This is an Accepted Manuscript of an article published by Taylor & Francis in PSYCHOTHERAPY RESEARCH on 05 Mar 2025, available at: https://doi.org/10.1080/10503307.2025.2467380

Trauma-Focused Cognitive-Behavioral Therapy for Long-term Posttraumatic Stress Disorder, Major Depressive Disorder and Anxiety Disorders in Victims of Terrorism: A Randomized Clinical Trial

Clara Gesteira[a], Maria Paz Garcia-Vera[a], Jesus Sanz[a], and James M. Shultz[b]

[a] Psychology Faculty. Complutense University of Madrid, Spain. Campus de Somosaguas S/N. 28223, Pozuelo de Alarcón, Madrid, Spain.

clara.gesteira@ucm.es; mpagarci@ucm.es; jsanzfer@ucm.es

[b] Department of Public Health Sciences and Global Institute for Community Health and Development, University of Miami Miller School of Medicine, 1120 NW 14 St., Miami, FL, 33136, USA

jshultz1@med.miami.edu

Corresponding author:

Clara Gesteira Santos, Ph.D

Facultad de Psicología. Universidad Complutense de Madrid. Campus de Somosaguas S/N 28223, Pozuelo de Alarcón, Madrid, Spain.

E-mail address: clara.gesteira@ucm.es; Telephone number: +34 91 394 28 32

Abstract

Objective: A parallel randomized clinical trial evaluated the efficacy of Trauma-Focused Cognitive-Behavioral Therapy (TF-CBT) for victims of terrorist attacks with long-term psychopathology. *Method*: 120 adult Spanish victims, who met the criteria for current posttraumatic stress disorder (PTSD), major depressive disorder (MDD), and/or anxiety disorders related to exposure to terrorist attacks that occurred 18 years ago, on average, were randomly assigned to 16 weekly sessions of TF-CBT (n = 60) or waiting list control conditions (n = 60). *Results*: Participants who completed TF-CBT (n = 25) experienced

This is an Accepted Manuscript of an article published by Taylor & Francis in PSYCHOTHERAPY RESEARCH on 05 Mar 2025, available at: https://doi.org/10.1080/10503307.2025.2467380

significant pre-post decreases in diagnostic rates and in posttraumatic stress, depression, and anxiety symptoms. Pre/post effect sizes for the TF-CBT-treated participants were large ($g_{PCL\text{-}S}$ = 1.25; $g_{BDI\text{-}II}$ = 1.03; g_{BAI} = 1.16), and between-groups effect sizes were medium-large ($g_{PCL\text{-}S}$= 0.94, $g_{BDI\text{-}II}$ = 0.72, g_{BAI} = 0.95). Most TF-CBT completers (78.3% to 91.7%) achieved sub-syndromal symptom levels by post-treatment. The benefits persisted to the 6-month follow-up (n = 22). Modified intention-to-treat analyses (n = 35 vs. n = 50) confirmed the significance of the findings for PTSD and were significant but less robust for MDD and anxiety disorders. *Conclusion*: TF-CBT appears to be efficacious when applied to victims of terrorism with long-term psychopathology.

Keywords: Terrorism; Cognitive Behavior Therapy; Posttraumatic Stress Disorder; Major Depression; Anxiety; Randomized Clinical Trial.

Clinical or Methodological Significance of this Article

TF-CBT was efficacious when applied to victims of terrorism with long-term PTSD. Results were significant but less robust for long-term MDD and anxiety disorders.

Objective

In 2023 there were 7,382 terrorist attacks worldwide that resulted in 21,596 people dead, 14,351 injured, and 3,921 kidnapped (Development Services Group, Inc. Global Terrorism Trends and Analysis Center, 2024). Systematic reviews focusing on the psychopathological consequences of terrorist attacks have determined that significant percentages of terrorism-exposed individuals will be diagnosed with posttraumatic stress disorder (PTSD), including 33-39% of the direct victims and 17-29% of the family members and friends of victims who were killed or injured in an attack (Garcia-Vera et al., 2016). While PTSD is the most commonly studied mental disorder among victims of terrorism, reviews document a much broader spectrum of event-related psychological distress and co-morbid mental disorders that

This is an Accepted Manuscript of an article published by Taylor & Francis in PSYCHOTHERAPY RESEARCH on 05 Mar 2025, available at: https://doi.org/10.1080/10503307.2025.2467380

may be diagnosed in victims of these attacks, most notably major depressive disorder (MDD) and anxiety disorders (Garcia-Vera et al., 2021; Rigutto et al., 2021).

Furthermore, the clinical course is variable. In most cases, these common mental disorders (CMDs) associated with trauma exposure will improve over time, but for a sizeable subset of victims, psychopathology that has been triggered by exposure to a terrorist attack will become chronic and persistent. This has been specifically observed for PTSD (Adams et al., 2019; Morina et al., 2014), but also for other disorders such as MDD (Jordan et al., 2019).

Despite the importance of the psychopathological consequences resulting from acts of terrorism, the systematic reviews conducted by Garcia-Vera et al. (2015) and Lowell et al. (2018), identified only five experimental studies that have thoroughly examined the efficacy of any sort of treatment for adult direct or indirect victims of terrorist attacks who have progressed to diagnosable CMDs associated with exposure to the event. These five studies examined two empirically supported psychological therapies. A single study (Schneier et al., 2012) explored the application of prolonged exposure therapy (Foa & Rothbaum, 1998) combined with pharmacotherapy with a selective serotonin re-uptake inhibitor (SSRI). The other four studies examined the efficacy of trauma-focused cognitive-behavioral therapy (TF-CBT), comparing it with a wait list control group (Duffy et al., 2007) or other active control conditions (Bryant et al., 2011; Difede, Cukor, et al., 2007; Difede, Malta, et al., 2007). The four studies that employed the TF-CBT intervention for treating victims of terrorism demonstrated treatment efficacy for PTSD and two of these studies demonstrated treatment efficacy for co-morbid conditions such as MDD (Bryant et al. 2011; Duffy et al. 2007). This sparse literature, characterized by few studies, and a primary therapeutic focus on treating PTSD, limits the ability to draw generalizable conclusions.

This is an Accepted Manuscript of an article published by Taylor & Francis in PSYCHOTHERAPY RESEARCH on 05 Mar 2025, available at: https://doi.org/10.1080/10503307.2025.2467380

Besides, study subjects were victims of terrorist attacks who exhibited chronic psychopathology. However, the time frames from exposure to terrorism to receiving the TF-CBT intervention varied across studies. Two studies delivered therapies 1 to 2 years following exposure (Bryant et al., 2011; Difede, Malta, et al., 2007). A third study initiated TF-CBT treatment across a broad range, extending from 5 months to 47 months post-exposure (Difede, Cukor, et al., 2007). Subjects in the fourth study (Duffy et al., 2007), received treatment 5.2 years post-terrorism exposure on average. Considering that 82-85% of victims of terrorism with PTSD recover spontaneously between 4-8 years after the attack (Cukor et al., 2011; Morina et al., 2014; Neria et al., 2010), it is difficult to ensure whether the positive results derived from interventions applied within shorter post-exposure time frames are due to the treatments themselves or to the natural recovery of terrorism survivors. Besides, the abovementioned studies can also be considered short-term interventions in the context of decades-long serial terrorist incidents in nations such as Spain. Although TF-CBT had previously been proven effective for Spanish victims (Moreno et al., 2019), no experimental study had tested intervention efficacy.

The objective of this paper is to present the findings of the first randomized clinical trial (RCT) designed to test the efficacy of a TF-CBT intervention adapted for use with victims of terrorism in Spain who were diagnosed with PTSD, MDD, and/or anxiety disorders subsequent to direct or indirect exposure to a series of terrorist attacks that occurred 4 to 40 years prior to treatment. It is expected that the intervention group will show a significantly lower percentage of participants meeting criteria for each examined diagnostic category and a significantly lower mean on all symptomatology variables than the wait list (WL) control group at the end of this trial. Since terrorism is a current and global social and clinical problem, all data provided in this regard is deemed pertinent and relevant.

This is an Accepted Manuscript of an article published by Taylor & Francis in PSYCHOTHERAPY RESEARCH on 05 Mar 2025, available at: https://doi.org/10.1080/10503307.2025.2467380

Method

Design

This study was a randomized, controlled, single-center, clinical trial, with two parallel groups (treatment and wait list) and a primary endpoint based on the percentages of PTSD, MDD, and/or anxiety disorders at the post-treatment assessment and at the 6-month follow-up (FU) assessment. CONSORT reporting guidelines (Schultz et al., 2010) were followed during the preparation of this study. During the study, there were no important changes to the methods after trial commencement. This RCT was registered at ClinicalTrials.gov (NCT05516368)

Participants

Researchers contacted the members of the Spanish Association of Victims of Terrorism (AVT) and invited them to an in-person diagnostic interview (pre-treatment evaluation) at the university. Three hundred and eighty-six (386) participants were assessed for eligibility, and 213 were deemed ineligible because they did not meet the following inclusion criteria: 1) being of legal age; 2) living in the same city or nearby; and 3) being diagnosed with PTSD, MDD, and/or anxiety disorders based on Diagnostic and Statistical Manual (DSM-IV) criteria (American Psychiatric Association, APA, 2000). Among the 173 candidates who fulfilled the inclusion criteria, 53 were deemed ineligible to participate based on matching one or more of the six defined exclusion criteria: 1) psychological condition unrelated to a terrorist attack; 2) psychiatric emergency; 3) declining to participate in the intervention before being diagnosed; 4) medical contraindication(s) likely to interfere with treatment effectiveness, including organic brain syndrome, severe cognitive or sensory impairment, current substance use disorder, active psychotic or bipolar disorder, or severe dissociative amnesia; 5) ongoing, in-process, trauma-focused psychotherapy; and/or 6) inability to attend treatment sessions. The

final sample consisted of 120 study eligible victims who were randomly assigned to the TF-CBT experimental condition or WL control condition.

