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Randomized trial of the efficacy of trial-based cognitive therapy for obsessive-compulsive disorder: preliminary findings

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ABSTRACT

Background/Objective: Obsessive-compulsive disorder (OCD) is the fourth most prevalent and disabling mental disorder. OCD is associated with anatomical and functional changes in the brain, in addition to dysfunctional cognitions. Selective serotonin reuptake inhibitors (SSRIs), cognitive-behavioral therapy (CBT), and exposure and response prevention (ERP) are the treatments of choice. Trial-based cognitive therapy (TBCT) is a recent and empirically validated psychotherapy with a focus on restructuring the dysfunctional negative core beliefs (CBs). The objective of this study was to evaluate the TBCT efficacy relative to ERP in the OCD treatment. Method: A randomized, single-blind clinical trial was conducted, randomizing 26 patients for individual treatment with TBCT (n = 12) or ERP (n = 14). The groups were evaluated at baseline, at the end of 3 months (12 sessions) and at 3-, 6- and 12-month follow-up. Results: Both approaches reduced the severity of symptoms with large effect sizes. These results were maintained in the 12-month follow-up assessment. Conclusion: TBCT may be a valid and promising treatment for this disorder.
Keywords: Obsessive-compulsive disorder; cognitive-behavioral therapy; trial-based cognitive therapy; exposure and response prevention; randomized clinical trial.

Introduction

Obsessive-compulsive disorder (OCD) is characterized by the occurrence of obsessions, which are intrusive, repetitive, undesirable, and inappropriate thoughts, as well as compulsions, characterized by behaviors that the individual performs in a ritualistic and repetitive way in response to obsessions.\(^1\) Approximately 60–70% of OCD patients experience sensory phenomena consisting of aversive or uncomfortable sensations or perceptions that drive repetitive behaviors (e.g., physical tension associated with anxiety).\(^2\) OCD is the fourth most frequent mental disorder, with equal proportions between males and females, and prevalence between 1 and 3% of the world population.\(^3\)–\(^6\) It is one of the most disabling conditions, and it is among the ten diseases with the most significant functional impairment,\(^7,8\) with half of those affected presenting suicidal thoughts.\(^1\) The disorder is associated with extensive disability that covers all aspects of functioning, increased healthcare use, and diminished quality of life.\(^9\)

The treatments of choice for OCD are the selective serotonin reuptake inhibiting drugs (SSRIs) combined with exposure and response prevention (ERP) or cognitive-behavioral therapy (CBT);\(^10,11\)
from a psychotherapeutic point of view, ERP is considered the gold standard treatment for the disorder.\textsuperscript{12-14}

ERP consists of directly exposing patients to stimuli that evoke obsessions and sensory phenomena and preventing them from executing compulsions.\textsuperscript{11} Although ERP is more effective than placebo and at least equal to the first choice SSRI drugs in the treatment of OCD,\textsuperscript{15,16} the proportion of OCD participants who respond to treatment is around 55%.\textsuperscript{17,18} The findings show that there is a low adherence to the treatment due to the high level of anxiety produced by exposure.\textsuperscript{11,14}

Cognitive therapy (CT) was proposed by Aaron Beck, in the early 1960s, as a structured psychotherapy model whose focus is the modification of dysfunctional thoughts and beliefs.\textsuperscript{19} Several models have emerged since its initial development, resulting in cognitive-behavioral therapies (CBTs), a label given to a diversity of psychotherapies that, despite philosophical differences, emphasize emotional, cognitive, and behavioral changes.\textsuperscript{20-22} Earlier studies that compared CT and ERP yielded comparable results.\textsuperscript{23-25}

Trial-based cognitive therapy (TBCT) is one of the most recent approaches in the CBT umbrella,\textsuperscript{26,27} inspired by Franz Kafka's novel, "The Trial." TBCT's main techniques are analogous to a legal trial, in which the patient plays the roles of the defendant, the defense attorney, the prosecutor, the juror, the witnesses, and the judge.\textsuperscript{28}
Although TBCT is a new CBT model, it has distinctive features such as a systematic set of step-by-step cognitive and behavioral techniques that integrate conventional CBT techniques; a new, organized, and systematic approach to modify dysfunctional core beliefs (CBs) that simulates a court trial; an easy-to-remember and straightforward case formulation model, easier for the patient to understand and for the therapist to use; and an integrative approach that allows cognitive, emotional and experiential work to be done simultaneously.\textsuperscript{29,30} This approach acts on the 3 levels of cognitions (automatic thoughts, underlying assumptions, and CBs) in 3 distinct phases, and in the final stages, it focuses on the development of metacognitive awareness, which is the ability to think critically about one's cognitive functioning.\textsuperscript{21,29}

