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# Does adding pharmaceutical medication contribute to empirically supported psychological treatment for anxiety disorders?

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## Abstract

**Background:** The goal of this work is to determine whether the combined use of empirically supported psychological treatments (ESTs) and pharmacological therapy (PT) achieves better results than the isolated use of ESTs in the treatment of Anxiety Disorders (AD) in a welfare clinical setting. **Method:** A quasi-experimental study was designed, with a sample of 287 patients with primary diagnosis of AD. Of the patients, 25.1% (n = 72) received ESTs+PT and 74.9% (n = 216), only ESTs. At pretreatment, no intergroup differences were observed in anxiety and depressive symptoms, duration of the problem and comorbidity, but there were differences for previous treatments (they were fewer in the EST group). **Results:** After the intervention, both groups showed similar degree of completion, compliance with treatment, task performance and similar effectiveness at post treatment but EST+PT was significantly longer (16.58 sessions vs. 13.04 sessions). **Conclusions:** It is concluded that adding PT to EST does not improve the results but it does increase the cost and duration of treatment, thereby reducing the efficiency of the intervention.

***Keywords:*** Anxiety disorders, empirically supported treatments, pharmacological treatment, treatment length, treatment effectiveness.

## Resumen

***¿Aporta algo añadir fármacos al tratamiento psicológico empíricamente apoyado para los trastornos de ansiedad?*** **Antecedentes:** el objetivo de este trabajo es determinar si, en el tratamiento de los Trastornos de Ansiedad en un contexto asistencial, el uso conjunto de Tratamientos Psicológicos Empíricamente Apoyados (TEAs) y Tratamiento Farmacológico (TF) consigue mejores resultados que el uso solo de TEAs. **Método:** se diseñó un estudio cuasiexperimental, con una muestra de 287 pacientes con diagnóstico primario de Trastorno de Ansiedad. El 25,1% de los pacientes (n= 72) recibió TEAs+TF y el 74,9% (n= 216) solo TEAs. En el pretratamiento no aparecieron diferencias intergrupo en el nivel de ansiedad y sintomatología depresiva, duración del problema y comorbilidad, pero sí en tratamientos previos (menos en el grupo de TEA). **Resultados:** tras la intervención ambos grupos mostraron valores similares en el porcentaje de éxito y efectividad, nivel de ejecución de tareas, puntualidad y asistencia, sin embargo hubo diferencias significativas en la duración del tratamiento, que fue significativamente más largo en el grupo de TEA+TF (16,58 sesiones frente 13,04 sesiones). **Conclusiones:** se concluye que añadir TF al TEA no mejora los resultados pero incrementa los costos y duración del tratamiento, reduciendo la eficiencia de la intervención.

***Palabras clave:*** trastornos de ansiedad, tratamientos empíricamente apoyados, tratamiento farmacológico, duración del tratamiento, efectividad.

Anxiety disorders (ADs) are frequently treated in clinical practice and are associated with important functional limitations of the people who suffer from them (Kessler, Chiu, Dernler, & Walters, 2005; Somers, Goldner, Waraich, & Hsu, 2006).

Empirically supported psychological treatments (ESTs) for ADs have been shown to be efficacious (Chambless & Ollendick, 2001; Labrador & Ballesteros, 2011; Norton & Price, 2007; Sánchez-Meca, Alcazar, & Olivares, 2004), using placebo control groups (Hofman & Smits, 2008) or in habitual clincial settings (Stewart & Chambless, 2009). In fact, there is increasing consensus considering ESTs the treatment of choice for ADs (National Institute for Health and Clinical Excellence [NICE], 2011).