Prior to enrollment and participation, eligible individuals were provided with informed consent, which detailed the purpose of the research, emphasized the voluntary nature of participation, and assured them of data confidentiality. The study was carried out in a single setting, a University in Spain. Approval was granted by the Ethics Committee of the University (October 10th, 2011). The study was performed in accordance with the 1964 Declaration of Helsinki and its later amendments.

Randomization and Masking

Random numbers generated by the Research Randomizer (Version 4.0) program (Urbaniack & Plous, 2013) were used to assign subjects to treatment conditions. Randomization was performed as a block with a 1:1 allocation. A single member of the research team generated the allocation sequence, enrolled participants, and informed the therapists of the results. Pre-intervention interviewers were blind to the final allocation, but neither participants nor therapists were. The experimental group received TF-CBT that commenced immediately while the WL control group received TF-CBT following a period of 4 months on the wait list. Nine of the 15 available therapists were assigned to the treatment group, while all the 15 were assigned to the control group. This imbalance was produced because 6 of the 15 potential therapists were still following their training program when the allocation started. Eight of the 9 therapists that participated in both conditions were equally represented, except for one of them who treated 11 (treatment) vs. 2 (control) participants. The post-intervention assessment was conducted by the same therapists that provided the therapies.

Intervention

This is an Accepted Manuscript of an article published by Taylor & Francis in PSYCHOTHERAPY RESEARCH on 05 Mar 2025, available at: https://doi.org/10.1080/10503307.2025.2467380

The modular TF-CBT therapy programme applied in this study consisted of 16 weekly individual sessions, each lasting 60-90 minutes. The participant was considered to have completed the intervention if all the main therapeutic objectives were achieved. Among those who completed the treatment, the average number of sessions was 16.24 (range: 15-19 sessions). For a detailed explanation on the treatment components, see the Table 1 from the supplemental material section.

The TF-CBT intervention was administered by a team of 15 psychologists who had completed postgraduate training in clinical psychology and/or general health psychology. Each of the therapists had successfully completed two intensive 20-hour training workshops and had attained proficiency in the provision of TF-CBT to victims of terrorism. The therapists were supervised by senior clinical psychologists and their cases were monitored weekly. Five of the 9 therapists assigned to the treatment group oversaw 84% of completed interventions (4 or 5 participants each), while the other 4 took care of the remaining 16% (1 participant each). Six of these 9 therapists had a success rate (number of completed cases from the total number of initiated cases) over 50% (range from 57.7% to 100%), while the remaining 3 had success rates that oscillated between 33.3% to 44.4%.

Outcome Measures

Pre-treatment, post-treatment, and 6-month FU assessments were conducted using the following battery of standardized diagnostic (primary outcomes) and symptom instruments (secondary outcomes).

Post-traumatic stress symptoms-The Spanish version of the *Posttraumatic Stress Disorder Checklist, specific version (PCL-S)* (Vazquez et al., 2006). The PCL-S is composed of 17 items that assess the presence and severity of the post-traumatic stress symptoms in the last month, according to the DSM-IV criteria. The instructions were modified to explicitly refer

This is an Accepted Manuscript of an article published by Taylor & Francis in PSYCHOTHERAPY RESEARCH on 05 Mar 2025, available at: https://doi.org/10.1080/10503307.2025.2467380

to the terrorist attack as the index trauma. Each item is assessed using a Likert-type scale ranging from "not at all" (1) to "extremely" (5), yielding a total score range of 17-85.

Major depressive disorder symptoms-The Spanish version of the *Beck Depression Inventory-II (BDI-II)* (Beck et al., 2011). The BDI-II is made up of 21 sets of four items that assess the presence and severity of depressive symptoms based on DSM-IV criteria. For each set, the respondent selects the statement that best describes the respondent's state of mind during the past two weeks. Answer options for each set are scaled from 0 to 3 points and summed across the 21 sets, yielding a total range of 0-63.

Anxiety symptoms-The Spanish version of the *Beck Anxiety Inventory (BAI)* (Beck & Steer 2011). The BAI is composed of 21 items that assess the presence and severity of anxiety symptoms based on DSM-IV criteria. The respondent must evaluate the degree to which each of the symptoms has bothered them in the past week on a Likert-type scale, from "not at all" (0) to "serious" (3), yielding a total range of 0-63.

Excellent Cronbach's Alpha coefficients were found for all symptomatology scales in the present study at baseline, post-intervention, and FU assessments (all PCL *alpha* = .91-.96; all BDI *alpha* = .94; all BAI *alpha* = .93-.96).

Diagnosis of PTSD, depressive and anxiety disorders-The Spanish version of the *SCID-I-CV*, modules F and A, was administered (First et al., 1999). The instructions were adapted to evaluate all diagnostic criteria using the attack as an index traumatic incident. A diagnosis was deemed to be related if it happened for the first time or was clearly exacerbated after the attack and there was no other precipitant that could plausibly explain its origin. For the above-mentioned disorders, high inter-rater and test-retest reliability indices in the fair-excellent range have been found for the SCID-I (Lobbestael et al., 2011; Zanarini et al., 2000). There were no changes to trial outcomes after the trial commenced.

This is an Accepted Manuscript of an article published by Taylor & Francis in PSYCHOTHERAPY RESEARCH on 05 Mar 2025, available at: https://doi.org/10.1080/10503307.2025.2467380

Statistical Analyses

According to Wang & Ji (2020), calculation of the sample size was based on the ability to detect a clinically relevant difference in diagnostic percentages (dichotomous primary outcome), with a superiority margin of 5% between the two trial arms. Assuming an improvement rate in PTSD diagnosis of 96% (Moreno et al., 2019) and considering an improvement of at least 50% in the control group, in order to achieve an 80% power at the 5% level of significance with equal allocation, the total sample size should be $N = 22$ ($n = 11$ in each group). However, considering an average drop-out rate of 23.5% in the efficacy studies conducted on victims of terrorism (Garcia-Vera et al., 2015), the aim was to recruit at least $N = 28$. Per-protocol (PP) analyses, or analyses with only treatment completers, and modified intention-to-treat (mITT) analyses, using multiple imputation for missing data, were considered for primary and secondary outcomes. Considering the possibility of the multiple imputations analyses being not accurate because of the small sample size of the present study, some extra analyses using the last observation carried forward (LOCF) were included as an additional way of checking on the representativeness of multiple imputations and can also be consulted in the supplemental material section.

As for the primary outcomes, contingency tables and chi^2 tests were used to assess post-treatment differences between the experimental vs. control groups in the percentage of individuals meeting diagnostic criteria for PTSD, MDD, and anxiety disorders. The McNemar's test was carried out for two related samples to compare the percentage of those diagnosed in the pre-treatment and the post-treatment for each one of the groups and in the FU for the experimental group.

To compare the post-treatment symptomatology level (secondary outcomes) of the two groups (treatment and control), a mixed analysis of variance (ANOVA) was carried out on

each of the symptomatology measures (PCL-S, BDI-II, and BAI), in which the within-subject factor was the time (pre-treatment and post-treatment), and the between-subject factor was the experimental condition (TF-CBT vs. WL). Moreover, for each study group, a pre-post analysis (or pre–FU for experimental group) of the symptomatology was conducted using repeated measures *t*-tests. Cohen's d with Hedges correction for small samples was taken as a measure of pre-post and pre-FU effect sizes and also as a between-groups effect sizes. Partial eta squared (η^2_p) was considered as the effect size measure for the ANOVA results.

Additional PP analyses were also performed just considering participants who completed either the intervention or the WL condition. Following the approach of Jacobson & Truax (1991) to examine clinically significant changes, the percentages of participants whose score in the post-treatment (or the FU) was below the cut-off score that marked the step from clinically significant symptomatology to "sub-syndromal" (the "C-score") were calculated. This is 29 points for the PCL-S (Sanz & Garcia-Vera, 2015) and 14 for the BAI and the BDI-II (Sanz, 2013, 2014). The *Reliable Change Index (RCI;* Jacobson & Truax, 1991; Mcglinchey et al., 2002) was also used for those who completed treatment. According to RCI data calculated by Sanz (2013, 2014; Sanz & Garcia-Vera, 2015) for the Spanish population, the disorders of the patients whose scores had dropped by 12 points or more for the PCL-S or 10 points or more in the BDI-II or the BAI, were designated as "*improved*". The disorders of the patients whose scores had increased by 12 or 10 points or more (for PCL-S or BDI-II and BAI respectively) were considered reliably "*deteriorated"*. This reliable deterioration and the existence of post-intervention new diagnosis (not diagnosed at the baseline assessment) were considered as measures of potential harmful effects.

