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Trial-based cognitive therapy: efficacy of a new CBT approach for treating social anxiety disorder with comorbid depression

Trial-Based Cognitive Therapy: Efficacy of a New CBT Approach for Treating Social Anxiety Disorder with Comorbid Depression.

Kátia A. S. Caetano[1,2*], Barbara Depreeuw[2,3]; Inka Papenfuss[3]; Joshua Curtiss[2]; Robbert J. Langwerden[2]; Stefan G. Hofmann[2]; & Carmem B. Neufeld[1].

[1] Department of Psychology, Faculty of Philosophy, Sciences and Languages of Ribeirão Preto, University of São Paulo, Ribeirão Preto, SP, Brazil.

[2] Department of Psychological and Brain Sciences, Boston University, Boston, MA, USA

[3] Center for the Psychology of Learning and Experimental Psychopathology, University of Leuven, Leuven, Belgium.

[4] Department of Psychology, University of Groningen, Groningen, the Netherlands.

[*] Corresponding author. Contact: kascaetano@gmail.com

Abstract

This study aims to evaluate the efficacy of Trial-Based Cognitive Therapy (TBCT), a new cognitive behavioral therapy approach, for generalized SAD (GSAD) in a population with high rates of comorbidity, especially depression. This two-arm randomized clinical trial included 39 adults (TBCT = 18; Waitlist group = 21) diagnosed with GSAD. The TBCT group received 16 weekly individual sessions. The participants were evaluated at pre- and post-test. There were reductions in social anxiety, social avoidance, and depression in the TBCT group, all associated with a large effect size. There were no differences between pre- and post-test scores in the waitlist group. Results also showed that comorbidity significantly moderated treatment efficacy. Treated patients with comorbid conditions showed greater reductions in social anxiety symptoms than those with SAD only. TBCT was effective in

reducing social anxiety and depression symptoms, and it seems to be particularly efficacious for patients with comorbidity.

Keywords**:** Trial-Based Cognitive Therapy; Social Anxiety Disorder; Depression; Comorbidity; Randomized Clinical Trial.

Social anxiety disorder (SAD) is characterized by intense fear of social situations in which individuals could be judged by other people. A central feature of SAD is fear of negative evaluation, which contributes to the avoidance of social situations (American Psychiatric Association, 2013). The condition carries a high disease burden and is one of the most common psychiatric disorders (Martin, 2003; Kessler et al., 2005). Despite the different prevalence rates found in the literature, most likely related to distinct assessment methods used across studies, SAD has a high lifetime prevalence. Its prevalence varies from 6.65% in European countries (Fehm, Pelissolo, Furmark, & Wittchen, 2005) to 12.1% in the United States (Kessler et al., 2005). A similar lifetime prevalence is observed in Brazilian community samples with a prevalence rate higher than 11% (Baptista, et al., 2012; Vorcaro, Rocha, Uchoa, & Lima-Costa, 2004). SAD is a chronic and impairing condition (Fehm at al., 2005; Martin, 2003), and is associated with a significantly reduced quality of life (e.g., Wittchen & Beloch, 1996; Wong, Sarver, & Beidel, 2012). Not only does SAD interfere with social functioning (e.g., Wittchen & Beloch, 1996; Ghaedi, Tavoli, Bakhtiari, Melyani, & Sahragard, 2010) but also with occupational (e.g., Wittchen & Beloch, 1996) and academic performance (e.g., Baptista et al., 2012, Stein & Kean, 2000).

Comorbid disorders are the rule rather than the exception for SAD, with major depressive disorder being frequently associated with social anxiety disorder (Klemanski, Curtiss, McLaughlin, & Nolen-Hoeksema, in press; Ohayon & Schatzberg, 2010). SAD is a significant risk factor for the subsequent occurrence of depressive symptoms, with anxiety

onset typically preceding that of depression (Kessler, Stang, Wittchen, Stein, & Walters, 1999). Furthermore, the combination of the two disorders has been associated with more severe suffering and impairment (Dalrymple & Zimmerman, 2007), making it to be difficult to treat (Belzer & Schneier, 2004). Notably, research has shown that avoidance mediates the relationship between social anxiety and depressive symptoms, suggesting that depression may be more likely due to behavioral avoidance, a key symptom of SAD (Moitra, Herbert, & Forman, 2008).