TBCT is an empirically validated therapy, with evidence of efficacy in the treatment of social anxiety disorder (SAD),\textsuperscript{30-32} post-traumatic stress disorder (PTSD),\textsuperscript{33} major depressive disorder (MDD),\textsuperscript{21} and possibly other disorders.\textsuperscript{34} Moreover, it has been used as a preventive approach for adolescents in schools.\textsuperscript{35}

The trial-based thought record (TBTR), a central TBCT technique, resulted in a better outcome than the Greenberger and Padesky’s\textsuperscript{36} seven-column thought record used in combination with the positive data log in patients with SAD.\textsuperscript{37} In this study, instead of facilitating exposure to feared social situations, the purpose of both interventions
was to modify CBs associated with SAD. Significant reductions in symptoms of social anxiety as well as physiological manifestations of anxiety were observed in both approaches, but participants receiving TBTR reported significantly greater reductions in fear of negative evaluation and social avoidance and distress, as well as more improvements in quality of life.\textsuperscript{32}

The TBCT protocol\textsuperscript{27} was used to evaluate TBCT efficacy for generalized SAD compared to a waitlist condition in a sample with high rates of comorbid depression.\textsuperscript{30} Reductions in social anxiety, social avoidance, and depression, all associated with a large effect size, were observed in the TBCT arm, whereas, no differences between pre- and post-treatment scores were observed in the waitlist condition. Interestingly, results also showed that comorbidity significantly moderated treatment efficacy, patients with comorbid conditions showing greater reductions in social anxiety symptoms across treatment relative to those with SAD only.

The efficacy of TBCT was compared to prolonged exposure (PE) in patients with PTSD in a randomized clinical trial (RCT) including patients who met DSM-IV-TR criteria for PTSD.\textsuperscript{33} Patients were randomly assigned to receive either TBCT (n = 44) or PE (n = 51). A significant reduction in PTSD symptoms was observed in both TBCT and PE, but no significant difference between treatments was found. However, significant differences in depressive symptoms in favor of
TBCT were observed, and the dropout rate was lower in the TBCT group relative to the PE group, suggesting that TBCT may be an effective alternative for treating PTSD.

TBCT efficacy was also compared with the efficacy of behavioral activation (BA) and treatment as usual (TAU) in the treatment of MDD in a RCT. In this study, patients with MDD were randomized to 1 of 3 groups evaluated at baseline, after 6 weeks and at week 12 (final evaluation). Both TBCT and BA (which also included antidepressants) were significantly better in reducing depressive symptoms than TAU (which included antidepressants alone). TBCT and BA were also better than TAU in reducing disability and quality of life physical domain scores, according to WHOQoL. The dropout rate was higher in the TAU group than in the TBCT and BA groups.

We identified 6 studies that compared CBT with ERP. As TBCT is a different format of CBT that modifies how CBT techniques are used and emphasizes CB change, we thought that, like CBT, TBCT could be at least as effective as ERP and should be tested as an OCD treatment. So, bearing in mind (1) that ERP for OCD has a high refusal and dropout rate; (2) that the work in the area of obsessive-compulsive-relevant beliefs (e.g., inflated responsibility, thought-action-fusion, intolerance of uncertainty) suggests that a more beliefs-based intervention could be useful for individuals with OCD; and (3) that TBCT was characterized as a transdiagnostic approach, effective
in the treatment of SAD, MDD, and PTSD, we decided to compare the efficacy of TBCT relative to ERP in the treatment of OCD.

**Method**

**Design and participants**

Seventy-five patients were assessed for participation, but only 26 who received a diagnosis of OCD according to the DSM-IV criteria and a score $\geq 16$ on the Yale-Brown Obsessive-Compulsive Scale (Y-BOCS) were included. From these, only 22 completed the post-treatment (TBCT = 9 and ERP = 13). The study sample included 14 female (61.54%) and 8 male (38.46%) adults, aged between 18 and 60 years old [mean (SD) = 32.8 (11.3)]. All patients were using antidepressant medications for at least 3 months in a stable dose before inclusion in the study; they were requested to maintain the doses unchanged during the active treatment. The patients who were undergoing psychotherapy or had received previous treatment with TBCT or ERP, and patients with neurological or mental disorders (mental retardation, psychotic disorder, severe personality disorder or report of ongoing substance abuse disorders) that could compromise the understanding and completion of the scales were not included. All patients who completed the treatment were assessed for follow-up.