But pharmacological treatments (PT), mainly based on anxiolytic and antidepressive medication, are a part of the habitual clinical treatment for anxiety problems (Ministerio de Sanidad y Consumo [Ministry of Health and Consumption], 2008), although EST has been shown to be more effective than the usual treatment (PT) provided in Primary Attention (Roy-Byre et al., 2010). Consumption of psychotropics for ADs is increasing exponentially each year and is higher in women, tending to increase with age (Alonso et al., 2004; Ministerio de Salud y Consumo, 2006). In Primary Care, 32.9-66.2% of the cases of anxiety problems were precribed PT (Secades et al., 2003; Demyttenaere et al., 2008).

Some studies have verified that adding EST to PT increases compliance with PT, reduces relapse rates, and improves maintenance of the gains (Barlow, Gorman, Shear, & Woods, 2000; Otto, Penava, Pollock, & Smoller, 1996; Otto, Smits, & Reese, 2005). On the other hand, some investigators argue that PT

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can promote and facilitate the implementation of EST techniques, such as relaxation, or favor the processes of desensitization and extinction in exposure techniques (Barlow et al., 2000; Blanco et al., 2010; Norberg, Krystal, & Tolin, 2008) as well as improving the effectiveness of EST. In contrast, some investigations report that including PT in EST is inappropriate because: (a) combining EST and PT contributes no benefits to the use of ESTs (Franklin, Abramowitz, Bux, Zoellner, & Feeny, 2002; Otto, McHugh, & Kantak, 2010; Van Balkom, de Haan, van Oppen, Spinhoven, Hoogduin, & van Dyck, 1998); or (b) PT can interfere negatively with the implementation of ESTs or with the therapeutic process itself (Barlow et al., 2000; Haug et al., 2003; Marks et al., 1993; Otto et al., 2005). However, the meta-analisis of Bandelow, Seidler-Brandler, Becker, Wedekind, & Rüther (2007) indicates that there is not enough evidence for some ADs, whereas for others, the evidence may be positive or negative, depending on the specific AD.

According to this state of the issue, the goal of this work is to identify whether there is any advantage to combining ESTs and PT for ADs in the assistential setting, in comparison with isolated EST. Specifically, it attempts to determine whether the combined treatment: (a) increases the percentage of therapeutic improvements and reduces anxiety levels; (b) reduces treatment duration (number of sessions); and (c) improves performance of the tasks to be carried out by the patients in their natural environment.

## Method

### *Sample and procedure*

The final sample comprised 287 self-referred patients, aged 18 years or older, who requested assistance at the University Clinic of Psychology of the Complutense University of Madrid. They all presented at least a diagnosis of anxiety according to criteria of the *Diagnostic and Statistical Manual of Mental Disorders IV-TR* (American Psychiatric Association [APA], 2000). Participants were nonrandomly assigned to one of the two treatment groups (EST+PT and EST), comprising an incidental sample. Of the patients, 74.9% (215 patients) were assigned to the EST Group. The participants who consumed at least anxiolytics or antidepressants (medications of choice for ADs [NICE, 2011; Ministerio de Salud y Consumo, 2008]) were assigned to the EST+PT Group (n = 72; 25.1%). Of these, 55.5% ($n$ = 40) only received anxiolytics, 11.1% ($n$ = 8) received antidepressants, and 33.3% ($n$ = 24) received two or more drugs that included at least one of the former.

The participants of the study had concluded their contact with the Clinic, either through discharge (successful end of treatment) or because they had dropped out of treatment. The therapists were licensed psychologists with, at least, a postgraduate title of specialization in Clinical Psychology. More detailed information about the University Psychology Clinic can be obtained in Labrador, Estupiñá, & García-Vera (2010). Interviews (Muñoz, 2003), questionnaires, and self-reports were used to establish the diagnosis. The EST, carried out in weekly 1-hour sessions, had a variable duration, and concluded either due to therapeutic discharge or dropout.

The use of EST techniques was homogeneous in both groups, and the most frequent were psychoeducation, deactivation techniques, exposure, cognitive techniques, and techniques to control internal dialogue (used in 80% of the cases, on average). Techniques such as problem solving and training in social skills played a secondary role (used in about 50% of the cases). PT was prescribed before contact with the center by outside professionals in 81.9% of the patients of the EST+PT group. The therapists in charge of the EST did not control the prescription, follow-up, or withdrawal of the PT.

