



# Rational-emotive and cognitive-behavior therapy (REBT/CBT) versus pharmacotherapy versus REBT/CBT plus pharmacotherapy in the treatment of major depressive disorder in youth; A randomized clinical trial

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## ABSTRACT

Major depressive disorder is a highly prevalent and debilitating condition in youth, so developing efficient treatments is a priority for mental health professionals. Psychotherapy (i.e., cognitive behavioral therapy/CBT), pharmacotherapy (i.e., SSRI medication), and their combination have been shown to be effective in treating youth depression; however, the results are still mixed and there are few studies engaging multi-level analyses (i.e., subjective, cognitive, and biological). Therefore, the aims of this randomized control study (RCT) were both theoretical – integrating psychological and biological markers of depression in a multi-level outcome analysis – and practical – testing the generalizability of previous results on depressed Romanian youth population. Eighty-eight ( $N=88$ ) depressed Romanian youths were randomly allocated to one of the three treatment arms: group Rational Emotive Behavior Therapy (REBT)/CBT (i.e., a form of CBT), pharmacotherapy (i.e., sertraline), and group REBT/CBT plus pharmacotherapy. The results showed that all outcomes (i.e., subjective, cognitive, and biological) significantly change from pre to post-treatment under all treatment conditions at a similar rate and there were no significant differences among conditions at post-test. In case of categorical analysis of the clinical response rate, we found a non-significant trend favoring group REBT/CBT therapy. Results of analyses concerning outcome interrelations are discussed.

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## 1. Introduction

### 1.1. The problem

Major depressive disorder in youth is one of the most prevalent and debilitating psychiatric disorders for this age group (Costello et al., 2003), with prevalence rates ranging from 2.8% in children under 13 and 5.6% in adolescents (Costello et al., 2006) and total incidence rate ranging from 5% in children to 20% in adolescents, similar to the adult incidence rate (Rohde et al., 2013). Depression in youth is associated with an increased risk for other psychiatric disorders (e.g., Costello et al., 2003) and/or difficulties in social functioning and school performance (National Institute for Health and Clinical Excellence/NICE, 2005), with a higher risk of reoccurrence in adulthood

(Harrington et al., 1990). Although there are evidence-based treatments for depression in youth, both pharmacological and psychotherapeutic, at least between one third and one half of depressed youth still do not respond to treatment (Bridge et al., 2007; Weisz et al., 2006), and almost half of treated youths experience recurrence within 4 years (Curry et al., 2011).

### 1.2. The treatment of depression in youth; a brief analysis

Following the principles of evidence-based practice, several major randomized control trials (RCTs) have shown that both psychosocial treatments, particularly cognitive behavioral therapy (CBT), and pharmacological treatments (i.e., medication), particularly selective serotonin reuptake inhibitors (SSRI), are effective, both separately and in combination (e.g., Bridge et al., 2007; Emslie et al., 1997; Vitiello, 2009) for treating youth depression.

For instance, one large-scale RCT, the TADS study (Treatment for Adolescents With Depression Study Team, 2004), compared CBT, pharmacotherapy, and their combination in treating major

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depressive disorder in adolescents and found that combining fluoxetine with CBT appears superior to the other treatments alone (i.e., on the Clinician's Global Index; CGI) at the end of the acute treatment (TADS team, 2007) and it is more effective in preventing suicidality in the long term (TADS team, 2007). Another large-scale RCT, the TORDIA study (Emslie et al., 2010), compared switching medication, and the combination of medication plus CBT in treating SSRI-resistant adolescent depression (i.e., major depressive disorder and dysthymia). The results confirmed that the combination is more effective than medication alone in reducing depressive symptoms.

However, other reviews have found only medium results for CBT in treating youth depression (Weisz et al., 2006) and the combination of CBT and medication has also yielded mixed results (Dubicka et al., 2010), with some data showing that, at least for moderate to severe major depression in adolescents, it is not clear that combining CBT with medication adds significantly to treatment efficacy (see the ADAPT study; Goodyer et al., 2008).

Therefore, conducting more RCTs investigating pharmacotherapy, CBT, and their combination in treating youth depression is extremely important, as many clinical aspects (e.g., multi-level analyses of the outcomes) related to treatment response (e.g., efficacy/effectiveness) and its mechanisms of change still remain to be clarified. In this sense, investigating new CBT approaches would be a promising direction given the fact that current treatments still elicit only a moderate success rate, with between one third and one half of youths still not responding to treatment (Bridge et al., 2007; Weisz et al., 2006). For instance, REBT, rational emotive behavior therapy/REBT – a form of CBT – which assumes that core irrational beliefs generate distorted automatic thoughts that further generate dysfunctional consequences (e.g., dysfunctional feelings, maladaptive behaviors) – has been found (see David et al., 2008) effective in treating major depressive disorder in adult population when compared to pharmacotherapy (being included in the NICE Guidelines; see NICE, 2010), but no such results have yet been reported for a youth population.