With regard to comorbidity, 9 (41%) of the patients had a comorbid Axis I disorder (DSM-IV criteria). Regarding the OCD
presentation, our sample was composed of “mixed” OCD subjects, namely, those having both obsessions and compulsions and score $\geq 16$ on the Y-BOCS severity scale according to criteria proposed by Shetti et al.$^{45}$

**Procedures**

Data collection was carried out (at baseline, post-treatment and follow-up) by trained and experienced interviewers who were blind to the intervention groups, and were available to answer questions and provide clarifications when necessary.

Patients were recruited through public health services, health professional offices and publicity. The volunteers who agreed to participate in this study read and signed the informed consent form, were evaluated for inclusion criteria, submitted to the collection of clinical and sociodemographic data, and randomized by the research coordinator to the ERP or TBCT groups. The interventions consisted of 12 individual psychotherapy sessions, with a weekly one-hour session, between the years 2014 and 2017 in Teresina, Brazil, at the Biotechnology Research Center, Science and Health Center of the State University of Piauí (UESPI). During the follow-up, both intervention groups were reevaluated at 3, 6, and 12 months after the end of the treatment. In the present study, only data from the 12-month follow-up are presented.
The study followed the principles of the Declaration of Helsinki, was approved by the Health Sciences Center of the State University of Piauí IRB (CCS/UESPI; Opinion 880996, CAAE 16179313.1.0000.5209), and was conducted in accordance with Resolution 466/2012 of the Brazilian National Health Council. This trial is registered on ClinicalTrials.gov (ID: NCT02656784).

**Instruments**

Patients were evaluated using scales and inventories to obtain socio-demographic and clinical data. The primary outcome measure was the Yale-Brown Obsessive-Compulsive Scale (Y-BOCS), and the secondary ones were Beck Depression Inventory (BDI) and Beck Anxiety Inventory (BAI). The evaluations took place at baseline, after sessions 6 and 12, and at 3-, 6-, and 12-month follow-up. The evaluators were blinded to the intervention group.

**Diagnostic Interview:** The Structured Clinical Interview for DSM-IV (SCID-I/P) was used for diagnosing Axis I (depression, anxiety) and Axis II (mental retardation and personality disorder) psychiatric disorders, validated for the Brazilian population.

**OCD severity:** The Brazilian Portuguese version of the clinician-rated Y-BOCS was used to assess OCD symptom severity. This scale was translated and validated for the Brazilian population (Cronbach’s alpha = 0.89). Y-BOCS is composed of items that assess
obsessions and compulsions, and provides a maximum score of 40 points. Scores from 8 to 15 are considered mild; 16 to 23, moderate; 24 to 31, severe; and 32 to 40, extreme. Scores ≥ 16 indicate clinical OCD. As we used the Y-BOCS to measure the severity of OCD symptoms, we decided to analyze the clinically significant change obtained with TBCT and ERP.

Secondary outcome measures: Depressive symptoms were assessed using the BDI, a self-administered scale with 21 items, with a maximum score of 63 points (Cronbach’s alpha = 0.80). Anxiety symptoms were assessed using the BAI, an instrument consisting of 21 items, with a maximum score of 63 points (Cronbach’s alpha = 0.88-0.92). Both inventories were translated and validated for the Brazilian population.

Therapists

Interventions were performed by 3 psychologists specialized in behavioral therapy for the ERP group, and 3 psychologists specialized in CBT for the TBCT group. All professionals had at least 6 years of clinical practice and were experienced in OCD treatment. The sessions were audio-recorded and evaluated by 2 supervisors, CM and ER, respectively for ERP and TBCT, to ensure fidelity to the protocol. ERP therapists were trained in Foa and Kozac’s model by CM, who was also in charge of their weekly supervision during the study. The TBCT
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therapists were initially trained in a 3-day workshop conducted by Professor de Oliveira, developer of TBCT, and received weekly supervision from the principal investigator (ER) during the study.

Treatments

Trial-Based Cognitive Therapy

The TBCT course is described over 12 sessions, according to its manual for clinicians. The protocol presented here is restricted to clinical trials. However, in day-to-day clinical care, this structure is flexible and can last much longer than 12 sessions. The TBCT formulation is organized in 3 levels and in 3 distinct phases, during which the therapist and patient engage in the discovery, assessment and restructuring of dysfunctional cognitions.