### *Measures*

*Sociodemographic variables*. Sex, age, civil status, number of people with whom they live, educational level, and work situation were obtained with an ad hoc questionnaire applied at the beginning of the intervention.

*Clinical variables*. These included diagnosis, level of depressive symptomatology, comorbidity and duration of the problem, and number of prior treatments. To measure depressive and anxious symptomatology, we used the Beck Depression Inventory-II (BDI-II; Beck, Steer, & Brown, 1996), Beck Anxiety Inventory (BAI; Beck, Epstein, Brown, & Steer, 1988; Sanz & Navarro, 2003), and other validated instruments for the assessment depending on the disorder under consideration, for example: Mobility Inventory for Agoraphobia (Chambless, Caputo, Jasin, Gracely, & Williams, 1985), the Penn State Worry Questionnaire (Meyer, Miller, Metzger, & Borkovec, 1990), Fear of Negative Evaluation Scale (Watson & Friend, 1969), The Maudsley Obsesional-Compulsive Inventory (Hodgson, 1977) or Fear Questionnarie (Mathew, Gelder, & Jhonston, 1986).

*Treatment variables*. Number of assessment, treatment, and follow-up sessions, level of task performance (percentage of tasks completed), punctuality and session attendance (percentage of missed sessions or unjustified delays), and treatment outcome (discharge/dropout) were obtained from the final treatment report written by the therapist. Also, pre-post changes in anxiety level were obtained from the questionnaires administered to patients who completed both the intervention and the posttreatment measures ($n$ = 113; 56.2% of the patients who completed treatment).

### *Data analysis*

To determine the existence of statistically significant differences, $t$-tests or $\chi^2$ were performed. The variables that were susceptible to covariation were included in a general linear univariate model to control for their influence on the analysis of intergroup differences in session attendance and punctuality, task performance, successful treatment outcome, and reduction of anxiety level at posttreatment. The scores of the patients who completed treatment and the posttreatment questionnaires were transformed to a 0-100 scale (100 corresponding to the highest pathological score). When more than one instrument was administered, the transformed mean was calculated. An intragroup and intergroup ANCOVA was conducted, and the intragroup effect size was calculated with the Cohen's $d$ statistic

## Results

### *Sociodemographic variables*

Mean age of the final sample was 30 years ($SD$ = 10.05), and 72.5% were female. Of the sample, 47% were students, and 44.6% lived with three or more people. The only significant group

differences in the sociodemographic variables were higher mean age in the EST+PT group [34.01 years vs. 28.7 years in the EST group, $t(285) = -3.56$, $p<.001$], a higher percentage of married people in the EST+PT group [38.9% vs. 22.8% in the EST group, $\chi^2(1) = 7.12$, $p = .008$], and a higher percentage of students in the EST group [53% vs. 29.2% in the EST+PT group, $\chi^2(1) = 13.97$, $p = .001$] (Table 1).

*Clinical variables*

a) Clinical variables assessed at *pretreatment:* there were only significant group differences in the percentage of prior treatments received; most of the EST+PT patients (81.9%) had had some prior treatment (either pharmacological, psychological, or both), versus 43.3% in the EST group, $\chi^2(1) = 32.10$, $p<.001$. In the remaining variables—level of anxious and depressive symptomatology, duration of the problem, comorbidity—no group differences were found. It is noteworthy that about 20% of the patients in both groups presented at least one other diagnosis in addition to AD. Regarding the mean duration of the problem, 24% of the sample could not place the onset of their problem at a specific time, or they were imprecise, the remaining 76% referred to a duration of the problem longer than 40 months, somewhat higher in the EST+PT group (52.17 months), although the differences were nonsignificant. The mean scores of anxious and depressive symptomatology indicated characteristic levels of moderate-to-severe pathology.

b) Clinical variables at *treatment:* There were no group differences in the number of assessment and follow-up sessions, but there were differences in the number of treatment sessions. Treatments for the EST+PT group were longer (mean of 16.58 sessions) than those of the EST group (13.3 sessions), $t(97) = -2$, $p = .04$. The combined treatment lasted an average of 3.5 sessions more, an increase of 21.4%.