Although pharmacotherapy is effective for SAD (Curtiss, Andrews, Davis, Smits, & Hofmann, 2017), cognitive behavioral therapy (CBT) is considered the gold standard treatment. Many protocols have been developed to successfully treat this condition (Hofmann & Otto, 2008). Several randomized clinical trials corroborate the efficacy of CBT for SAD (Barkowski et al., 2016; Hofmann et al., 2013; Hofmann & Smits, 2008; Ponniah & Hollon, 2006; Otte, 2011), with a mean effect size of .70 (Acaturk, Cuijpers, Van Straten, & De Graaf, 2009). Even though the findings show that exposure interventions and cognitive techniques significantly reduce social phobia symptoms (Barkowski et al., 2016; Federoff & Taylor, 2001; Feske & Chambless, 1995; Gould, 1997; Otte, 2011; Taylor, 1996), the emphasis on changing cognitions has been shown to be more effective in SAD treatment in individual format (Mörtberg, Clark, Sundin, & Wistedt, 2007; Stangier, Heidenreich, Peitz, Lauterbach, & Clark, 2003). Some findings suggest that individual cognitive therapy is more effective than exposure (Clark et al., 2006; Mayo-Wilson et al., 2014; Ougrin, 2011) and some forms of group CBT (Mörtberg et al., 2007), which highlight the importance of targeting cognitions in SAD treatment. Indeed, current literature has suggested that cognitive factors function as maintenance factors in SAD (Hofmann, 2007).

Despite the well-established efficacy of CBT as a gold treatment for SAD, a significant proportion of patients do not improve after treatment. Many patients remain

symptomatic after undergoing CBT (Hofmann, 2007), with 40% of patients requesting additional treatment within a year after having received CBT (Gilian et al., 1984), and just 48% of the patients being classified as responders after the treatment (Heimberg et al., 1998). Research shows that CBT for comorbid SAD and depression reduces anxiety symptoms, yet depression symptoms remain elevated (Joormann, Kosfelder, & Schulte, 2005). Also, patients with comorbid diagnoses of SAD and depression drop out more frequently than patients with depression alone (Brown et al., 1996). These findings underscore the importance of improving the current treatments in the field.

Trial-Based Cognitive Therapy (TBCT) is a CBT intervention that was recently developed in Brazil at the beginning of the 2000s. TBCT has its foundation in the cognitive-behavioral approach. Like CBT, TBCT contains psycho-education, cognitive restructuring, and exposure along with homework assignments. However, this variation of the CBT approach has its own specific cognitive conceptualization, techniques, and instruments, making it a unique intervention (de Oliveira, 2015a; de Oliveira et al., 2015b; Morrison et al., 2015).

The Trial is the main TBCT technique and is designed to challenge and restructure dysfunctional core beliefs (CBs) using a metaphor with the law in an experiential way. It is a structured seven-step approach in which the therapist uses a seven-column worksheet to guide the patient through a role-play of a court trial. Inspiration for this technique was found in *The Trial*, a novel wrote by Franz Kafka (Kafka, 1998). In this novel, the main character, Joseph K., is arrested, convicted, and executed of a crime of which he had no knowledge. Making a parallel with the CBT perspective, de Oliveira (2011) proposes that the self-accusations correspond to core beliefs (CBs) about the self, and, similar to Joseph K., most patients are not aware of these. They commonly react and accept CBs as the truth about themselves. Through the Trial, an inquiry is established where the patients become aware of

their self-accusations (CBs) and, different from Joseph K., have a chance to construct a proper defense (de Oliveira, 2011). The Trial incorporates different cognitive behavioral techniques, such as examining the evidence and the downward arrow technique, in a unique way. An experiential approach is employed using the empty-chair technique (De Oliveira et al., 2012), which is widely used in Gestalt therapy (Perls, 1973).

Preliminary studies support this approach. In 30 patients with different diagnoses, this treatment effectively decreased the attachment to the dysfunctional CBs, as well as the emotional intensity, during a session (De Oliveira, 2008). In a replication of this study, De Oliveira et al. (2012) evaluated the effect of the intervention in 166 patients with different diagnoses as well as different comorbidities. Results from this study showed a significant reduction in the attachment to dysfunctional CBs and in the emotional intensity. When comparing therapists with different levels of experience, there were no differences in treatment outcome, indicating that the treatment may be a helpful tool even for clinicians that are relatively unfamiliar with it. Another study showed that TBCT was effective for 39 patients with different diagnoses, substantiating TBCT as a putative transdiagnostic intervention (Delavechia et al., 2016).