Finally, because 35% of the study-enrolled victims were taking psychiatric medications, exploratory statistical analyses were performed to verify that experimental vs. control

This is an Accepted Manuscript of an article published by Taylor & Francis in PSYCHOTHERAPY RESEARCH on 05 Mar 2025, available at: https://doi.org/10.1080/10503307.2025.2467380

differences in treatment efficacy—for study completers—were not attributable to the medications. A mixed three-way (2 x 2 x 2) ANOVA was carried out on each of the symptomatology measures (PCL-S, BDI-II, and BAI), in which the within-subject factor was time (pre-treatment and post-treatment) and the between-subject factors were the experimental condition (treatment vs. WL) and the psychiatric medication (with vs. without medication). An additional mixed ANOVA with only one between-subject factor (psychiatric medication) was conducted to compare pre-treatment and FU.

All PP analyses (analyses with completers) were performed with SPSS-29.0.2.0, while mITT analyses with multiple imputations were conducted with both SPSS and the R package for multivariate imputation by chained equation (MICE; van Buuren & Groothuis-Oudshoorn, 2011)

Missing Data

The percentage of missing data in the general dataset ranged from 0 to 3.5% for baseline diagnoses and symptomatology scales, 11.8% for diagnoses after intervention, and from 16.5 to 17.6% for post-treatment PCL, BAI and BDI measures. The percentage of missing data for the treatment group at 6-months FU was 37.1% for both diagnosis and symptomatology measures. Although these percentages were high, they were not too large to discard a multiple imputations analysis in a RCT (Jakobsen et al., 2017). Even though Little´s test was non-significant (p = .817), the MCAR (missing completely at random) hypothesis did not seem entirely plausible, considering the significant differences found between completers and dropouts (further explained in the next section, *Participant flow and characteristics)*. Instead, missing data were deemed to be missing at random (MAR), an assumption that supports prediction of missing values based on available data and consequently, that allows for the use of multiple imputations techniques (Jakobsen et al., 2017). All available data related to

diagnosis and symptomology scores from pre- and post-treatment (and FU for the experimental group) were used to impute missing outcome values. The socio-demographic variables that proved to be significantly different in the comparison between participants who completed the treatment and those who discontinued the intervention were also included in the imputation model (i.e., age and current psychological intervention). Considering the high rate of participants taking psychiatric medication, this variable was also included in the model. To preserve interaction between treatment condition and other variables, the dataset was split, and multiple imputations were computed separately for treatment and control groups. Nevertheless, two diagnostic variables, PTSD and depression, were constant for the treatment group at post-intervention, and PTSD was also constant at FU (all treatment completers had 0% of diagnoses at those stages). Thus, to ensure enough variability, they were imputed considering the complete database but including the experimental condition and its interactions with the rest of variables as predictors. Since the analysis of missingness showed a non-monotone pattern for both groups, fully conditional specification (FCS), also known as multivariate imputation by chained equation, was used for the generation of multiple imputations. The scores from 100 imputations were pooled to conduct mITT analyses. Density plots evidenced that the imputed data were plausible and that there was good convergence with original data. Kolmogorov-Smirnov tests also outlined similar distributions for both imputed and original continuous variables (all treatment $ps \geq .383$; all control $ps = 1$). Finally, chi^2 tests and Mann-Whitney U tests for separate measurements showed that there were no significant differences between imputed and original data in terms of diagnosis frequency (all treatment $ps \geq .094$; all control $ps = 1$) and median symptomatology variables (all treatment $ps \geq .198$; all control $ps \geq .805$). Missing data were handled with SPSS 29.

This is an Accepted Manuscript of an article published by Taylor & Francis in PSYCHOTHERAPY RESEARCH on 05 Mar 2025, available at: https://doi.org/10.1080/10503307.2025.2467380

Results

Participant Flow and Characteristics

According to the CONSORT flow diagram (see Figure 1 from the supplementary materials section), the 120 study eligible victims were randomly assigned to the TF-CBT experimental condition (n = 60) or the wait list (WL) control condition (n = 60). The eligible participants were recruited beginning in March 2012 and finishing in January 2015. The 120 study participants were ages 27 to 81 years (*mean* = 50.47; *SD* = 11.83) and two-thirds (67.5%) were female. Among the participants, 46.7% were direct victims, 41.7% were relatives of persons who had died in the attacks, and 13.3% were relatives of people physically injured during the attacks, although some participants could belong to more than one category. Exposure to a terrorist attack was a historical event, occurring 18.43 years prior to study enrollment on average (*SD* = 11.22). Sixty percent and 60.8% had received either psychological or psychiatric interventions at any point after the attacks, and at the time of baseline evaluation, 9.2% of the participants were receiving some form of psychological assistance (other than TF-CBT) and 35% of the study subjects were receiving prescribed psychiatric medications. Regarding the clinical characterization, 49.2% of the participants met DSM-IV criteria for a diagnosis of PTSD, 40.8% of participants met criteria for MDD, and 75.8% met criteria for at least one of the following anxiety disorders: unspecified anxiety disorder (27.5%), specific phobia (21.7%), panic disorder (18.3%), generalized anxiety disorder (12.5%), obsessive-compulsive disorder (10.8%), agoraphobia without history of anxiety (10.8%), social phobia (6.7%) and adjustment disorder with anxiety symptomatology (3.3%). 28.8% and 18.6% of those diagnosed with PTSD had comorbid MDD and anxiety disorders respectively, while 39% of them presented with triple comorbidity (PTSD+MDD+anxiety disorders). The chi^2 or *Student's t-test* comparisons for separate

measurements showed that there were no significant differences in terms of any sociodemographic or clinical characteristics between the treatment (n = 60) and the control (n = 60) groups (Table 2, supplemental material section).

Among the 60 victims randomized to the treatment group, 35 agreed to participate and started the treatment, while 25 who had initially agreed to participate ultimately chose to decline the intervention and did not receive the treatment. Analyses with the *chi*^{2} or *Student's t-test* for separate measurements showed that the group of individuals who did not even start the treatment (n = 25) included a higher number of relatives of people murdered in a terrorist attack, $\chi^2(1) = 5.17$, $p = .023$. Among the 35 individuals who accepted and started the therapy, 10 discontinued it, and therefore, 25 finally completed the treatment and post-treatment evaluation, and 22 also took part in a follow-up assessment (FU), 6 months after completion of the trial. FU recruitment took place from January 2013 to January 2016. Analyses with the *chi*^{2} or *Student's t-test* for separate measurements showed that those individuals who discontinued the treatment (n = 10) were older, $t(33) = 3.71$, $p < .001$, and more likely to have received (non-TF-CBT) psychotherapy, compared to the 25 who completed treatment, $\chi^2(1) = 4.91$, $p = .003$. Treatment dropouts also had significantly higher scores for anxiety, depressive and posttraumatic symptoms (all $ps \leq .025$).

Among the 60 victims randomized to the WL, 50 agreed to participate and started the WL condition, while 10 who had initially agreed to participate ultimately chose to decline the intervention. Among the 50 who accepted the WL condition, all completed the post-treatment evaluation. Analyses with the *chi*^{2} or *Student's t-test* for separate measurements showed that the group of individuals who did not even start the WL process (n = 10) included a lower number of people directly injured in a terrorist attack, $\chi^2(1) = 4.82$, $p = .028$, and this terrorist incident took place significantly earlier, $t(17) = 2.15$, $p = .046$. Of the 50 participants in the

This is an Accepted Manuscript of an article published by Taylor & Francis in PSYCHOTHERAPY RESEARCH on 05 Mar 2025, available at: https://doi.org/10.1080/10503307.2025.2467380

control group who completed the post evaluation after waiting list, 29 accepted and started treatment, while 21 refused. Furthermore, among those 29 who initiated the intervention, 12 discontinued it while 17 participants ultimately completed the treatment.

The trial ended in January 2016, when there were no more potential participants to assess. mITT analyses were conducted for the 35 participants who accepted the treatment and the 50 participants who accepted the WL condition. PP analyses were conducted for the 25 participants who completed the treatment (22 in the FU) and the 50 participants who completed the WL (see Figure 1, supplementary materials).