*Table 1*
Sociodemographic characteristics of EST and EST+PT patients

| | Type of treatment | | $\chi^2$ / t [a] | *p* |
|---|---|---|---|---|
| | **EST** ***N* = 215** | **EST+PT** ***N* = 72** | | |
| Sex *n* (%) | | | | |
| Males | 59 (27.4) | 20 (27.8) | .003 | .956 |
| Females | 156 (72.6) | 52 (72.2) | | |
| Age | | | | |
| *M* (*SD*) [Range] | 28.7 (10.05) [18-77] | 34.01(13.05) [18-72] | -3.586 | <.001*** |
| Civil status *n* (%) | | | | |
| Single | 166 (77.2) | 44 (61.1) | 7.12 | .008** |
| Married/Partner | 49 (22.8) | 28 (38.9) | | |
| Social support *n* (%) (People with whom patient lives) | | | | |
| Nobody | 16 (7.7) | 5 (6.9) | .848 | .838 |
| One person | 47 (22.6) | 20 (27.8) | | |
| Two people | 49 (23.6) | 15 (20.8) | | |
| Three or more people | 96 (46.2) | 32 (44.4) | | |
| Educational level *n* (%) | | | | |
| Primary incomplete | 2 (0.9) | 1 (1.4) | 4.445 | .349 |
| Primary complete | 9 (4.2) | 7 (9.9) | | |
| Secondary | 71 (33) | 26 (36.6) | | |
| University diploma | 45 (20.9) | 11 (15.5) | | |
| University degree | 88 (40.9) | 26 (36.6) | | |
| Work situation *n* (%) | | | | |
| Active | 80 (37.2) | 36 (50) | 13.97 | <.001*** |
| Student | 114 (53) | 21 (29.2) | | |
| Other | 21 (9.8) | 15 (20.8) | | |

*Note*: EST = empirically supported therapy, EST+PT = empirically supported therapy + pharmacological therapy.
[a] *t*-tests were performed for continuous variables. For noncontinuous variables, $\chi^2$ was performed.
* $p<.05$; ** $p<.01$; *** $p<.001$

*Table 2*
Clinical characteristics of EST and EST+PT patients

| | Type of treatment | | $\chi^2$/t[a] | *P* |
|---|---|---|---|---|
| | **EST** ***N* = 215** | **EST+PT** ***N* = 72** | | |
| Prior treatments *n* (%) | | | | |
| None | 119 (56.7) | 13 (18.1) | 32.104 | < .001*** |
| One or more | 91 (43.3) | 59 (81.9) | | |
| Comorbidity *n* (%) | | | | |
| No | 169 (78.6) | 56 (77.8) | .022 | .88 |
| At least one additional diagnosis | 46 (21.4) | 16 (22.2) | | |
| Duration of problem (months)[o] *M* (*SD*) [Range] | 40.44 (57.47) [1-480] | 52.17 (82.50) [1-456] | -.99 | .33 |
| Number of assessment sessions *M* (*SD*) [Range] | 3.40 (1.12) [1-7] | 3.57 (1.44) [1-8] | -.92 | .36 |
| Number of treatment sessions *M* (*SD*) [Range] | 13.03 (9.94) [1-66] | 16.58 (13.89) [1-66] | -2.00 | .04* |
| Number of follow-up sessions *M* (*SD*) [Range] | 1.08 (1.54) [1-3] | 1.44 (1.74) [1-4] | -1.49 | .14 |
| Pretreatment depressive symptomatology (BDI-II) *M* (*SD*) [Range] | 20.79 (11.12) [0-47] | 22.15 (10.90) [2-51] | -.80 | .42 |
| Pretreatment anxious symptomatology (BAI) *M* (*SD*) [Range] | 20.96 (13.49) [3-59] | 28.14 (11.52) [8-43] | -1.66 | .11 |