In the context of treating SAD, a randomized clinical trial compared TBCT techniques and conventional CBT techniques in treating generalized SAD (GSAD). In this study, 36 GSAD participants were randomly assigned to be treated with either the TBCT technique or traditional cognitive techniques in 12 individual sessions. Both treatments followed the same protocol in the first five sessions, differing, however, from sessions 6 through 12. The results showed that TBCT is at least as efficacious as conventional CBT techniques in reducing social anxiety symptoms and improving quality of life, and more efficacious than CBT in reducing fear of negative evaluation, social avoidance, and distress (De Oliveira et al., 2012b; Powell et al., 2013).

The specific focus of TBCT on promoting in cognitive changes may make this a promising new approach to the treatment of SAD, since the literature shows that treatments focusing on cognitive change are effective in treating this condition (Clark et al., 2006; Mörtberg, Clark, Sundin, & Wistedt, 2007; Ougrin, 2011). In addition, the literature has shown that this new CBT technique is effective not only for SAD, but for different psychiatric conditions as well (De Oliveira, 2008; De Oliveira et al., 2012a; De Oliveira et al., 2012b; Delavechia et al., 2016; Powell et al., 2013). However, further investigation is needed to better demonstrate the efficacy of TBCT as a treatment for SAD and other disorders.

The aim of this study is to evaluate the efficacy of TBCT for generalized Social Anxiety Disorder in a population with high rates of comorbidity, especially depression. As the CBT literature shows that cognitive change is a potent factor for SAD treatment, we hypothesize that participants who received TBCT will experience reduced social anxiety symptoms compared to participants randomized to a control condition, as this new CBT approach uses different techniques to promote cognitive restructuring. In addition, we hypothesize that patients treated with TBCT will have reduced comorbid depressive symptoms, which would be consistent with prior literature supporting TBCT as a transdiagnostic intervention. As the literature shows that the presence of comorbidity, especially depression, affects the treatment outcome for SAD, this study also aims to examine comorbidity as a hypothesized treatment moderator on symptom change. As far as we know, there have been no studies evaluating the application of the entire TBCT protocol treatment for individuals diagnosed with SAD and other conditions. Thus, this is the first randomized clinical trial comparing the effect of a TBCT intervention to a waitlist condition for SAD.

Method

Design

This is a two-arm randomized clinical trial comparing TBCT and a waitlist control condition (delayed intervention) for treatment of generalized SAD. An independent researcher not participating in the study provided the randomization schedule of the participants between the two conditions. The treatment was delivered in sixteen 1.5 hour sessions using the individual format during a total span of four to five months. The treatment was administered by the main researcher of this study, and followed the therapist manual for TBCT (De Oliveira, 2015) and a specifically tailored treatment for SAD (De Oliveira et al., 2012b; Powell et al., 2013). The therapist is a clinical psychologist with five years of experience who attended four TBCT trainings administered by Prof. Dr. Irismar Reis de Oliveira, the TBCT founder. The recruitment, selection, and treatment occurred at Ribeirão Preto, a southeast city in Brazil. The Institutional Review Board at the Faculty of Philosophy, Sciences and Letters at Ribeirão Preto, University of São Paulo, Brazil, approved the study (23789213.2.0000.5407). The Brazilian Clinical Trials Registry approved the study (RBR-98qjbw) as well.

Participants

Participants were recruited from the community via advertisements that were posted in public health center areas, interviews on local radio and television about the research, and the marketing channels of the University of São Paulo. Participants were enrolled in the study between August 20, 2014, and December 18, 2015. Participants interested in enrolling the study contacted LaPICC-USP (Cognitive Behavioral Research and Laboratory – University of São Paulo) through e-mail or telephone. Those who were between 18 to 45 years old were invited for a diagnostic interview with clinical psychologists from LaPICC-USP. Those researchers are CBT psychologists who have a minimum of five years of experience in using structured clinical interviews and diagnostic assessments. They underwent CBT training for one and half years. Of the 158 participants who expressed interest to participate, 124 were

interviewed, of whom 62 met inclusion criteria and were eligible. They were randomly assigned by an independent researcher to TBCT treatment (n = 27) or Waitlist control (n = 35). Of the 27 participants who were assigned to TBCT treatment, 9 were excluded from the analysis for the following reasons: 1 participant withdrew after the random allocation, 1 participant was excluded after the first session for receiving other psychotherapy simultaneously, and 7 withdrew before finishing half of the treatment (these participants received less than 7 sessions). Thus, all the 18 patients in the TBCT group included in the analyses received at least 85% of the treatment (1 patient received 14 sessions and 17 patients received 16 sessions). Of the 35 participants who were assigned to Waitlist control, 14 were excluded from the analysis for the following reasons: 1 participant was excluded for taking anxiolytic medication during the pre- and post- test interval, and 13 withdrew after the pre-test assessment. Thus, the TBCT group has 18 participants, and the Waitlist control 21 participants. Figure 1 depicts the progress of participants in the study.