The first phase corresponds to the beginning of the treatment and involves the presentation of the cognitive model through the TBCT conceptualization diagram and includes the initial sessions. The second phase occurs from session 5 to session 9, and includes the Trial I technique, in which the patient plays the role of the different characters of a court room, and uses the preparation for the appeal homework assignment for the patient to be more prepared for new trials to restructure even more dysfunctional CBs, like “I’m vulnerable, weak, defective, irresponsible, mean, different,” and so on. The last phase occurs from session 10 to session 12, which aims to engage the patient
in a metacognitive awareness consolidation process, observing the
nature of thoughts, and realizing that there is no need to behave
according to them, once they are dysfunctional. This is the TBCT
relapse prevention phase.

**Exposure and Response Prevention**

The ERP treatment used was based on the protocol of Foa and
Kozak, adapted for 12 sessions. The behavioral model of OCD
indicates that a stimulus elicits obsessive responses, emotional
responses of fear and anxiety (acquired by respondent conditioning),
evoking operative responses (compulsions) to remove or reduce
anxiety and obsessions and resulting in negative reinforcement of
compulsive responses. The mechanism of clinical change in ERP is the
habituation to emotional responses and the extinction of
escape/avoidance behavior.

The ERP protocol consists of, in the first sessions, explaining
the behavioral model of OCD. A hierarchy of feared situations of lesser
to higher intensity is established, starting in the second session and
assessed with the SUDS. The patient is instructed not to perform
compulsions during the exposure, even if he or she feels compelled to
perform them. Then, *in-vivo* exposure is applied, which consists of up
to one hour of coping with the dreaded stimuli without the compulsions.
Exposures to stimuli with low subjective discomfort that were started
during the sessions are then assigned to be implemented as homework. From session 6 on, the patient is encouraged to be exposed to stimuli with SUDS scores between 6 and 7 ranging in a scale from 0 to 10. From session 9 to session 12, the patient is invited to be exposed to stimuli with scores higher than 7.\textsuperscript{56,57}

**Statistical analyses**

The software used for statistical analyses and data storage was the Statistical Package for Social Sciences - SPSS, version 22.0 (SPSS Inc., Chicago, USA). Descriptive statistical analyses were performed with data on prevalence, percentages, means, and standard deviations. In the descriptive analyses, the chi-square test ($X^2$) or Fisher’s exact test were used for the dichotomous variables, and mean differences between groups at baseline were assessed with Student’s t-test and ANOVA.

Missing data were analyzed by intention-to-treat (ITT), which included all patients randomized in the study, regardless of the moment of abandonment\textsuperscript{58} and with multiple imputation (MI),\textsuperscript{59} which imputed 5 databases including age, sex and intervention group, and assuming the random loss mechanism (MAR). In order to compare the efficacy measures between TBCT and ERP groups and over time (initial and final evaluations), generalized estimating equations (GEE) were conducted, with a first-order autoregressive work matrix. Analysis of
the time x group interaction was also performed. The level of statistical significance that was assumed was 0.05.

Cohen’s $d$ effect sizes (ESs) between the groups were calculated, with values of .20, .50, and .80 being considered, respectively, small, medium, and large. All the outcome measures entered in the between-group analysis were computed. A positive $d$ was in favor of ERP and a negative one in favor of TBCT. Although small, a $d > 0.25$ was considered as having a possible clinical significance.

Results

Participants

After screening 75 subjects, a sample of 26 patients was randomized (TBCT = 12; ERP = 14). Four patients dropped out after randomization (TBCT = 3; ERP = 1), with 22 subjects having completed all the psychotherapy sessions (TBCT = 9; ERP = 13).

In this study, 61.54% were women ($n = 16$), no difference being observed regarding gender ($p = .75$), nor for baseline clinical data between groups: Y-BOCS: [F (1.24) = .500, $p = .48$]; BAI: [F (1.24) = .001, $p = .98$]; BDI: [F (1.24) = .766, $p = .39$]. The mean age of the sample was 32.8 (SD = 11.3) years [TBCT = 32.4 (SD = 13.9) and ERP = 33.0 (SD = 11.1)]. Figure 1 shows the study design flowchart.
**Figure 1** – Illustrative Flow Diagram (CONSORT)

TBCT: Trial-based cognitive therapy; ERP: Exposure and response prevention. CONSORT: Consolidated Standards of Reporting Trials.\(^{61}\)
Main results

Differences within and between groups in primary measures

Table 1 shows the baseline and final Y-BOCS (total, obsessions, and compulsions), BDI, and BAI patients' scores, with ITT and MI.