Efficacy Analysis According to the Diagnosis of PTSD, MDD, and Anxiety Disorders

McNemar's tests were used to compare pre- to post-treatment prevalence of PTSD, MDD and anxiety disorders within each group. As for the treatment completers, PTSD prevalence significantly decreased from 48% to 0%, MDD decreased from 56% to 0%, and anxiety disorders decreased from 80% to 28% (all *p*s < .001), while for the WL participants, PTSD prevalence only declined from 58% to 50%, MDD from 40% to 28%, and anxiety disorders from 70% to 68%, with none of these three reductions reaching significance (all *p*s ≥ .07). There were no treatment completers who had any new diagnosis in the post-treatment, whereas that was the case for 4 patients (8%) in the control group. Multiple imputations mITT analyses revealed that, for the treatment group, PTSD prevalence significantly decreased from 48.6% to 10.1%, MDD from 48.6% to 9.4%, and anxiety disorders from 80% to 31.6% (all *ps* ≤ .008), with no significant reductions for the WL group (all *ps* ≥ .077). Comorbidities in the mITT analyses can be consulted in the Figure 2 of the supplemental material section. LOCF analyses also confirmed these results, with significant reductions for the treatment group (all *ps* ≤ .001), but not for the WL control group. Furthermore, the treatment group maintained significant reductions in diagnoses that extended from pre-

This is an Accepted Manuscript of an article published by Taylor & Francis in PSYCHOTHERAPY RESEARCH on 05 Mar 2025, available at: https://doi.org/10.1080/10503307.2025.2467380

treatment to the 6-month FU evaluation in both the completers and the mITT analysis (all *p*s ≤.010). For completers, PTSD prevalence remained 0%, MDD prevalence only reached 4.5% and the percentage of anxiety disorders went from 81.8% to 27.3% at FU. Only one participant who completed the 6-month FU (4.5%) was diagnosed with a new condition (social phobia). mITT analyses revealed that PTSD continued to be 0% at FU, and MDD and anxiety disorders only reached 13.1% and 30.9% respectively. These results were also supported by the LOCF approach (see Tables 3 and 4 in the supplemental materials).

The differential patterns of diagnosis/symptom decrements observed for the experimental and control groups were also evident when comparing the experimental conditions at the post-treatment assessment. According to *chi*^{2} tests, the prevalence of all diagnosable common mental disorders (CMDs) was significantly less for the treatment group compared to the WL group in the completers analysis (all *ps* ≤ .009). The mITT analysis also replicated this effect for both PTSD and anxiety disorders (all *ps* ≤ .002) but did not display significant differences between groups for the diagnosis of MDD (*p* = .081) (see Table 1). LOCF approach showed significant differences for all disorders (see Table 5 from the supplemental materials)

Table 1

PP (completers) and mITT Analyses of the Differences in the Prevalence of PTSD, MDD and Anxiety Disorders between Treatment and Waiting list (WL) Groups at Post-treatment

PP Analysis (completers)			
	Treatment vs. WL Group at Post-treatment		
	Treatment Group (*n* = 25)	WL Group (*n* = 50)	χ^2
PTSD	0 (0%)	25 (50%)	18.75***

Mental disorders prevalence	MDD	0 (0%)	14 (28%)	8.61**
	Anxiety disorders	7 (28%)	34 (68%)	10.76**
mITT Analysis†				
		Treatment vs. WL Group at Post-treatment		
		Treatment Group (n = 35)	WL Group (n = 50)	χ^2
Mental disorders prevalence	PTSD	3.53 (10.1%)	25 (50%)	10.93***
	MDD	3.28 (9.4%)	14 (28%)	3.05
	Anxiety disorders	11.06 (31.6%)	34 (68%)	9.18**

Note: †Pooling procedures in multiple imputations analysis can result in absolute frequencies with decimals; * $p < .05$. ** $p < .01$. *** $p < .001$.

Efficacy Analysis According to the Reduction in the Posttraumatic, Depressive and Anxiety Symptomatology.

As shown in Table 2, the *t-tests* were used to compare pre- to post-intervention symptoms levels within each group and they revealed that the symptom levels of the treatment group dropped significantly from pre- to post-treatment in both the PP and the mITT analyses (all *ps* < .001), with effect sizes ranging from 1.03, 95% CI (0.54, 1.51) (BDI-II) to 1.25, 95% CI (0.70, 1.78) (PCL-S) in the PP analysis, and from 0.69, 95% CI (0.32, 1.06) (BDI-II) to 0.96, 95% CI (0.56, 1.36) (PCL-S) in the mITT analysis. In contrast, the control group only showed significant pre-post declines in the PP analyses and only for the PCL-S and BDI-II symptom levels (all *p*s ≤ .020), with smaller pre-post effect sizes, ranging from 0.22, 95% CI (-0.74, 0.51) (BAI) to 0.31, 95% CI (0.10, 0.60) (PCL-S) and 0.31, 95% CI (0.13, 0.61) (BDI-II) in the PP analysis, and from 0.18, 95% CI (-0.10, 0.46) (PCL-S) to 0.22, 95% CI (-

0.06, 0.50) (BAI) in the mITT analysis. Regarding the results of the treatment group at FU, the *t*-tests revealed that the symptom levels dropped significantly from pre-treatment to 6-month FU in both the PP and the mITT analyses (all *ps* < .005), with effect sizes ranging from 0.59, 95% CI (0.14, 1.01) (BAI) to 0.90, 95% CI (0.40, 1.37) (PCL-S) in the PP analysis, and from 0.76, 95% CI (0.38, 1.14) (BAI) to 1.04, 95% CI (0.63, 1.45), (PCL-S) in the mITT analysis (see Table 3, supplemental material section). LOCF replicated the significant decrease of symptoms in the treatment group, in the post intervention and the FU, with similar or higher effect sizes (Tables 4 and 6 from the supplemental material section). The reduction of symptoms in both groups also manifested when examining ANOVA outcomes. Thus, the PP analysis documented significant effects of time [PCL-S $F(1, 66) = 37.22$, $p < .001$; BDI-II $F(1, 66) = 34.04$, $p < .001$; BAI $F(1, 67) = 20.47$, $p < .001$], that were confirmed in the mITT analysis with multiple imputations [PCL-S $F(1, 1665.25) = 13.69$, $p < .001$; BDI-II $F(1, 1162.74) = 9.02$, $p = .003$; BAI $F(1, 3410.52) = 7.44$, $p = .006$]. However, the analyses of the interactions also showed that the decrement in the scores on the symptom scales differed by experimental condition. A significant experimental group x time interaction was found for all measurements in the PP analysis [PCL-S $F(1, 66) = 13.16$, $p < .001$; BDI-II $F(1, 66) = 12.18$, $p < .001$; BAI $F(1, 67) = 6.64$, $p = .012$], with large between-groups differences at post-treatment for PCL-S and BAI [$g = 0.94$, 95% CI (0.42, 1.45), and $g = 0.95$, 95% CI (0.44, 1.46), respectively], and medium for the BDI-II [$g = 0.72$, 95% CI (0.21, 1.22)]. The significance of these results was also replicated in the mITT analyses for both PCL-S and BDI-II [PCL-S $F(1, 2771.19) = 8.40$, $p = .004$; BDI-II $F(1, 1960.69) = 5.45$, $p = .020$], but not for the BAI [BAI $F(1, 5886.29) = 3.69$, $p = .054$]. However, the between-groups effect sizes were still medium for PCL [$g = 0.59$, 95% CI (0.15, 1.03)], and for BAI [$g = 0.55$, 95% CI (0.11, 1.00)], but small for the BDI-II [$g = 0.29$, 95% CI (-0.14,

0.72)] (See Table 2). The LOCF approach showed a significant interaction for all symptoms, with similar between-groups effect sizes (Table 6 from the supplemental material section).

Efficacy Analysis According to the Clinical Significance

Analyses of the clinical significance of the results document the findings that 91.7% of TF-CBT treatment completers dropped below the C-score for the BDI-II and BAI measures as did 78.3% of completers on the PCL-S, indicating that they had achieved "sub-syndromal" symptom levels. These findings were highly significant in comparison with the WL control group (all *p*s ≤ .003), where 40.4%, 52.2%, and 51.1% of people scored lower than the C-cutoff point for the PCL-S, BDI-II and BAI respectively. About half of completers also achieved "improvement" as assessed by the RCI, a proportion significantly higher compared to WL control subjects (56.5 vs. 31.1% PCL-S; 45.8% vs. 20.5% BDI-II; 54.2% vs. 26.7% BAI) (all *p*s ≤ .043). No person from the treatment group was reliably "deteriorated" after the intervention, while 13.3%, 9.1% and 15.6% from the control group had worsened their post-traumatic, depressive and anxiety symptoms, although these percentages were not significantly higher according to the chi^2 tests. At the 6-month FU, 86.4% and 72.7% of completers remained below the C-score for the BAI and BDI-II respectively, as did 68.6% for the PCL-S. According to the RCI, at FU, 45.5% and 36.4% of the completers still achieved "improvements" on BDI-II and BAI respectively, and 54.5% also reached this level for PCL-S. On the contrary, 5.6% and 11.1 % were reliably "deteriorated" in the PCL and the BAI respectively, although none had done so in the BDI-II.