The mean age of the sample was 29.56 (SD = 5.52). The majority of the sample was female (n = 29), had a college degree (n = 19), and 56.4% of participants (n = 22) were employed. Diagnostic interviews revealed that 24 participants had at least one additional comorbid conditino, with depression being the most common additional diagnosis (n = 16). In the TBCT group, 4 participants received only a GSAD diagnosis, and 14 had at least one additional comorbid condition. In the Wait list group, 3 participants had only GSAD, and 18 had at least one additional secondary diagnosis. Thus, only 7 participants presented with GSAD as the unique diagnosis. Regarding psychotropic medication intake, 28.2% of the patients (n = 11) were receiving a stable dose of anxiolytic or antidepressant medication before the beginning of the study (71.8% did not use this type of medication), and 23% (n = 9) had already received a previous SAD diagnosis. Participants in the group that received TBCT treatment differed from the Waitlist control regarding psychotropic medication intake

and previous SAD diagnosis. There were more patients in the treated group taking this type of medication [$\chi^2(1) = 7.84$, $P = .005$] and with a previous SAD diagnosis [$\chi^2(1) = 4.70$, $P = .03$]. This may indicate that the patients randomized to the TBCT group might have a more chronic and severe SAD, which may affect the treatment response. Thus, psychotropic medication intake and previous SAD diagnosis were entered as covariates in subsequent analyses, as well as the other demographic variables. No other group differences were observed in the demographic variables, nor were there any differences present at between assessment measures at baseline. Table 1 shows the sample characteristics.

Assessment

We used the SAD module of the Structured Clinical Interview for DSM-IV – Research Version (SCID-I/P 2.0), developed by First, Spitzer, Gibbon & Williams (2002) to determine SAD diagnosis. In addition, we used the clinician version of the SCID (SCID-CV) developed by First, Spitzer, Gibbon & Williams (1996) to determine other psychiatric diagnoses. These are gold-standard structured clinical interviews based on the DSM-IV.

The Social Phobia inventory (SPIN) was used as the primary outcome measure. It is a 17-item self-report Likert scale that measures physiological, emotional, and behavioral symptoms of SAD (Conner et al., 2000). The SPIN discriminates socially anxious people from normal controls using a 19 cut-off point and is a reliable measure for evaluating treatment changes in social anxiety symptoms (Conner et al., 2000; Osório, Crippa & Loureiro, 2009). Additional SAD measures included the Fear of Negative Evaluation (FNE) and the Social Avoidance and Distress Scale (SADS), which evaluate central social anxiety characteristics: fear of negative evaluation, avoidance behavior, and the distress related to entering social situations (Watson & Friend, 1969). The depression measure included the Beck Depression Inventory (BDI-II) (Beck, Steer & Brown, 1996), which was used as secondary outcome measure. All instruments were utilized at intake (baseline/pre-test) and at

post-test (2 weeks after the last session), with exception of the SCID-IV which was used only at intake to diagnostic purpose.

Study criteria

We used the following inclusion criteria: age ranging between 18 and 45 years old; diagnosis of generalized Social Anxiety Disorder using DSM-IV criteria; scores higher or equal to 19 points on the SPIN; and ability to read and sign the informed consent. Exclusion criteria included psychotic symptoms, high suicide risk, diagnosis of Post-Traumatic Stress Disorder, and SAD diagnosis secondary to other disorders according to SCID-IV. Furthermore, we excluded patients presently in psychotherapy who did not want to stop their concurrent treatment or who were taking psychotropic medication that was not stabilized for at least one month before the assessment.

