9 in weeks 2–4, sessions 10–15 in weeks 5–10 and Sessions 16–20 in weeks 11–24.

2.3. Therapists

Four trained clinical psychologists at Ph.D. level served as therapists and were responsible for delivering the CBT program. All therapists underwent 1-month training by qualified CBT trainers from Hong Kong, UK and USA to familiarize themselves with the interventions prior to the study and then a one-hour supervision on delivery of the CBT program per week during the study period.

2.4. Measurements and evaluation

The 17-item HAMD – Chinese version (Hamilton, 1960; Xie and Shen, 1984), a widely used interviewer-rated scale with well-established psychometric properties, was used to measure the severity of depressive symptoms within the past week serving as the comparator rating instrument in this study.

The Chinese version of the 16-item Quick Inventory of Depressive Symptomatology-Self-Report (C-QIDS-SR) total score measured the severity of depressive symptoms within the past week.

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