Efficacy Analysis Controlling for Psychiatric Medication

In order to verify that the differences between experimental and control groups in analyses with completers were not due to the psychiatric medications, 2 (psychiatric medication: with

This is an Accepted Manuscript of an article published by Taylor & Francis in PSYCHOTHERAPY RESEARCH on 05 Mar 2025, available at: https://doi.org/10.1080/10503307.2025.2467380

vs. without medication) x 2 (treatment group: TF-CBT vs. WL) x 2 (time: pre-treatment vs. post-treatment) mixed ANOVAs were also conducted on the PCL-S, BDI-II, and BAI scores. No significant interaction between psychiatric medication, experimental group, and time was found on any of the measurements [PCL-S $F(1, 64) = 0.55$, $p = .460$, $\eta^2_p = .01$; BDI-II $F(1, 64) = 0.23$, $p = .634$, $\eta^2_p = .00$; BAI $F(1, 65) = 0.22$, $p = .644$, $\eta^2_p = .00$]; There was also no significant interaction between psychiatric medication and time (all $ps \geq .086$).

Within the TF-CBT treatment group, no significant interaction between psychiatric medication and time was found at FU [PCL-S $F(1, 20) = 3.49$, $p = .077$, $\eta^2_p = .15$; BDI-II $F(1, 20) = 1.94$, $p = .179$, $\eta^2_p = .09$; BAI $F(1, 20) = 2.00$, $p = .173$, $\eta^2_p = .09$].

Discussion

The objective of this paper was to present the results of a RCT designed to test TF-CBT, an evidence-based treatment for PTSD, but applied to long-term victims of terrorism, and not only considering PTSD but also MDD and anxiety disorders. The results of this study have demonstrated that the TF-CBT protocol was an efficacious treatment for victims who suffered from long-term PTSD. TF-CBT also appeared to be beneficial for long-term MDD and anxiety disorders, although these results were less conclusive. Therefore, the intervention continued to be efficacious but very specific for the treatment of PTSD, while the adaptations specifically done for the treatment of MDD and anxiety disorders were insufficient.

As for the PTSD, all treatment group "completers" who initially met diagnostic criteria at pre-treatment no longer met diagnostic criteria for PTSD at the post-treatment or follow-up assessments (0%), and these results were significantly better than those obtained by the control group (50%). Regarding the mITT analysis, this between-groups difference at post-treatment was still significant (10.1% vs. 50%).

This is an Accepted Manuscript of an article published by Taylor & Francis in PSYCHOTHERAPY RESEARCH on 05 Mar 2025, available at: https://doi.org/10.1080/10503307.2025.2467380

Table 2

PP (completers) and mITT Analyses of the Differences in the Psychological Symptomatology between Pre-treatment (Pre) and Post-treatment (Post) in the Treatment and Waiting list (WL) Groups and between Groups at Post-treatment

	Treatment Group					WL Group					Treatment vs. WL		
	Pre	Post	*Mean diff (SD diff)* [95% CI]	*t*	*g*	Pre	Post	*Mean diff (SD diff)* [95% CI]	*t*	*g*	*F* interact	$\eta^2 p$ inter	*g*
PP Analysis (completers)													
PCL	42.61 [a]	25.57 [a]	17.04 (13.17)	6.21***	1.25	41.60 [b]	37.27 [b]	4.33 (13.91)	2.09*	0.31	13.16***	0.17	0.94[e]
(SD)	(16.34)	(5.75)	[11.34, 22.74]			(14.54)	(15.22)	[0.15, 8.51]					
BDI	21.54 [c]	7.63 [c]	13.92 (13.08)	5.21***	1.03	19.25 [d]	15.75 [d]	3.5 (10.99)	2.11*	0.31	12.18***	0.16	0.72[f]
(SD)	(14.38)	(8.26)	[8.39, 19.44]			(12.69)	(12.35)	[0.16, 6.84]					
BAI	16.88 [c]	4.96 [c]	11.92 (9.93)	5.88***	1.16	19.18 [b]	15.91 [b]	3.27 (14.73)	1.49	0.22	6.64*	0.09	0.95[g]
(SD)	(12.48)	(6.50)	[7.72, 16.11]			(15.07)	(13.27)	[-1.15, 7.69]					
mITT Analysis													
	Treatment Group					WL Group					Treatment vs. WL		

	Pre [h]	Post [h]	*Mean diff* *(SD diff)* [95% CI]	*t*	*g*	Pre [i]	Post [i]	*Mean diff* *(SD diff)* [95% CI]	*t*	*g*	*F* interact	η^2p inter	*g* [j]
PCL	45.89	28.75	17.13 (17.41)	5.82***	0.96	40.47	37.62	2.85 (15.58)	1.29	0.18	8.40**	.06	0.59
(SD)	(15.50)	(14.55)	[11.33, 22.91]			(15.32)	(15.12)	[-1.47, 7.16]					
BDI	24.90	11.47	13.43 (19.02)	4.18***	0.69	18.36	15.77	2.59 (13.11)	1.40	0.19	5.45*	.04	0.29
(SD)	(15.17)	(16.81)	[7.25, 19.74]			(13.02)	(12.88)	[-1.04, 6.22]					
BAI	20.74	8.23	12.51 (15.32)	4.83***	0.80	19.51	15.82	3.69 (16.39)	1.59	0.22	3.69	.03	0.55
(SD)	(14.34)	(14.38)	[7.43, 17.59]			(16.07)	(13.17)	[-0.85, 8.24]					

Note: [a] $n = 23$; [b] $n = 45$; [c] $n = 24$; [d] $n = 44$; [e] *n treatment* = 23 *n WL = 47*; [f] *n treatment* = 24 *n WL = 46*; [g] *n treatment* = 24 *n WL = 47*; [h] $n = 35$; [i] $n = 50$; [j] *n treatment* = 35 *n WL = 50; SD* = Standard Deviation; * $p < .05$. ** $p < .01$. *** $p < .001$.

According to PP analyses (with completers), posttraumatic symptoms decreased significantly in the treatment group, with a large pre-post effect size (g = 1.25), that was comparable to other efficacy RCT on victims of terrorism with a WL control group design (d = 1.74 in Duffy et al., 2007) and to other non-experimental studies on Spanish victims of terrorism (d = 2.52 in Moreno et al., 2019). This pre-post effect size was also comparable to that shown in other studies on the treatment of trauma in general. According to the review conducted by Cahill et al. (2009), except for war veterans, the weighted mean effect size for victims of traumatic events who had completed treatment, was 1.73. The outcomes obtained in the mITT analysis were comparable to those found in similar WL RCTs on victims of terrorism that reported mITT evidence (g = 0.96 in the current study; d = 1.25 in Duffy et al., 2007). These results in the treatment group were also maintained in the 6-month follow-up, when posttraumatic symptomatology remained significantly lower, although the pre-follow-up effect size was lower in both PP and mITT analysis (g = 0.90, and g= 1.04, respectively), thus less comparable to the findings encountered in the previous scientific literature (g = 1.78 in Bryant et al., 2011; d = 2.10 in Duffy et al., 2007; d = 2.22 and 2.29 in Moreno et al., 2019) The results derived from the present study were significantly better than those obtained by the control group, with a large between-groups effect size in the PP analysis (g = 0.94). These findings corroborated the large effect sizes found in other efficacy trials with active control group conditions (g = 0.96 in Bryant et al., 2011; d = 1.54 in Difede, Cukor, et al., 2007; d = 1.37 and 1.66 in Difede, Malta, et al., 2007), although the between-groups effect size found in the mITT analyses was smaller (g = 0.59). The results were also comparable but smaller than other RCTs testing the efficacy of TF-CBT in all sorts of traumatic events. Among the WL RCTs included in Macedo et al. (2018) meta-analysis, some reported between-groups effect sizes that went from 1.52 to 1.92 in the case of completers (Chard, 2005; Foa et al., 1999). In

contrast, other WL RCTs conducted with victims of war with very long-term trauma (65 years before in Knaevelsrud et al., 2017) showed smaller between-group effect sizes (0.42). In turn, and according to the completers analyses, 78.3% of the individuals who had completed the treatment had sub-syndromal posttraumatic symptomatology levels according to the PCL-S, and 56.5% had improved in terms of their PTSD diagnosis. These outcomes were comparable or superior to those obtained in the other efficacy trials, whose weighted mean value was 50.9%, according to the review by Garcia-Vera et al. (2015). No short-term potential harms were found, since none of those who completed the intervention was reliably deteriorated, and there was no new diagnosis at the end of the treatment. However, 5.6% and 11.1 % of those who completed the 6-month FU were reliably "deteriorated" in their posttraumatic and anxiety symptoms, and one participant developed new diagnosis.

As for MDD and anxiety disorders, in the present study, a very high proportion of treatment completers no longer met diagnostic criteria at the conclusion of TF-CBT. In fact, at post-treatment, none of the TF-CBT treatment completers met criteria for MDD (0%), and the prevalence of anxiety disorders declined sharply and significantly from 80% at the beginning of the trial to 28% at the end, with these rates being very similar to those achieved in the follow-up (4.5% for MDD, and 27.3% for anxiety disorders). Once more, these results were significantly better than those from the control group, where 28% and 68% of the participants still had MDD and anxiety disorders at post-treatment, respectively. The differences between the treatment and control groups remained significant based on the mITT analysis (9.4% vs. 28% for MDD and 31.6% vs. 68% for anxiety disorders). However, with multiple imputations, the difference was not statistically significant for MDD.