Treatment

The patients randomized to the treatment group received 16 individual sessions of TBCT. Each session lasted one and a half hours. Session 1 covered a psychoeducation concerning anxiety, SAD, and the treatment overview. Session 2 provided a discussion about the cognitive model, automatic thoughts and cognitive distortions, using the TBCT case conceptualization diagram. In session 3 patients were introduced to the Cognitive Distortions Questionnaire, a TBCT instrument that helps the patients be aware of cognitive distortions that occur during the week. The patients filled this questionnaire from session 3 onward. The main agenda of sessions 4 and 5 was to promote a restructuring of dysfunctional automatic thoughts using the Intrapersonal Thought Record, a TBCT thought record. Sessions 6 to 8 were used to promote restructuring of the conditional beliefs/rules that are normally related to safety behaviors, such as avoidance. The Consensual Role-Play technique was used during these sessions to target both conditional beliefs and avoidance behavior. This TBCT technique is designed to help patients to understand and resolve their approach / avoidance

conflict: the ambivalence towards their behaviors that they would like to do (approach), but are still afraid of (avoidance).

During sessions 9 to 13 dysfunctional core beliefs were restructured using *the Trial*. In TBCT *it* is used to engage patients in a simulation of a court trial. This form of role-play helps them to be aware of and evaluate the dysfunctional CBs. In addition, it helps the patients to activate and strengthen more functional CBs (De Oliveira, 2007). Sessions 14 and 15 covered a discussion about metacognition and the patients were involved in the Trial II.

As in *the Trial*, the Trial II is another role-play technique that engages the patients in a simulation of a court trial to foster awareness of the self-accusatory nature of dysfunctional CBs. Finally, session 16 covered relapse prevention and a review of the whole treatment. For homework, the patients were encouraged to complete exposures between the sessions and fill out the TBCT sheets discussed during the sessions.

Data analysis

To address our primary hypothesis, a latent change score modelling approach was adopted. We chose this approach because it: 1) better handles the dependent nature of longitudinal data, 2) can handle missing data with full information maximum likelihood estimation (FIML), and 3) can provide fit indices to assist in determining model fit. Such analyses invoke a latent variable to estimate change across two individual time points (McArdle, 2009). In accordance with the procedures described by Coman et al. (2013), a latent change model was specified such that the mean of the latent variable represents the difference between the pre-treatment (T1) and post-treatment means (T2). The T2 variable was regressed on both the latent change variable and the T1 variable, and both pathways were fixed to 1. Furthermore, the pathway from T1 to the latent change score was fixed to 0, which indicates stability in changes. If this assumption was not upheld, as indicated by poor model fit, then a covariance parameter between T1 and the latent change score was permitted.

Furthermore, the variance of the latent change score was fixed to 1, and the intercept of the T2 was fixed to 0.

To estimate a conditional latent change score model, the latent change score was regressed on a dummy variable representing treatment condition (1= TBCT, 2= Waitlist). Consistent with the hypotheses of the current study, these models were estimated to determine whether TBCT resulted in greater changes in social anxiety symptoms and depression symptoms relative to the waitlist control. The SPIN and the BDI-II were used to assess for symptoms of social anxiety and depression, respectively. Furthermore, we examined the interaction effects between treatment condition and some hypothesized moderators, such as pre SAD diagnosis and psychotropic medication intake on symptom change. All continuous moderators were mean centered to facilitate interpretation and mitigate undue collinearity.

Missing data were accommodated with full-information maximum likelihood estimation. The following fit indices were examined to evaluate global model fit: chi square statistic, comparative fit index (CFI), Tucker-Lewis index (TLI), and the root mean squared error of approximation (RMSEA). In addition to the presence of a non-significant chi square statistic, good model fit was evidenced by CFI and TLI values exceeding .90, as well as RMSEA values less than .08 (Hu & Bentler, 1998). The latent change score analyses were estimated in R with the latent variable program Lavaan (Rosseel, 2012). For effect size estimates, we abided by conventional guidelines for Cohen's *d* (i.e., small = 0.30, medium = 0.50, and large = 0.80) (Cohen, 1988).

Results

Pre-treatment to post-treatment and between group differences

As indicated in Table 2, TBCT resulted in statistically significant reductions in all outcome measures except fear of negative evaluation between pre- and post-treatment

analysis, and in social anxiety and depression symptoms in ANCOVA, controlling for baseline differences and baseline levels of each outcome variable. Consistent with established precedent (Cohen, 1988), all of the within and between-group effect sizes were in the large range. Individuals in the waitlist control group did not evidence significant change from pre-treatment to post-treatment, and all of the effect sizes were in the small range. To address multiple comparisons, all p-values were submitted to false discovery rate correction.