<table>
<thead>
<tr>
<th>Measures</th>
<th>Baseline M (SD)</th>
<th>Post-treatment M (SD)</th>
<th>( p^* ) between-groups</th>
<th>( p^{**} ) within-groups</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Y-BOCS (total)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TBCT</td>
<td>24.92 (6.94)</td>
<td>13.19 (9.36)</td>
<td>.45</td>
<td>.0005</td>
</tr>
<tr>
<td>ERP</td>
<td>26.79 (6.03)</td>
<td>15.24 (5.68)</td>
<td>-</td>
<td>.001</td>
</tr>
<tr>
<td><strong>Y-BOCS (obs)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TBCT</td>
<td>12.83 (4.16)</td>
<td>6.64 (4.89)</td>
<td>.25</td>
<td>.0005</td>
</tr>
<tr>
<td>ERP</td>
<td>14.00 (2.84)</td>
<td>8.69 (3.08)</td>
<td>-</td>
<td>.0005</td>
</tr>
<tr>
<td><strong>Y-BOCS (comp)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TBCT</td>
<td>12.08 (3.59)</td>
<td>6.53 (4.74)</td>
<td>.80</td>
<td>.002</td>
</tr>
<tr>
<td>ERP</td>
<td>12.79 (3.63)</td>
<td>6.52 (3.08)</td>
<td>-</td>
<td>.0005</td>
</tr>
<tr>
<td><strong>BDI</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TBCT</td>
<td>25.17 (13.38)</td>
<td>8.89 (10.08)</td>
<td>.66</td>
<td>.0005</td>
</tr>
<tr>
<td>ERP</td>
<td>20.79 (11.30)</td>
<td>10.42 (9.07)</td>
<td>-</td>
<td>.0005</td>
</tr>
<tr>
<td><strong>BAI</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TBCT</td>
<td>29.42 (13.02)</td>
<td>9.63 (10.78)</td>
<td>.44</td>
<td>.0005</td>
</tr>
<tr>
<td>ERP</td>
<td>29.57 (12.90)</td>
<td>15.14 (9.61)</td>
<td>-</td>
<td>.0005</td>
</tr>
</tbody>
</table>

BAI: Beck Anxiety Inventory; BDI: Beck Depression Inventory; ERP: Exposure and response prevention; ITT: Intention-to-treat; M: Mean; MI: Multiple imputation; GEE: Generalized estimation equations; SD: Standard deviation; TBCT: Trial-based cognitive therapy; Y-BOCS: Yale-Brown Scale for Assessment of Obsessive-Compulsive Symptoms (obsessions, compulsions and total).

*\( p \)-value for group difference (ERP taken as reference).

**\( p \)-value for pre- to post-treatment difference.

Y-BOCS (total)

Regarding the total Y-BOCS score, there was a statistically significant reduction over time in the TBCT and ERP groups (\( \beta = -\))
There were no statistical differences in the reduction of scores when comparing TBCT and ERP ($\beta = -1.194, p = .45$). A complete case analysis did not show any statistical differences between groups ($p > .50$).

With respect to within-group analyses, there was a significant effect in the TBCT ($\beta = -11.737, p < .0005$) and in the ERP ($\beta = -11.628, p < .001$) groups. In other words, there were significant decreases in the Y-BOCS scores within both TBCT and ERP from pre- to post-treatment.

In terms of the interaction, results showed that there was no effect of time $\times$ group in the Y-BOCS total scores ($\beta = -.109, p = .97$), indicating that the reduction of symptoms over time (from pre- to post-treatment) was not different between the treatment groups.

**Y-BOCS (obsessions)**

There was a statistically significant reduction over time in the Y-BOCS scores (obsessions) in both intervention groups in the analysis of complete cases ($\beta = -5.890, p < .001$). Likewise, the analysis with MI showed significant reductions of these scores in both psychotherapies over time ($\beta = -5.739, p < .001$).

In the parameter estimates comparisons, there was a lack of evidence of difference between TBCT and ERP concerning Y-BOCS-obsessions: ($\beta = -1.572, p = .25$). The result of the within-group
analyses showed a significant effect in TBCT [Y-BOCS (obsessions; $\beta = -6.284, p < .0005)] and in ERP [Y-BOCS (obsessions; $\beta = -5.272, p < .0005)]. In terms of the interaction, results showed that there was no effect of time $\times$ group ($\beta = -.811, p = .65$).