*Note*: EST = empirically supported therapy, EST+PT = empirically supported therapy + pharmacological therapy.
[a] *t*-tests were performed for continuous variables. $\chi^2$ was performed for noncontinuous variables
* $p<.05$; ** $p<.01$; *** $p<.001$.
[o] Refers to the 76% of the sample who situated the onset of their problem at a certain time. The remaining 24% stateed that they had always had this problem or they did not know when it started

*Variables of treatment course and outcome*

After including the variables susceptible to covariation in the general univariate model (Tables 1 and 2), we confirmed the absence of significant differences between the EST and EST+PT groups in the following variables: discharges/dropouts, level of task performance, punctuality and session attendance, and reduction of anxiety levels al posttreatment. The high percentage of discharges (69.3% in the EST group and 72.2% in the EST+PT group) is noteworthy. Also notable is the fact that about two thirds of the patients performed at least 75% of the tasks assigned, as well as their high attendance and punctuality (about 85% of the patients in both criteria).

There were no pretreatment differences between EST and EST+PT in anxiety levels on the modified scale (0-100) derived from the questionnaires. There were significant intragroup reductions of anxiety level, $F(1,110) = 18.40$, $p<.001$, with an effect size of $d = 1.32$ for EST and $d = 1.46$ for EST+PT. However, such reductions were nonsignificant as a function of the treatment group, $F(1,110) = .73$, $p = .87$ (Table 3).

*Table 3*
Variables of treatment course and outcome

| | Type of treatment | | $\chi^2$ / t[a] | *p* |
|---|---|---|---|---|
| | **EST** *N* = 215 | **EST+PT** *N* = 72 | | |
| Completed successfully/dropped out *n* (%) | | | | |
| Discharged | 149 (69.3) | 52 (72.2) | .22 | .64 |
| Dropouts | 66 (30.7) | 20 (27.8) | | |
| Level of task performance *n* (%) | | | | |
| Higher than 75% performance | 133 (66.2) | 45 (63.4) | | |
| Between 50 and 75% performance | 40 (19.9) | 19 (26.8) | 1.87 | .39 |
| Below 50% performance | 28 (13.9) | 7 (9.9) | | |
| Punctuality and session attendance *n* (%) | | | | |
| Attended sessions and arrived punctually at least 75% of the times | 173 (85.2) | 45 (86.1) | | |
| Missed sessions or arrived late without warning between 50 and 75% of the times | 40 (12.3) | 19 (11.1) | .09 | .96 |
| Missed sessions or arrived late without warning more than 50% of the times | 28 (2.5) | 7 (2.8) | | |
| Pre-posttreatment level of anxiety[b] *N* = 113 (n) | (81) | (32) | | |
| Pretreatment mean (*SD*) | 45.5 (18.4) | 40.9 (15.7) | .76 | .44 |
| Posttreatment mean (*SD*) | 21.1 (14.8) | 17.8 (13.1) | | |
| Intragroup factor: $F^c = 18.40$; $p<.001$*** | | | | |
| Intergroup factor (EST, EST+PT): $F^c = .07$, $p = .78$ | | | | |

*Note*: EST = empirically supported therapy, EST+PT = empirically supported therapy + pharmacological therapy.
[a] *t*-tests were performed for continuous variables. $\chi^2$ was performed for noncontinuous variables.
[b] Level of anxiety on a 0-100 scale after transforming the questionnaire scores (100 = maximum pathology).
[c] F resulting from the ANCOVA with intergroup factor Type of Treatment (EST or EST+PT) and with intragroup factor Pre-Post Treatment.
* $p<.05$; ** $p<.01$; *** $p<.001$

## Discussion

Of the 287 patients who made up the sample, 25.2% consumed anxiolytics, antidepressants, or both (EST+PT group). These data are somewhat lower than those found in the studies of the ESEMeD showing that these medications are consumed by about 33% of people with anxiety problems (Alonso et al., 2004; Demyttenaere et al., 2008).

