



# Mindfulness-based cognitive therapy vs. psycho-education for patients with major depression who did not achieve remission following antidepressant treatment



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## ABSTRACT

Mindfulness-based cognitive therapy (MBCT) showed efficacy for currently depressed patients. However, most of the available studies suffer from important methodological shortcomings, including the lack of adequate control groups. The present study aims to compare MBCT with a psycho-educational control group designed to be structurally equivalent to the MBCT program but excluding the main putative “active ingredient” of MBCT (i.e., mindfulness meditation practice) for the treatment of patients with major depression (MD) who did not achieve remission following at least 8 weeks of antidepressant treatment. Out of 106 screened subjects, 43 were randomized to receive MBCT or psycho-education and were prospectively followed for 26 weeks. MD severity was assessed with the Hamilton Rating Scale for Depression (HAM-D) and the Beck Depression Inventory-II (BDI-II). Measures of anxiety, mindfulness, and quality of life were also included. All assessments were performed at baseline, 4, 8, 17 and 26-weeks. Both HAM-D and BDI scores, as well as quality of life and mindfulness scores, showed higher improvements, which were particularly evident over the long-term period, in the MBCT group than in the psycho-education group. Although limited by a small sample size, the results of this study suggest the superiority of MBCT over psycho-education for non-remitted MD subjects.

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## 1. Introduction

Major depression (MD) is one of the most common psychiatric disorders in the general population, as well as one of the main causes of morbidity in the world. About 350 million people are currently thought to be affected by MD and this disorder currently represents one of the leading causes of disability worldwide (WFMH, 2012). Current pharmacological and psychological treatments have been found to significantly reduce depressive symptoms, as well social and work-related dysfunctions associated with MD (WFMH, 2012). However, available evidence shows that response and remission rates

to current treatments are far from being satisfactory. Indeed, a large proportion of patients does not achieve full symptom remission, even following several treatment steps of medications and/or psychotherapy (Rush et al., 2006; Pigott et al., 2010; Aguglia et al., 2014). Furthermore, even patients who meet remission criteria following pharmacological and/or psychological treatments carry a high risk for relapse (Ramana et al., 1995; Hollon et al., 2005) especially when they continue to experience residual depressive symptoms (Paykel et al., 1995; Judd et al., 1999; Pincus et al., 2004; Israel, 2010).

Mindfulness-based cognitive therapy (MBCT) is a manualized 8-week meditation-based skills-training group program originally designed to prevent depressive relapse and recurrence that builds on a strong foundation of empirical research examining predictors of depressive relapse (Segal et al., 2002). It utilizes the structure and many practices of the mindfulness-based stress reduction program (MBSR) developed by Kabat-Zinn (1990) and it includes elements of cognitive behavioral therapy for MD (Beck et al., 1979), such as psycho-education about the cognitive model of MD.

By means of mindfulness meditation practice, MBCT teaches patients to become more aware of their incoming thoughts, feelings, and bodily sensations, and to relate to them with an accepting and

Abbreviations: BAI, Beck Anxiety Inventory; BDI-II, Beck Depression Inventory-II; FFMQ, Five Facet Mindfulness Questionnaire; HAM-D, Hamilton Rating Scale for Depression; ITT, intent to treat sample; MBCT, mindfulness-based cognitive therapy; MD, major depression; MBSR, mindfulness-based stress reduction program; PGWB, Psychological General Well Being Index; TAU, treatment as usual

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nonjudgmental attitude. The main aim of the program is to help patients who have suffered from MD to develop a “decentered” perspective toward their inner experience in order to become more aware of and to relate differently to the dysfunctional and automatic cognitive styles – and related emotional responses – that underpin depressive relapse/recurrence (Segal et al., 2002).

Consistent evidence has suggested so far the superiority of MBCT plus treatment as usual (TAU) over TAU alone or placebo, as well as the comparable efficacy of MBCT associated with gradual discontinuation of pharmacotherapy with maintenance pharmacotherapy alone or psycho-education, for the prevention of MD relapse in patients with three or more prior depressive episodes (Chiesa and Serretti, 2011; Piet and Hougaard, 2011; Williams et al., 2014). On the basis of these findings, MBCT has been recommended by international guidelines as a treatment choice for relapse prevention in recurrent MD patients (National Institute of Health and Clinical Excellence, 2009; American Psychiatric Association, 2010; Crane and Kuyken, 2013). In addition, more recent studies have shown that MBCT can be efficacious for patients suffering from acute MD (Barnhofer et al., 2009; Manicavasgar et al., 2011; van Aalderen et al., 2012; Omid et al., 2013; Strauss et al., 2014), for patients with residual depressive symptoms – regardless of the number of previous depressive episodes (T. Kingston et al., 2007; Geschwind et al., 2012; Batink et al., 2013), as well as for patients suffering from treatment-resistant MD (Kenny and Williams, 2007; Eisendrath et al., 2008).

Despite these encouraging findings, it is worth mentioning that most of the available studies on MBCT suffer from important methodological shortcomings. A main shortcoming of these studies concerns the lack of a control group or the comparison between MBCT and inactive control groups (i.e., waiting lists) that do not allow to distinguish between the specific effects of MBCT, such as those related to mindfulness meditation practice, and the non-specific effects of treatment, such as benefit's expectation, teacher's care, and group support (Chiesa and Serretti, 2011; Goyal et al., 2014).