**Y-BOCS (compulsions)**

Concerning compulsions, there was a statistically significant reduction over time: ($\beta = -5.967, p < .0005$), the same occurring with the complete case analysis ($\beta = -6.258, p < .0005$). There were no statistical differences in the reduction of scores between TBCT and ERP in MI: ($\beta = -.330, p = .80$). Regarding the results of within-group analyses, a significant effect in both TBCT [Y-BOCS (compulsions; $\beta = -5.556, p = .002$)], and ERP [Y-BOCS (compulsions; $\beta = -6.302, p < .0005$)] was observed, indicating that there were significant decreases in Y-BOCS (compulsions) scores in both TBCT and ERP from pre- to post-treatment. In terms of the interaction, results showed that there was no effect of time $\times$ group ($\beta = .726, p = .69$).

**Clinically significant changes**

We replicated the analysis conducted by Belloch et al., who used the criteria proposed by Jacobson and Truax. Patient improvement and recovery at post-treatment and at follow-up were calculated according to the following criteria: Improvement = YBOCS $\leq 12$, plus
YBOCS pre- *versus* post-treatment decrease of at least 6 points; Recovery = YBOCS ≤ 7 plus YBOCS pre- *versus* post-treatment decrease of at least 6 points.

In the post-treatment, 55.6% (5 out of 9) patients met the improvement criteria in the TBCT arm, relative to 23.1% (3 out of 13) in the ERP group (Fisher’s exact test: *p* = .18). Regarding recovery, 33.3% (3 out 9) patients met criteria for recovery in the TBCT arm compared to 7.7% (1 out of 13) patients in the ERP group (Fisher’s exact test: *p* = .26).

Also replicating Belloch et al.’s study, and considering that the 3-, 6- and 12-month follow-up results were similar, we report here the latter. In the 12-month follow-up, 66.7% (6 out of 9) patients met the improvement criteria in the TBCT arm, relative to 23.1% (3 out of 13) in the ERP group (Fisher’s exact test: *p* = 0.07). On the other hand, 55.6% (5 out 9) completers met criteria for recovery in the TBCT arm compared to only 7.7% (1 out of 13) in the ERP group (Fisher’s exact test: *p* = .02).

**Differences within and between groups in secondary measures**

In both TBCT and ERP, there was a significant reduction in the BDI scores over time (β = -13.148, *p* <.001), but no evidence that the treatments were different from each other in reducing depressive symptoms [BDI (β = 1.540, *p* = .66)]. Within-group analysis showed
a decrease of BDI scores from pre- to post-treatments in TBCT [BDI ($\beta = -13.095, p = .001$)] and in ERP [BDI ($\beta = -13.192, p < .001$)]. In terms of the interaction, results showed that there was no effect of time $\times$ group ($\beta = -5.682, p = .36$).

There was a reduction in the anxiety scores measured by BAI over time in both treatments [$\beta = -16.943, p < .001$]. There was no evidence of statistical difference between TBCT and ERP [BAI ($\beta = -2.743, p = .44$)]. Within-group analysis showed a decrease of BAI scores from pre- to post-treatments in TBCT [BAI ($\beta = -18.135, p < .001$)] and for ERP [BAI ($\beta = -15.921, p < .001$)]. In terms of the interaction, results showed that there was no effect of time $\times$ group ($\beta = -5.177, p = .45$).

**Effect sizes**

Table 2 shows intra- and between-group effect sizes (Cohen’s $d$). All variables presented large or very large intra-group ESs, with a $d > 0.80$, both at post-treatment and 12-month follow-up. Between-group ESs were clinically significant favoring TBCT on BDI and BAI ($d > -.50$ at post-treatment, and on all measures at 12-month follow-up ($d$ range $-.33$ to $-.58$).
Table 2: Intra- and between-groups effect sizes at post-treatment and 12-month follow-up.