Another important issue is related to reported outcomes. First, for instance, when a psychosocial intervention is used, investigators typically focus on psychological outcomes (e.g., subjective, cognitive, behavioral) and often ignore biological outcomes. When a pharmacotherapy intervention is used, typically the focus is on the clinical symptoms and biological outcomes (e.g., platelet serotonin reuptake, Axelson et al., 2005; dopamine, norepinephrine, platelet serotonin, Goodnick et al., 1995), and key psychological outcomes and mechanisms of change (e.g., cognitions) are ignored.

Second, most of the studies investigating cognitive factors have been conducted on adult population. Secondary analyses conducted within the TADS study have shown that, for example, clinical improvement is mediated by changes in perfectionism (Jacobs et al., 2009), but there are still very few studies employing measures of distorted thinking with adolescents receiving CBT.

Third, although research focusing on biological markers of depression (i.e., biological factors) has found evidence for the role of monoamines in the onset of depression, particularly serotonin (5-HT) and norepinephrine (NE), few RCTs including a psychotherapy arm have included biological parameters as outcomes or if they did, they were mainly related to adult rather than to adolescent depression. For instance, changes in serotonin uptake have been correlated to improvements in depressive symptoms following SSRI treatment (e.g., Axelson et al., 2005) and platelet serotonin is related to symptom severity in adult patients treated with citalopram (Fišar et al., 2008). Studies investigating SSRI treatment response correlates of depressive symptoms have found that platelet serotonin levels decrease after SSRI treatment (e.g., Goodnick et al., 1995; Maurer-Spurej et al., 2003), while the results

for plasmatic serotonin remain unclear, with some studies reporting a downward trend with fluoxetine treatment (e.g., Alvarez et al., 1999), while other studies report increases in serotonin levels following fluoxetine treatment (Blardi et al., 2002). With regard to norepinephrine, studies found that administering sertraline to healthy subjects leads to a decrease in plasma norepinephrine compared to placebo (Shores et al., 2001) and the trend appears to be downward for other antidepressants or electroconvulsive therapy (Owens, 1996).

### 1.3. Overview of the present study

Given that youth depression is a complex disorder, measuring multi-level outcomes in a RCT involving psychotherapy, pharmacotherapy, and their combination would bring relevant information about treatment effects.

Therefore, the current RCT aimed to: (1) examine the efficacy of group REBT/CBT, pharmacotherapy, and their combination for depression in youth; this is necessary due to the mixed nature of the previous results; (2) bring new innovations in the field by engaging in the same design: (a) a multi-level analysis of the outcomes (e.g., subjective, cognitive, and biological) and (b) a new and potentially more efficacious CBT strategy (i.e., rational emotive behavior therapy/REBT); this is fundamental because although the standard CBT strategies seem to work, they still miss a large segment of patients; and (3) investigate the generalizability and stability of the current results on a new population (i.e., Romanian); this is necessary as most of the previous studies were conducted on English-speaking populations.

In order to provide a more cost-effective intervention, we used a group format for this study, given the fact that group CBT has been shown to be effective in treating youth depression (David-Ferdon and Kaslow, 2008), yielding similar results to individual psychotherapy (Weisz et al., 2006).

## 2. Method

### 2.1. Protocol and design

We used a three-arm randomized control trial in order to test the efficacy of group REBT/CBT, pharmacotherapy, and their combination in treating youths with major depressive disorder. Prior to conducting the study, ethical approval was obtained from the involved institutions.

### 2.2. Participants

Adolescents ( $N=88$ ) were recruited starting 2007, through specialized youth mental health services, namely: (1) the Clinic of Child and Adolescent Psychiatry and the Psychological Counseling Center in Cluj-Napoca; (2) the Institute for the Advanced Studies of Psychotherapy and Applied Mental Health (Babes-Bolyai University, Cluj-Napoca); (3) the Romanian Association for Cognitive-Behavioral Therapies; (4) the private practice of team members; and (5) public service announcements. Prior to recruitment, all participants and their parents signed an informed consent, agreeing to participate in the trial. All participants were diagnosed with major depressive disorder, following the DSM-IV, by using Structured Clinical Interview for DSM-IV (KID-SCID, Hien et al., 1994). The participants were aged 11–17 ( $m=15.25$ ,  $S.D.=1.91$ ), 49 were females and 39 were males. Only adolescents with an IQ score of at least 80 were included in the current sample. Our exclusion criteria were: bipolar disorder, severe conduct disorder, substance use/abuse/dependence, pervasive developmental disorders, psychotic disorders, being actively suicidal or having homicidal ideation, concurrent treatment with psychotropic drug (stable stimulant for ADHD permitted) or psychotherapy outside study, two previous failed SSRI trials or a failed trial of CBT for depression, and intolerance to sertraline. A flow diagram of the progress through the phases of the trial is presented in Fig. 1. There were no significant differences among patients in the three groups concerning demographic and pretreatment variables, including comorbidities (see Table 1).

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