Pertaining to the reduction of depressive symptoms in currently depressed patients, only a few studies have compared MBCT with active comparators so far. As an example, employing a randomized controlled design, Manicavasgar et al. (2011) recently found in a sample of 45 patients suffering from non-melancholic MD that MBCT could be as effective as group cognitive-behavior therapy on the reduction of depressive symptoms. More recently, Omid et al. (2013) confirmed and extended these findings in a sample of 90 subjects randomized to MBCT, cognitive-behavior therapy or to a waiting list. In this study MBCT was as effective as cognitive behavior therapy and both active treatments were superior to the waiting list on the reduction of several psychological outcome measures including depressive symptoms (Omid et al., 2013). Although both studies compared MBCT with active control groups, which efficacy for MD had already been established, none of them helped distinguish between the specific effects of MBCT and the non-specific effects of treatment that are thought to be common to all group psychological treatments. Furthermore, both studies were limited by the lack of an *a priori* power calculation that did not allow to understand to what extent the similar efficacy observed between MBCT and active control groups was actually the result of a lack of statistical power rather than of a real comparable efficacy of the two interventions. A possible way to overcome this limitation could be to directly compare MBCT with a control group designed to be structurally equivalent to the MBCT program but excluding the main claimed “active ingredient” of MBCT, i.e., mindfulness meditation practice, for the treatment of symptomatic patients with MD.

A further limitation of the majority of previous studies focusing on non-remitted MD patients is the dearth of follow-up data following the end of the treatment period (J. Kingston et al., 2007; Crane et al., 2008; Barnhofer et al., 2009; Omid et al., 2013). It is therefore largely unknown the extent to which benefits observed

over the short-term period tend to maintain over the long-term period as well.

As a consequence, the present study is aimed at investigating the short-term (8 weeks) and long-term (26 weeks) effects of MBCT as compared with a psycho-educational active control group (1) on the reduction of depressive symptoms and (2) on the modulation of further clinical variables, such as anxiety symptoms and quality of life, in a sample of patients suffering from MD who did not achieve remission after at least 8 weeks of adequate antidepressant treatment.

## 2. Methods

### 2.1. Participants

Participants for this study included both patients treated for MD at the Institute of Psychiatry of the University of Bologna and subjects from the general community informed of the study through special handouts. The recruitment of subjects began in October 2010 and ended in October 2012. During this period interested subjects were contacted by telephone by an operator and placed in a waiting list. Overall, six groups (three MBCT groups and three psycho-education control groups) were conducted. Data about the pilot group (one MBCT group and one psycho-education control group) have already been published in a previous paper (Chiesa et al., 2012) and have been included in the present paper as well.

In the 2 weeks before the start of each program, interested subjects were contacted for the screening interview and received detailed instructions of the study procedures. Inclusion criteria were as follows: (1) age between 18 and 65 years; (2) diagnosis of MD, single or recurrent episode, according to the criteria of the DSM-IV-TR, as measured by the Mini-International Neuropsychiatric Interview (Sheehan et al., 1998); (3) being on treatment with antidepressants at adequate dosages for at least 8 weeks before study beginning, and (4) failure to achieve remission during the screening visit, defined as a 21-items Hamilton Rating Scale for Depression (HAM-D) (Hamilton, 1960) score at study entry  $\geq 8$ . Exclusion criteria were as follows: (1) current or past psychosis, bipolar disorder, or substance abuse; (2) severe physical or neurological conditions that could interfere with the engagement in mindfulness practices; (3) no antidepressant treatment or inadequate antidepressant treatment; (4) high suicide risk, defined by item 3 of HAM-D score  $\geq 3$ ; (5) concurrent psychotherapy or engagement in any meditation or yoga practice. Drugs and doses at baseline had to remain stable during the study period. Treatment adequacy has been defined in accordance with current recommendations of the Maudsley guidelines for the treatment of MD (Taylor and Kapur, 2012).

All patients meeting inclusion criteria were fully informed about the nature and purpose of the study and gave written informed consent prior to the beginning of the trial. The study protocol was approved by the local ethical committee.

### 2.2. Outcome measures

Hamilton Rating Scale for Depression (HAM-D). The 21-item version of the HAM-D (Hamilton, 1960) is a standardized interview measuring the severity of depressive symptoms on a 0–63 score range. It is a multidimensional scale that covers a set of affective, behavioral, and biological symptoms. It showed good psychometric properties, such as good overall levels of internal consistency, inter-rater and test–retest reliability (Trajkovic et al., 2011). The HAM-D was assessed by a single research assistant with master's degree in psychology blind to the allocation of study participants who had received extensive training in HAM-D administration consisting in rating eight videotaped HAM-D interviews with patients varying in strength of residual depressive symptoms.

Beck Depression Inventory-II (BDI-II). BDI-II (Beck et al., 1996) is a 21-item self-report questionnaire measuring cognitive, affective, somatic, and vegetative symptoms of depression on a scale of 0–3. Score ranges from 0 to 63. The BDI-II has shown high internal reliability, ability to discriminate between depressed and non-depressed subjects, and good concurrent, content, and structural validity (Wang and Gorenstein, 2013).

Beck Anxiety Inventory (BAI). The BAI (Beck and Steer, 1990) is a self-report questionnaire developed to assess the severity of anxiety symptoms. The scale includes 21 items rated on a range from 0 to 3, with a maximum score of 63. Each item is descriptive of subjective, somatic, or panic-related symptoms of anxiety. The scale has shown high internal consistency and good test–retest reliability over 1 week (Beck et al., 1988).

Five Facet Mindfulness Questionnaire (FFMQ). The FFMQ is one of the most used empirically-based mindfulness questionnaires. It is a 39-item self-report instrument derived from the integration of five mindfulness questionnaires by means a factor analytic approach (Baer et al., 2006). The analysis provided five facets of trait mindfulness: observing, describing, acting with awareness, non-judging of inner experience, and non-reactivity to inner experience. FFMQ measures each subscale separately. Its construct validity has been recently confirmed in both meditating and non-meditating samples (Baer et al., 2008).

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