As observed in other works, almost two thirds of our patients with AD were female (Labrador et al., 2010; Ministerio de Sanidad y Consumo, 2006; Valero & Ruiz, 2003), with similar percentages in both experimental groups. There were age differences (the EST+PT group had a mean age of 34 years vs. 27.8 years in the EST group), in accordance with the findings of the National Health Survey of Spain and ESEMeD (Alonso et al., 2004; Demyttenaere et al., 2008; Ministerio de Sanidad y Consumo, 2006), and the likelihood of consuming anxiolytics and antidepressants increases with age. This may also explain the significantly higher number of patients with prior treatments, the longer duration of the problem, and married and employed people found in the EST+PT group versus the EST group.

Also noteworthy is the low comorbidity (around 22%), with no group differences, and lower than that usually estimated in the literature, which is about 50% (Goisman, Goldenberg, Vasile, & Keller, 1995; Kessler, 2011; Kessler et al., 2005). In this work, the diagnosis may have been more accurate due to the possibility of a more exhaustive assessment (3.5 sessions on average). Nevertheless, although the percentage of cases with an additional diagnosis is small, the mean value of depressive symptoms in both groups is about 21.5 (according to the BDI-II), indicating the well-known high relation between ADs and depressive symptomatology (Goisman et al., 1995; Kessler et al., 2005).

The number of assessment and follow-up sessions, similar in both groups (around 3.5 assessment sessions and 1 follow-up session), was high—albeit habitual— for assessment and low for follow-up (Labrador et al., 2010).

According to the 0-100 transformed scale, prior levels of anxiety were similar in both groups (and even somewhat higher in the EST group), and both groups showed similar effectiveness at posttreatment, with very similar effect sizes ($d = 1.32$ and $d = 1.46$, for EST and EST+PT, respectively). They were slightly higher than those found, for example, by Bados, Balaguer, & Saldaña (2007), who reported an effect size of $d = 1.09$ in cognitive-behavioral therapy for anxiety problems. There were no significant group differences in the level of task performance (about 65% of the patients completed at least 75% of the tasks) and punctuality and session attendance (about 85.5% of the patients had high levels). Also, the number of discharges (about 71%) and drop-outs (about 29%) was similar in both groups and to that reported in other works examining effectiveness (Bados et al., 2007). However, treatment in the EST+PT group was significantly longer (a mean of 16.58 sessions) than in the EST group (a mean of 13 sessions). That is, duration of the psychological treatment was prolonged by 21.4% in the EST+PT group.

This indicates that adding medication to psychological ESTs for anxiety problems does not contribute clinical benefits in terms of treatment success, supporting the findings of prior works (Barlow et al., 2000; Haug et al., 2003; Marks et al., 1993; Otto et al., 2005), and, moreover, such a combination significantly prolongs treatment duration, so that EST+PT entails higher costs. Taking as

reference the minimum fees proposed by the Official Association of Psychologists in 2009 (48€ per session), increasing by 3.5 sessions involves an additional cost of 168€. To this, one would have to add the cost of the PT and the cost of the professional and the center.

This is a cuasiexperimental study, with nonrandom allocation, so it has the methodological limitations that are characteristic of the clinical setting in which it was carried out. In addition, only 113 patients completed the questionnaires at posttreatment (56.2% of the patients who completed treatment).

This work analyzes two types of treatment (EST and EST+PT) for ADs. We therefore consider that it would be interesting to observe whether the same results are found in future works when the type of AD diagnosis is also taken into account.

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