Treatment completers also significantly decreased their symptom levels of BDI-II and BAI, according to PP analysis, with large pre-post effect sizes (g = 1.03 for BDI-II; g = 1.16 for BAI). These results underscored the findings from a limited number of other experimental

and non-experimental studies on victims of terrorism that examined co-morbid depression (*d* = 1.24 in Duffy et al., 2007; *d* = 2.06 in Moreno et al., 2019) or anxiety symptoms (*d* = 2.52 in Moreno et al., 2019). Significant treatment effects were also observed in the mITT analyses, with medium pre-post effect sizes (*g* = 0.69 for BDI-II; *g* = 0.80 for BAI), findings that were lower but still comparable to those found in other studies (*d* = 1.05 for depressive symptoms in Duffy et al., 2007). These results can also be compared with more general studies. In the Cuijpers et al., (2014) meta-analysis on the effectiveness of psychotherapy for major depression in adults, patients' BDI-II scores at post-intervention had decreased 12.7 points on average in the case of CBT and 15.1 points in the case of all types of psychotherapies, while in the present study that reduction was of 13.91 points (from 21.54 in pretreatment to 7.63 in posttreatment). Norton & Price (2007) estimated, in their meta-analysis of CBT for anxiety disorders in adults, pre-post effect sizes of 1.27-1.80.

The beneficial treatment results were maintained at 6-month follow-up for depressive symptomatology (*g* = 0.75 for BDI-II), as documented in a small number of prior studies (*g* = 1.22 in Bryant et al., 2011; *d* = 1.45 in Duffy et al., 2007; *d* = 2.06 and 2.52 in Moreno et al., 2019). Nevertheless, these pre-FU effect sizes were lower for anxiety (*g* = 0.59), contrary to what was observed in the previous study with Spanish population (*d* = 1.48 and 1.26 in Moreno et al., 2019). However, the pre-FU effect sizes were higher when mITT methodology was applied (*g* = 0.91 for BDI-II; *g* = 0.76 for BAI).

The outcomes obtained by the treatment group in relation to depressive and anxious symptomatology were significantly better than those obtained for the control group, with large between-groups effect sizes for completers in the BAI (*g* = 0.95) and medium for the BDI (*g* = 0.72), corroborating previous between-groups effect sizes for depression (*g* = 0.81 in Bryant et al., 2011; *d* = 0.86 in Difede, Malta, et al., 2007). Nevertheless, the effect sizes were smaller, according to the mITT analysis (*g* = 0.29 for BDI-II and *g* = 0.55 for BAI), and

did not reach significance for anxiety symptoms measured by the BAI. These results were comparable to those obtained on more general studies. For example, according to the meta-analysis of Werson et al., (2022) on the efficacy of CBT for depression in adult populations, effect sizes of $g = 0.48$ were found, favoring efficacy of CBT treatment over other conditions (passive or active control groups).

Moreover, 91.7% of the individuals who had completed the treatment had sub-syndromal depressive and anxiety symptoms, and 45.8% and 54.2% respectively had reliably improved. These data were coherent with those found by Springer et al. (2018), where the overall mean remission rates of anxiety disorder after the application of CBT was 51%.

However, the most distinguishing finding in the present study is that TF-CBT is efficacious for victims of terrorism whose traumatic exposure dates back two decades on average, when spontaneous recovery is very unlikely (Cukor et al., 2011; Morina et al., 2014; Neria et al., 2010). No other experimental study that was reviewed has enrolled patients whose exposure to a terrorist attack dates back almost 20 years, so these findings provide new evidence and generalisability on the efficacy of TF-CBT administered to victims of terrorism with long-duration and seemingly intractable CMDs.

An additional salient finding is that TF-CBT was equally efficacious for treatment completers regardless of whether they were currently taking prescribed psychiatric medications, something essential to explore, considering that almost 61% of participants had been prescribed psychiatric medications at some point in their lives after the terrorist attack.

Study Limitations

Several important methodological limitations should be noted. As a RCT with a WL control group, it was not possible to make the participants blind for their experimental conditions, since it was obvious if they would start their treatment immediately or delayed. The therapists were not blind either and were not equally distributed across conditions, and the post-

intervention interviewers were the therapists themselves. Lastly, the retrospective application of the SCID can be prone to bias and inter-rater reliability of the SCID interview was not assessed, something that could constrain the strength of the results. On the other hand, the sample size had an imbalance in the number of people in the treatment and control conditions. This imbalance was produced because 25 of 60 persons allocated to the experimental group declined the treatment and were not replaced in the randomization process. Although the baseline characteristics of the two groups (experimental and control) were comparable, the equivalence of those groups might have been disappeared by drop-out due to treatment refusal. The modified ITT analyses used in this study did not include all those refusals, something that could also be prone to bias (Abraha & Montedori, 2010). Besides, attrition was a major issue in this study. The drop-out rate prior to intervention was high, with 42% of both treatment and control groups not even accepting to initiate the therapy. Study abandonment or discontinuation was also noticeable, with 25 of 35 participants in the experimental group, and 17 of 29 participants in the control group who started TF-CBT completing the full course of intervention sessions while the other 10 (28.6%) and 12 (41.4%) abandoned treatment once it was underway. These rates of study abandonment were higher compared to findings of other psychotherapeutic interventions conducted with victims of terrorism (23.5%, according to Garcia-Vera et al. 2015). It cannot be ruled out that this dropout rate can be due to common factors, such as the differential success rate between therapists. However, it is also very likely that this pronounced attrition level could be related to two characteristics inherent to the study design: victims were offered treatment an average of 20 years after having suffered the terrorist attack, and they were recruited through an outreach approach, instead of responding to a direct or indirect request from them. It is also possible that many of those dropouts were sceptical of any type of therapy, considering that 60% and 60.8% of the total sample (n = 120), had already received

psychological or psychopharmacological help after the attack with no positive results. Additionally, there was a significantly higher number of relatives of people deceased in a terrorist attack among those who rejected to start the treatment, being the rate of spontaneous remission of anxiety-depressive symptomatology especially low in this particular group of victims (Garcia-Vera et al., 2021). Besides, the participants who abandoned the intervention proved to be older and displayed significantly higher symptomatology. These differences might indicate that the treatment was not tolerable for people with more severe and enduring symptomatology, and therefore, the conclusions gathered from this study should be considered with this caution. However, the reasons provided for not participating in the TF-CBT, for those who abandoned treatment were primarily related to other issues (e.g., time incompatibilities or unexpected events) (see Figure 1 from the supplemental material section). Also, of great importance is the finding of significantly favorable treatment effects for participants who attended a partial course of TF-CBT, considering the multiple imputations analysis. This methodology has proved its robustness even when up to 50% of the data are missing (Schafer & Graham, 2002) and its use with a reduced sample size does not seem to have overestimated the benefits of the intervention, since the results were always more conservative than the ones obtained with the LOCF approach.

Future Directions

The promising findings of the present study suggest several fruitful avenues for future research endeavors. First, the comparative efficacy of this treatment should be tested, replacing the WL group by more active and robust forms of control groups. Second, given the complexity of a multi-session intervention, a logical next step is to examine the specific contribution of both common and specific factors that could be playing a role. Third, it will be necessary to devise concrete motivational strategies for people in older age groups, with more severe and enduring symptoms, and for the group of relatives of those killed in terrorist

attacks. Fourth, it is clearly important to better adapt the intervention to the specificities of MDD and anxiety disorders. Fifth, although the positive outcomes derived from TF-CBT did not change when controlling for medication, the efficacy of psychiatric medications as an adjunct to TF-CBT deserves additional study.

Conclusions

Until new studies are published that obtain more favorable results on the efficacy of other psychological and psychopharmacological therapies, the results of this paper strongly support the idea that the TF-CBT is efficacious for victims of terrorism with prolonged and protracted PTSD. TF-CBT also appears to be beneficial for long-duration MDD and anxiety disorders. Nevertheless, the results for these last disorders are less conclusive.

Declarations and Ethic Statements

Ethical approval: This study has been approved by a university ethic committee (October 10th, 2011); **Clinical trial registration:** This RCT was registered at ClinicalTrials.gov (NCT05516368); **Consent to participate and publish:** Prior to participating, eligible individuals were provided with informed consent, which detailed the purpose of the research, the voluntary nature of participation, and data confidentiality. The participants consented to publish their data in a scientific journal; **Competing interests:** This work was supported by the Spanish Ministry of Science and Innovation (PSI2011-26450; PGC2018-098387-B-I00), the Spanish Ministry of Economy and Competitiveness (PSI2014-56531-P); the Spanish Association of Victims of Terrorism (270-2012, 283-2013, 53-2014, 100-2014, 192-2014, 40-2015, 134-2015, 22-2016); and the Complutense University of Madrid (FPI, 2010). The authors have no financial interest in promoting the psychological intervention presented here (e.g., manuals or courses); **Acknowledgements:** We want to thank the Spanish Ministry of Science and Innovation; the Spanish Ministry of Economy and Competitiveness; the Spanish Association of Victims of Terrorism; and the Complutense University of Madrid.