Latent change score analyses

Results of the latent change score analyses are presented in Table 3. The conditional latent change score model for social anxiety symptoms evidenced good fit with a non-significant chi-square statistic ($\chi^2 = 2.54$, $p = .27$), as well as good fit indices (i.e., CFI = 0.98; TLI = 0.98; and RMSEA = 0.08) (Figure 2). Our primary hypothesis was corroborated, as treatment condition significantly predicted the latent change score ($\gamma = -22.73$, $p < .01$). This suggests that, on average, individuals in the TBCT condition experienced significantly greater reductions in social anxiety symptoms relative to waitlist control. Moreover, this between group difference was associated with a large effect size ($d = 1.53$).

The original conditional latent change score model for depression symptoms exhibited mediocre fit with a significant chi-square statistic ($\chi^2 = 12.95$, $p = .01$), as well as poor fit indices (i.e., CFI = 0.35; TLI = 0.00; and RMSEA = 0.29). Thus, we permitted a covariance parameter between the latent change score and pre-treatment depression symptoms, which relaxes the assumption that change across time must be stable. The new model evidenced good fit with a non-significant chi-square statistic ($\chi^2 = 2.40$, $p = .30$), as well as good fit indices (i.e., CFI = 0.97; TLI = 0.93; and RMSEA = 0.07). A chi-square difference test comparing the two models was significant ($\chi^2\Delta = 14.55$, $df = 2$, $p < .01$), suggesting that the new model exhibits significantly better fit than does the original model. Furthermore, the hypothesis for differential efficacy for depression outcome was supported, as treatment

condition significantly predicted the latent change score ($\gamma = -11.15$, $p < .01$). This suggests that, on average, individuals in the TBCT condition experienced significantly greater reductions in depression symptoms relative to waitlist control. Moreover, this between group difference was associated with a large effect size ($d = 1.05$).[i]

To determine whether demographic and clinical characteristics moderated treatment outcome, a number of models including interaction terms were pursued. Results revealed that only comorbidity significantly moderated treatment efficacy ($\gamma = -11.35$, $p < .05$). Specifically, individuals with comorbid conditions evidenced greater reductions in social anxiety symptoms ($\gamma = -27.64$, $p < .01$) than did those with only social anxiety disorder ($\gamma = -16.29$, $p < .01$). None of the other interaction effects were significant, including age ($\gamma = 0.38$, $p = 0.44$), gender ($\gamma = -5.69$, $p = 0.35$), prior history of a social anxiety disorder diagnosis ($\gamma = -5.30$, $p = .95$), or psychotropic medication intake ($\gamma = -6.86$, $p = .26$).

Discussion

The present study sought to evaluate the efficacy of TBCT for generalized SAD in a population with high rates of comorbidity, especially depression. It is the first two-arm randomized clinical trial comparing TBCT and a control condition (waitlist group) for the treatment of generalized SAD.

Consistent with our primary hypothesis, TBCT was effective in reducing social anxiety symptoms as the participants in the TBCT group experienced greater reductions in SPIN relative to participants in the waitlist condition. Moreover, this between group difference was associated with a large effect size ($d = 1.53$). Moreover, TBCT was effective in reducing symptoms of social avoidance and distress as measured by the SADS. It is important to note that these symptoms are the cardinal characteristics of social anxiety disorder, and the between group difference for these symptoms was associated with a large effect size ($d = 1.07$). Additionally, TBCT was effective in reducing depression symptoms as

the TBCT participants experienced significantly greater reductions in BDI-II relative to waitlist condition. This between group difference was also associated with a large effect size (d = 1.05).

This study aligns with previous research about the efficacy of CBT on SAD symptoms. It is consistent with a recent meta-analysis that evaluated the effect of CBT in treating SAD (Acarturk et al., 2009), and recent studies that show that CBT is highly effective in treating SAD (Barkowski et al., 2016; Hofmann et al., 2013; Ponniah & Hollon, 2006; Otte, 2011). That meta-analysis only included randomized clinical trials, and found a mean effect size of .70 for SAD measures. Considering the studies that compared the treatment with waitlist control groups only, the authors found a significantly larger effect size of .86. In our study, which also compares the intervention with a waitlist condition, we found even a larger effect for TBCT (d = 1.53). The mean effect size observed in studies that delivered the intervention only in individual format was .61, which additionally supports the efficacy of the TBCT in treating SAD symptoms. Moreover, the mean effect size of CBT treatment on depression measures was .70, and in our study we observed a larger effect size (d = 1.05), indicating that TBCT may be very effective in treating the depression symptoms associated with SAD condition. Finally, it is important to highlight that the authors found a mean effect size for social avoidance and distress measure of .70. We also found that TBCT was effective in reducing symptoms of social avoidance and distress, although with a larger effect size (d = 1.07) than previously found.

The results of this randomized clinical trial are consistent the TBCT literature as well (De Oliveira, 2008; De Oliveira et al., 2012; Delavechia et al., 2016), especially those related to SAD **(**De Oliveira et al., 2012b; Powell et al., 2013). In a recent trial that evaluated the effect of the main TBCT technique (*the Trial*) compared to conventional CBT techniques for generalized SAD, it was observed that *the Trial* was as effective as conventional CBT tools,

with a large within-group effect size (d = 1.01 for the TBCT technique *vs* d = .83 for conventional CBT tools) (De Oliveira et al., 2012b; Powell et al., 2013). In our study, we also found a large within-group effect size for the social anxiety measure (d = 2.1), with a similar sample size and drop-out rates as previous studies.

Interestingly, results showed that comorbidity significantly moderated treatment efficacy. The individuals in the TBCT group with comorbid conditions evidenced greater reductions in social anxiety symptoms than those with SAD only, and were those most benefited by the treatment. These results indicate that TBCT may be effective not only in reducing social anxiety symptoms, but other comorbid conditions as well, especially depression. Alongside the large effect size found for TBCT on depression symptoms, results support TBCT as a promising intervention to treat not just SAD, but also the comorbid symptoms. This is an important finding as the presence of comorbidity in SAD is the rule rather than the exception. Clinicians that treat patients with SAD commonly have to deal with depression and other conditions associated with social anxiety. Thus, the presence of comorbidity in this clinical trial increases its external validity, and this study may be particularly helpful for researchers and clinicians that work in realistic clinical settings.

Although TBCT contains CBT techniques, such as psychoeducation, evaluation of automatic thoughts, and exposure, the main TBCT technique (*the Trial*) is a novel approach in the field designed to challenge and restructure dysfunctional CBs (de Oliveira, 2015a; de Oliveira et al., 2015b). *The Trial* is an emotional and experiential tool that the therapist uses to help the patients to evaluate their CBs through a role-play of a court trial. By playing the roles of prosecutor, defense attorney, juror, and defendant, the patients create a distance between themselves and their dysfunctional core beliefs, and get the opportunity to experience in session restructured and more realistic beliefs on an experiential level (de Oliveira, 2008; de Oliveira, 2012[1]). Cognitive change is promoted through (metaphorically)

challenging and deeply evaluating the CBs. Eventually, more constructive and positive core beliefs are developed and activated in the form of a lawsuit during *the Trial* (de Oliveira, 2008; de Oliveira, 2012[1]).

The systematic use of imagination and experiential exercises is one of the main distinctions between TBCT and other classic CBT. It is well-known that imagination can strongly evoke emotion, and literature argues that imagery can affect the behavior. Different therapeutic techniques have used imagery approaches to target dysfunctional behaviors, emotions, and beliefs (Holmes et al., 2016; Holmes, & Mathews, 2010). Thus, it is possible that the strong emotional benchmark involved in *the Trial*, and the continuous use of it in TBCT, leads patients to repeatedly imagine themselves behaving in a different way, which may elict more positive emotional states and promote cognitive restructuring.

It is possible that the promising results of this study may be attributed to *the*, as the individuals in the TBCT completed roleplay exercises involving a simulated court trial for seven sessions (*the Trial* was used from sessions 9 to 13, and *the Trial* II from sessions 14 to 15). Patients may experience an improvement in different symptoms by imaging different descriptions of self. Studies that evaluated the effect of *the Trial* technique in various psychiatric disorders (De Oliveira, 2008; De Oliveira et al., 2012; Delavechia et al., 2016), and also in generalized SAD (De Oliveira et al., 2012b; Powell et al., 2013) show that this technique is effective in reducing the attachment to dysfunctional CBs and the associated emotional intensity, as well as social anxiety symptoms. However, further research is necessary to evaluate which components of the TBCT intervention are related to the decrease in social anxiety and depression symptoms, and which one may be the most effective approach in increasing the efficacy of the treatment of SAD.

The present study is not without limitations. The first one is related to significant baseline differences across the two conditions. Although the subjects were randomized by an

independent researcher, the number of subjects in the experimental group with a prior SAD diagnosis and psychotropic medication at intake was higher than in the waitlist condition. Nevertheless, significant group differences emerged even after controlling for baseline differences.

The second limitation of this study concerns the control condition used. Research suggests that individuals with SAD randomized to waitlist condition exhibit small changes waiting for the intervention, and remain symptomatic after this period (Steinert, Stadter, Stark, & Leichsenring, 2016). Additionally, waitlist conditions have a larger effect size than studies that compare the treatment with placebo or treatment-as-usual control groups (Acarturk et al., 2009). Thus, the results obtained in the present study could be inflated given the adopted control condition. However, when compared with randomized clinical trials that evaluated the effect of CBT using waitlist conditions, the effect size of this study is even larger (Acarturk et al., 2009). Additionally, it is important to highlight that data based on effects of waitlist condition may be helpful as a benchmark in pilot studies that evaluate new treatments (Steinert, Stadter, Stark, & Leichsenring, 2016). This may make the waitlist condition in this study more appropriate, as this is the first randomized clinical trial that evaluated the effect of TBCT for generalized SAD. Thus, the results obtained at the present study may be useful for future TBCT research.

Another limitation is related to potential therapist effects, which has implications for evaluating the treatment outcome (Thompson, Cachelin, Striegel-Moore, Barton, Shea, & Wilson, 2012; Walwyn & Roberts, 2010). As only one therapist delivered the treatment in this study, it is not possible to evaluate therapist bias. However, there is a lower therapist effect when interventions follow a manual-based treatment or protocol, when therapists receive solid training in the intervention, and have a considerable clinical experience

(Thompson, et al., 2012). In the current study, a manualized protocol was used, and the therapist received extensive training in the intervention.

Additionally, the reliance on self-report measures to assess primary outcomes might be a limitation. Self-report instruments are amenable to a number of response biases (e.g., social desirability, consistency seeking, etc.). Given that this is a pilot study, it was not feasible to use biological markers of anxiety (e.g., cortisol, heart rate variability, etc.), yet this will be an important future direction. Furthermore, it should be noted that prior research has indicated that self-report measures may be a more conservative estimate of treatment efficacy than clinician rated assessments (Cuijpers, Li, Hofmann, & Andersson, 2010). This could suggest that estimates of treatment efficacy were not overestimated in the current study.

Finally, a further limitation of this study is the small sample size. Thus, the results must be interpreted as preliminary. Further research with a larger sample size and with active comparison conditions, such as conventional CBT, should be conducted to evaluate the effect of TBCT treating generalized SAD with comorbid disorders.

This study suggests that TBCT is effective in reducing social anxiety symptoms and depression symptoms, and it seems to be particularly efficacious in patients with comorbid conditions. TBCT may be a promising treatment for chronic GSAD patients that do not benefit from current CBT, especially those with comorbid condition.

Footnotes

These analyses were re-conducted controlling for baseline differences. The effects of treatment condition on changes in symptoms of social anxiety and depression remained significant ($\gamma = -20.70$, $p < 0.01$; $\gamma = -10.90$, $p < 0.01$, respectively).

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Figure 1.

Flow diagram of participants' progress through the study

Figure 2.

Conditional latent change score model for social anxiety

Note: Intercepts and residuals are displayed. All path coefficients denote unstandardized estimates.

Table 1

Participant Characteristics

Table 2

Differences between pre- and post-treatment

Note: All p-values were submitted to false discovery rate correction. TBCT = Trial Based Cognitive Therapy; *SD* = Standard Deviation; *d* = Cohen's d; * $p < .05$; ** $p < .01$.

Table 3.

Freely estimated parameters of conditional latent change score model

Note: $\alpha_{Pre\text{-}Sx}$ = intercept of pre-treatment social anxiety (or depression); α_{LCS} = intercept of latent change score; $\phi_{PreSx*LCS}$ = covariance between pre-treatment depression and latent change score; $\phi_{PreSx*PreSx}$ = variance of pre-treatment social anxiety (or depression); $\phi_{LCS*LCS}$ = variance of latent change score; λ_{Exp} = unstandardized path coefficient from experimental condition to the latent change score. * $p < .05$; ** $p < .01$.