<table>
<thead>
<tr>
<th>Measures</th>
<th>Baseline M (SD)</th>
<th>Post-treatment M (SD)</th>
<th>12-month follow-up M (SD)</th>
<th>d intra-groups</th>
<th>d between-groups</th>
<th>d intra-groups</th>
<th>d between-groups</th>
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</thead>
<tbody>
<tr>
<td>Y-BOCS (total)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>TBCT</td>
<td>24.92 (6.94)</td>
<td>13.19 (9.36)</td>
<td>12.01 (2.65)</td>
<td>1.42</td>
<td>-.02</td>
<td>2.46</td>
<td>-.33</td>
</tr>
<tr>
<td>ERP</td>
<td>26.79 (6.03)</td>
<td>15.24 (5.68)</td>
<td>16.14 (2.27)</td>
<td>1.97</td>
<td>—</td>
<td>2.35</td>
<td>—</td>
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<tr>
<td>Y-BOCS (obs)</td>
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<tr>
<td>TBCT</td>
<td>12.83 (4.16)</td>
<td>6.64 (4.89)</td>
<td>5.81 (1.47)</td>
<td>1.36</td>
<td>-.24</td>
<td>1.94</td>
<td>-.46</td>
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<tr>
<td>ERP</td>
<td>14.00 (2.84)</td>
<td>8.69 (3.08)</td>
<td>8.66 (1.29)</td>
<td>1.78</td>
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<td>1.48</td>
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<tr>
<td>Y-BOCS (comp)</td>
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<tr>
<td>TBCT</td>
<td>12.08 (3.59)</td>
<td>6.53 (4.74)</td>
<td>6.23 (1.31)</td>
<td>1.31</td>
<td>.19</td>
<td>2.16</td>
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<td>ERP</td>
<td>12.79 (3.63)</td>
<td>6.52 (3.08)</td>
<td>7.59 (1.12)</td>
<td>1.86</td>
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<td>1.97</td>
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<td>TBCT</td>
<td>25.17 (13.38)</td>
<td>8.89 (10.08)</td>
<td>8.41 (2.75)</td>
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<td>ERP</td>
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<td>10.42 (9.07)</td>
<td>11.30 (2.23)</td>
<td>1.01</td>
<td>—</td>
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<tr>
<td>TBCT</td>
<td>29.42 (13.02)</td>
<td>9.63 (10.78)</td>
<td>9.21 (3.08)</td>
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<td>-.40</td>
<td>2.46</td>
<td>-.48</td>
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<tr>
<td>ERP</td>
<td>29.57 (12.90)</td>
<td>15.14 (9.61)</td>
<td>15.88 (2.52)</td>
<td>1.26</td>
<td>—</td>
<td>1.48</td>
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</table>

BAI: Beck Anxiety Inventory; BDI: Beck Depression Inventory; ERP: Exposure and response prevention; M: Mean; SD: Standard deviation; TBCT: Trial-based cognitive therapy; Y-BOCS: Yale-Brown Scale for Assessment of Obsessive-Compulsive Symptoms (obsessions, compulsions and total).

1 Cohen’s d intragroup at post-treatment (Scores at baseline taken as reference).
2 Cohen’s d between-group at post-treatment (ERP taken as reference).
3 Cohen’s d intragroup at 12-month follow-up (Scores at baseline taken as reference).
4 Cohen’s d between-group at 12-month follow-up (ERP taken as reference).

Discussion

The results of this study indicate that both ERP and TBCT were able to reduce baseline symptom scores measured by Y-BOCS. Although both interventions helped to reduce the OCD symptoms, there was a lack of evidence of statistical difference between groups. Regarding the follow-up, both TBCT and ERP maintained the therapeutic gains for twelve months.
In the present study, TBCT decreased pre-post-treatment symptoms by 47.1%, and ERP by 43.1%; TBCT also decreased pre-follow-up symptoms by 52.6%, and ERP by 44.0%. Thus, both TBCT and ERP Y-BOCS mean scores were in the ranges observed in previous studies regarding changes from baseline.\textsuperscript{24,40,41}

Whittal et al’s study\textsuperscript{40} compared CBT with ERP delivered in individual format, and showed that there was no significant difference in Y-BOCS scores between the interventions at post-treatment and 3-month follow-up. Our results were similar but we were able to show a longer sustained gain during the 12-month follow-up in both TBCT and ERP. The authors suggested that CBT was as effective as ERP, when delivered individually, and that CBT might be considered the treatment of choice in cases where ERP is difficult to apply, as it is the case with primary obsessions. As the results in our study suggest, TBCT is at least as effective as ERP, and is especially focused on restructuring CBs. Thus, a larger RCT being conducted to test TBCT use in OCD patients compared to ERP and conventional CBT should be encouraged.

A 16-week duration study\textsuperscript{24} compared CBT with intensive ERP in OCD patients. The response rate was similar in the 2 groups. However, BDI scores were significantly more improved by CBT at post-treatment. The authors concluded that CBT and ERP were equally effective on OCD, but at post-test CBT had specific effects on depression that were stronger than those in the ERP group. In the present study, it was not
possible to demonstrate any difference between TBCT and ERP regarding depressive symptoms, probably due to the small sample size. However, in the PTSD study comparing TBCT and prolonged exposure,\textsuperscript{33} despite not showing any significant difference between groups concerning PTSD symptoms, significant differences in depressive symptoms in favor of TBCT were observed, as well as in the dropout rate that was lower in the TBCT group. Considering that TBCT has been shown to be effective in MDD,\textsuperscript{21} this intervention might be considered in OCD patients with comorbid depression. TBCT is a transdiagnostic approach that has been also shown to be effective in SAD\textsuperscript{27} with comorbid depression and PTSD.\textsuperscript{33} Thus, it might be promising in OCD patients with such comorbid conditions.