References

Abraha, I., & Montedori, A. (2010). Modified intention to treat reporting in randomised controlled trials: systematic review. *BMJ (Clinical research ed.)*, *340*, c2697. https://doi.org/10.1136/bmj.c2697

Adams, S. W., Allwood, M. A., & Bowler, R. M. (2019). Posttraumatic stress trajectories in World Trade Center Tower survivors: Hyperarousal and emotional numbing predict symptom change. *Journal of Traumatic Stress*, *32*(1), 67–77. https://doi.org/10.1002/jts.22357

American Psychiatric Association. (2000). *Diagnostic and Statistical Manual of Mental Disorders, (4th d., text rev.).* American Psychiatric Association.

Beck, A. T., & Steer, R. A. (2011). *Manual. BAI. Inventario de Ansiedad de Beck [Manual. BAI. Beck Anxiety Inventory]* (Spanish adaptation by Sanz, J.). Pearson Educación.

Beck, A. T., Steer, R. A., & Brown, G. K. (2011). *Manual. BDI-II. Inventario de Depresión de Beck-II [Manual. BAI. Beck Depression Inventory]* (Spanish adaptation by Sanz, J., & Vázquez, C.). Pearson Educación.

Bryant, R. A., Ekasawin, S., Chakrabhand, S., Suwanmitri, S., Duangchun, O., & Chantaluckwong, T. (2011). A randomized controlled effectiveness trial of cognitive behavior therapy for post-traumatic stress disorder in terrorist-affected people in Thailand. *World Psychiatry: Official Journal of the World Psychiatric Association (WPA)*, *10*(3), 205–209. https://doi.org/10.1002/j.2051-5545.2011.tb00058.x

Cahill, S. P., Rothbaum, B. O., Resick, P. A., & Follette, V. M. (2009). Cognitive-behavioral therapy for adults. In E. B. Foa, T. M. Keane, M. J. Friedman, & J. A. Cohen (Eds.), Effective treatments for PTSD: Practice guidelines from the International Society for Traumatic Stress Studies (2nd ed., pp. 139–222). The Guilford Press.

Chard K. M. (2005). An evaluation of cognitive processing therapy for the treatment of posttraumatic stress disorder related to childhood sexual abuse. *Journal of consulting and clinical psychology*, *73*(5), 965–971. https://doi.org/10.1037/0022-006X.73.5.965

Cuijpers, P., Karyotaki, E., Weitz, E., Andersson, G., Hollon, S. D., & van Straten, A. (2014). The effects of psychotherapies for major depression in adults on remission, recovery and improvement: a meta-analysis. *Journal of affective disorders*, *159*, 118–126. https://doi.org/10.1016/j.jad.2014.02.026

Cukor, J., Wyka, K., Mello, B., Olden, M., Jayasinghe, N., Roberts, J., Giosan, C., Crane, M., & Difede, J. (2011). The longitudinal course of PTSD among disaster workers deployed to the World Trade Center following the attacks of September 11th. *Journal of Traumatic Stress*, *24*(5), 506–514. https://doi.org/10.1002/jts.20672

Development Services Group, Inc. Global Terrorism Trends and Analysis Center (2024). *Annex of Statistical Information 2023. Country Reports on Terrorism 2023.* U.S. Department of State Bureau of Counterterrorism.

Difede, J., Cukor, J., Jayasinghe, N., Patt, I., Jedel, S., Spielman, L., Giosan, C., & Hoffman, H. G. (2007). Virtual reality exposure therapy for the treatment of posttraumatic stress disorder following September 11, 2001. *The Journal of Clinical Psychiatry*, *68*(11), 1639–1647. http://doi.org/10.4088/JCP.v68n1102

Difede, J., Malta, L. S., Best, S., Henn-Haase, C., Metzler, T., Bryant, R., & Marmar, C. (2007). A randomized controlled clinical treatment trial for World Trade Center attack-related PTSD in disaster workers. *The Journal of Nervous and Mental Disease*, *195*(10), 861–865. https://doi.org/10.1097/NMD.0b013e3181568612

Duffy, M., Gillespie, K., & Clark, D. M. (2007). Post-traumatic stress disorder in the context of terrorism and other civil conflict in Northern Ireland: Randomised controlled

trial. *BMJ (Clinical Research ed.)*, *334*(7604), 1147. https://doi.org/10.1136/bmj.39021.846852.BE

First, M. B., Spitzer, R. L., Gibbon, M. & Williams, J. B. W. (1999). *Guía del Usuario para la Entrevista Clínica Estructurada para los Trastornos del Eje I del DSM-IV. Versión Clínica. SCID-I [User's Guide to the Structured Clinical Interview for DSM-IV Axis I Disorders. Clinical Version. SCID-I]*. Masson.

Foa, E. B., Dancu, C. V., Hembree, E. A., Jaycox, L. H., Meadows, E. A., & Street, G. P. (1999). A comparison of exposure therapy, stress inoculation training, and their combination for reducing posttraumatic stress disorder in female assault victims. *Journal of consulting and clinical psychology*, *67*(2), 194–200. https://doi.org/10.1037//0022-006x.67.2.194

Foa, E. B., & Rothbaum, B. O. (1998). *Treating the Trauma of Rape: Cognitive-Behavioral Therapy for PTSD*. Guilford Press.

Garcia-Vera, M. P., Moreno, N., Sanz, J., Gutierrez, S., Gesteira, C., Zapardiel, A., & Marotta, S. (2015). Eficacia y utilidad clínica de los tratamientos para las víctimas adultas de atentados terroristas: una revisión sistemática. [Efficacy and clinical utility (effectiveness) of treatments for adult victims of terrorist attacks: A systematic review]. *Psicología Conductual- Behavioral Psychology, 23*, 215-244. https://www.behavioralpsycho.com/product/efficacy-and-clinical-utility-effectiveness-of-treatments-for-adult-victims-of-terrorist-attacks-a-systematic-review/?lang=en

Garcia-Vera, M. P., Sanz, J., & Gutierrez, S. (2016). A Systematic Review of the Literature on Posttraumatic Stress Disorder in Victims of Terrorist Attacks. *Psychological Reports*, *119*(1), 328–359. https://doi.org/10.1177/0033294116658243

Garcia-Vera, M. P., Sanz, J., & Sanz-Garcia, A. (2021). Ten Things Every Psychologist Should Know About Treating Psychological Disorders in Victims of Terrorism. *Psicothema*, *33*(2), 177–187. https://doi.org/10.7334/psicothema2021.33

Jacobson, N. S., & Truax, P. (1991). Clinical significance: a statistical approach to defining meaningful change in psychotherapy research. *Journal of Consulting and Clinical Psychology, 59*(1), 12–19. https://doi.org/10.1037//0022-006x.59.1.12

Jakobsen, J. C., Gluud, C., Wetterslev, J., & Winkel, P. (2017). When and how should multiple imputation be used for handling missing data in randomised clinical trials - a practical guide with flowcharts. *BMC medical research methodology*, *17*(1), 162. https://doi.org/10.1186/s12874-017-0442-1

Jordan, H. T., Osahan, S., Li, J., Stein, C. R., Friedman, S. M., Brackbill, R. M., Cone, J. E., Gwynn, C., Mok, H. K., & Farfel, M. R. (2019). Persistent mental and physical health impact of exposure to the September 11, 2001 World Trade Center terrorist attacks. *Environmental Health: A Global Access Science Source*, *18*(1), 12. https://doi.org/10.1186/s12940-019-0449-7

Knaevelsrud, C., Böttche, M., Pietrzak, R. H., Freyberger, H. J., & Kuwert, P. (2017). Efficacy and Feasibility of a Therapist-Guided Internet-Based Intervention for Older Persons with Childhood Traumatization: A Randomized Controlled Trial. *The American journal of geriatric psychiatry : official journal of the American Association for Geriatric Psychiatry*, *25*(8), 878–888. https://doi.org/10.1016/j.jagp.2017.02.024

Lobbestael, J., Leurgans, M., & Arntz, A. (2011). Inter-rater reliability of the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID I) and Axis II Disorders (SCID II). *Clinical Psychology & Psychotherapy*, *18*(1), 75–79. https://doi.org/10.1002/cpp.693

Lowell, A., Suarez-Jimenez, B., Helpman, L., Zhu, X., Durosky, A., Hilburn, A., Schneier, F., Gross, R., & Neria, Y. (2018). 9/11-related PTSD among highly exposed populations:

a systematic review 15 years after the attack. *Psychological Medicine*, *48*(4), 537–553. https://doi.org/10.1017/S0033291717002033