Akin to what was found in Belloch et al’s study\textsuperscript{52} regarding mean total Y-BOCS pre-treatment scores, patients in our study fell into the range of severe OCD (TBCT = 27.8 and ERP = 27.7 in this study; CBT = 26.40 and ERP = 24.69 in Belloch et al’s study). Both their study and ours had small sample sizes and a 12-month follow-up of the patients. Our results were comparable, suggesting that both TBCT and ERP were at least equally effective for the treatment of severe OCD symptoms. However, using the same calculations that Belloch et al\textsuperscript{52} used for improvement and recovery, our data showed that there were significantly more recovered patients in the TBCT treatment group at 12-month follow-up.
CBT focuses on identifying and restructuring distorted thoughts and dysfunctional CBs. Thus, acting on obsessions and reducing their frequency and intensity is a possible underlying mechanism of improvement. Unfortunately, we did not measure the CBs. However, three TBCT studies\textsuperscript{26,34,37} demonstrated that after a single session using the trial-based thought record (TBTR), a central TBCT technique, there was a reduction in the degree to which clients were attached to dysfunctional negative CBs and in associated negative emotions. Also, a study\textsuperscript{34} indicated that the inclusion of the empty-chair technique during the TBTR use might boost efficacy over the conventional static TBTR in reducing attachment to CBs and the intensity of the accompanying emotions, possibly because of the empty chair’s more experiential feature.

On the other hand, ERP does not act directly in modifying the cognitive contents of obsessions but proposes to confront them, preventing the performance of rituals.\textsuperscript{17,23,62} So, when the patient is exposed to stimuli that produce obsessions and anxious responses, resisting them, habituation occurs. Also, since the patient is not allowed to perform the compulsions, the feared consequences do not occur, leading to the extinction of the escape/avoidance response (i.e., the rituals).\textsuperscript{63} In the present study, it is suggested that both the changes in the content of thoughts and beliefs by TBCT, without direct
exposure, and the change in the way of relating to cognitions by not performing compulsions, reduced OCD symptoms.

Finally, we consider that both automatic thoughts and CBs are related to the meaning (interpretation) to be restructured in OCD. Although the main TBCT techniques target CBs, like “I’m vulnerable, weak, defective, irresponsible, mean,” and so on, the underlying assumptions are also targeted with behavioral experiments, optimized with two other TBCT techniques, namely: 1) the color-coded symptom hierarchy (CCSH), which tends to make behavioral experiments more palatable; and 2) the consensual role-play (CRP), which also incorporates the experiential empty chair approach, making defying the rituals less challenging. The goal of both CCSH and CRP is to change the underlying assumptions (e.g., “If I forget to turn off the stove, then a catastrophe will ensue”) that maintain the OCD coping strategies (rituals), but this is done primarily by helping patients change behaviors.

This study carries a significant limitation, which is the small sample size. Considering that the required sample size was 32 patients per arm, unfortunately our study included fewer patients than the expected number. Small-sample studies may produce false-positive results or overestimate the magnitude of an association.\(^{64}\) Although it is not a problem that could invalidate the study, the reduced sample requires more caution in its interpretation. Four other possible
limitations were 1) not having measured sensory phenomena, considering their high frequency in OCD patients; 2) although participants were asked to keep their medications stable, this was not monitored; 3) lack of evaluation of satisfaction of the interventions; and 4) the absence of a detailed and quantitative method to measure fidelity to the protocols. However, to minimize the latter problem, the sessions recordings were heard by the supervisors and discussed with the therapists in the weekly supervision meetings.

As for strengths, this study used MI, a modern approach to deal with missing data. Besides, it was possible to collect follow-up data, which allowed the observation of the maintenance of gains over 12 months. Further clinical research should be conducted with TBCT and ERP, with larger samples, so that a possible difference (or not) between TBCT over ERP can be more accurately measured, as suggested by the results observed in this study.

**Conclusion**

In conclusion, TBCT was not different from ERP in reducing obsessive-compulsive symptoms in OCD patients. Both TBCT and ERP were able to maintain the therapeutic gains in the 12-month follow-up. However, TBCT yielded significantly more recovered patients.

This preliminary study suggests that further studies are needed to investigate the long-term effects of TBCT for OCD.
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