McGlinchey, J. B., Atkins, D. C., & Jacobson, N. S. (2002). Clinical significance methods: which one to use and how useful are they? *Behavior Therapy, 33*, 529-550. http://doi.org/10.1016/S0005-7894(02)80015-6

Macedo, T., Barbosa, M., Rodrigues, H., Coutinho, E. D. S. F., Figueira, I., & Ventura, P. (2018). Does CBT have lasting effects in the treatment of PTSD after one year of follow-up? A systematic review of randomized controlled trials. *Trends in psychiatry and psychotherapy*, *40*(4), 352–359. https://doi.org/10.1590/2237-6089-2017-0153

Moreno, N., Sanz, J., Garcia-Vera, M. P., Gesteira, C., Gutiérrez, S., Zapardiel, A., Cobos, B., & Marotta-Walters, S. (2019). Effectiveness of trauma-focused cognitive behavioral therapy for terrorism victims with very long-term emotional disorders. *Psicothema*, *31*(4), 400–406. https://doi.org/10.7334/psicothema2018.165

Morina, N., Wicherts, J. M., Lobbrecht, J., & Priebe, S. (2014). Remission from post-traumatic stress disorder in adults: a systematic review and meta-analysis of long term outcome studies. *Clinical Psychology Review*, *34*(3), 249–255. https://doi.org/10.1016/j.cpr.2014.03.002

Neria, Y., Olfson, M., Gameroff, M. J., DiGrande, L., Wickramaratne, P., Gross, R., Pilowsky, D. J., Neugebaur, R., Manetti-Cusa, J., Lewis-Fernandez, R., Lantigua, R., Shea, S., & Weissman, M. M. (2010). Long-term course of probable PTSD after the 9/11 attacks: a study in urban primary care. *Journal of Traumatic Stress*, *23*(4), 474–482. https://doi.org/10.1002/jts.20544

Norton, P. J., & Price, E. C. (2007). A meta-analytic review of adult cognitive-behavioral treatment outcome across the anxiety disorders. *The Journal of nervous and mental disease*, *195*(6), 521–531. https://doi.org/10.1097/01.nmd.0000253843.70149.9a

Rigutto, C., Sapara, A. O., & Agyapong, V. (2021). Anxiety, Depression and Posttraumatic Stress Disorder after Terrorist Attacks: A General Review of the Literature. *Behavioral Sciences (Basel, Switzerland)*, *11*(10), 140. https://doi.org/10.3390/bs11100140

Sanz, J. (2013). 50 años de los inventarios de depresión de Beck: Consejos para la utilización de la adaptación española del BDI-II en la práctica clínica. [50 years of the Beck Depression Inventories: Recommendations for the use of the Spanish adaptation of the BDI-II in clinical practice]. *Papeles Del Psicólogo, 34*(3), 161-168. https://www.papelesdelpsicologo.es/pdf/2275.pdf

Sanz, J. (2014). Recomendaciones para la utilización de la adaptación española del inventario de ansiedad de beck (BAI) en la práctica clínica [Recommendations for the use of the Spanish adaptation of the Beck Anxiety Inventory (BAI) in clinical practice]. *Clínica y Salud-Clinical and Health, 25*(1), 39-48. http://doi.org/10.1016/S1130-5274(14)70025-8

Sanz, J., & Garcia-Vera, M. P. (2015). Técnicas para el análisis de diseños de caso único en la práctica clínica: ejemplos de aplicación en el tratamiento de víctimas de atentados terroristas [Techniques for the analysis of single-case designs in clinical practice: Examples of application in the treatment of victims of terrorist attacks]. C*línica y Salud-Clinical and Health, 26*, 167-180. http://doi.org/10.1016/j.clysa.2015.09.004

Schafer, J. L., & Graham, J. W. (2002). Missing data: our view of the state of the art. *Psychological methods*, *7*(2), 147–177. http://doi.org/10.1037//1082-989X.7.2.147

Schneier, F. R., Neria, Y., Pavlicova, M., Hembree, E., Suh, E. J., Amsel, L., & Marshall, R. D. (2012). Combined prolonged exposure therapy and paroxetine for PTSD related to the World Trade Center attack: A randomized controlled trial. *The American Journal of Psychiatry*, *169*(1), 80–88. https://doi.org/10.1176/appi.ajp.2011.11020321

Schulz, K. F., Altman, D. G., Moher, D., & CONSORT Group (2010). CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMJ (Clinical research ed.)*, *340*, c332. https://doi.org/10.1136/bmj.c332

Springer, K. S., Levy, H. C., & Tolin, D. F. (2018). Remission in CBT for adult anxiety disorders: A meta-analysis. *Clinical psychology review*, *61*, 1–8. https://doi.org/10.1016/j.cpr.2018.03.002

Urbaniak, G. C., & Plous, S. (2013). *Research Randomizer* (Version 4.0) [Computer software]. Social Psychology network. http://www.randomizer.org/

van Buuren, S., & Groothuis-Oudshoorn, K. (2011). mice: Multivariate Imputation by Chained Equations in R. *Journal of Statistical Software*, *45*(3), 1–67. https://doi.org/10.18637/jss.v045.i03

Vazquez, C., Perez-Sales, P., & Matt, G. (2006). Post-traumatic stress reactions following the March 11, 2004 terrorist attacks in a Madrid community sample: a cautionary note about the measurement of psychological trauma. *The Spanish Journal of Psychology*, *9*(1), 61–74. https://doi.org/10.1017/s1138741600005989

Wang, X., & Ji, X. (2020). Sample Size Estimation in Clinical Research: From Randomized Controlled Trials to Observational Studies. *Chest, 158*(1S), S12–S20. https://doi.org/10.1016/j.chest.2020.03.010

Werson, A. D., Meiser-Stedman, R., & Laidlaw, K. (2022). A meta-analysis of CBT efficacy for depression comparing adults and older adults. *Journal of affective disorders*, *319*, 189–201. https://doi.org/10.1016/j.jad.2022.09.020

Zanarini, M. C., Skodol, A. E., Bender, D., Dolan, R., Sanislow, C., Schaefer, E., Morey, L. C., Grilo, C. M., Shea, M. T., McGlashan, T. H., & Gunderson, J. G. (2000). The Collaborative Longitudinal Personality Disorders Study: reliability of axis I and II

diagnoses. *Journal of Personality Disorders*, *14*(4), 291–299.

https://doi.org/10.1521/pedi.2000.14.4.291

Appendix

*Page numbers according to the complete version of the manuscript, with author details

Reporting checklist for randomised trial.

Based on the CONSORT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the CONSORTreporting guidelines, and cite them as:

Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials

		Reporting Item	Page Number
Title and Abstract			
Title	#1a	Identification as a randomized trial in the title.	1
Abstract	#1b	Structured summary of trial design, methods, results, and conclusions	1-2
Introduction			
Background and objectives	#2a	Scientific background and explanation of rationale	2-4
Background and objectives	#2b	Specific objectives or hypothesis	4
Methods			

Trial design	#3a	Description of trial design (such as parallel, factorial) including allocation ratio.	4-5
Trial design	#3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5
Participants	#4a	Eligibility criteria for participants	5
Participants	#4b	Settings and locations where the data were collected	5
Interventions	#5	The experimental and control interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6 Supplemental materials (Table 1)
Outcomes	#6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	7-8
Outcomes	#6b	Any changes to trial outcomes after the trial commenced, with reasons	8
Sample size	#7a	How sample size was determined.	8
Sample size	#7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomization – Sequence generation 6	#8a	Method used to generate the random allocation sequence.	
Randomization - Sequence generation	#8b	Type of randomization; details of any restriction (such as blocking and block size)	

6			
Randomization - Allocation concealment mechanism	#9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Randomization - Implementation	#10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to interventions	6
Blinding	#11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how.	6
Blinding	#11b	If relevant, description of the similarity of interventions	6
Statistical methods	#12a	Statistical methods used to compare groups for primary and secondary outcomes	8-10
Statistical methods	#12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	10
Results			
Participant flow diagram (strongly recommended)	#13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	12-14 Figure 1 Supplemental materials
Participant flow	#13b	For each group, losses and exclusions after randomization, together with reason	13-14

Recruitment	#14a	Dates defining the periods of recruitment and follow-up	12, 13
Recruitment	#14b	Why the trial ended or was stopped	14
Baseline data	#15	A table showing baseline demographic and clinical characteristics for each group	Table 2, supplementary materials
Numbers analysed	#16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	14
Outcomes and estimation	#17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	14-18
Outcomes and estimation	#17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	#18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	18-19
Harms	#19	All important harms or unintended effects in each group (For specific guidance see CONSORT for harms)	15, 18
Discussion			
Limitations	#20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	25-27

Generalisability	#21	Generalisability (external validity, applicability) of the trial findings	25
Interpretation	#22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	19-25
Registration	#23	Registration number and name of trial registry	5, 28
Protocol	#24	Where the full trial protocol can be accessed, if available	5, 28
Funding	#25	Sources of funding and other support (such as supply of drugs), role of funders	28

Other information

 This checklist can be completed online using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai