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The mediating role of emotion regulation in transdiagnostic cognitive behavioural therapy for emotional disorders in primary care: Secondary analyses of the PsicAP randomized controlled trial

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ABSTRACT

Background: Emotional disorders are highly prevalent in primary care. Transdiagnostic cognitive behavior therapy (TD-CBT) is a promising treatment of emotional disorders. In this study, we evaluated several emotion regulation strategies as potential mediators of treatment outcomes in a clinical sample of primary care.
Methods: A total of 1061 primary care patients were included in a randomized clinical trial comparing treatment-as-usual (TAU) to TD-CBT+TAU. Of these, 631 (TAU=316; TD-CBT+TAU=315) completed the full treatment and all pre- and post-treatment scales to assess symptoms (anxiety, depression, somatization), emotion regulation strategies (worry, rumination, negative metacognition, suppression, cognitive reappraisal), overall functioning, and quality of life (QoL).
Results: Treatment and direct effects showed that TD-CBT+TAU was superior to TAU alone. On the multivariate mediation analysis of indirect effects, three maladaptive strategies (worry, rumination and negative metacognition) had significant effects on all emotional symptoms. Suppression was also significant for depression. Rumination and negative metacognition were significant mediators of functioning, while only negative metacognition was significant for QoL. Reappraisal had no effect on any outcome.
Limitations: We focused mainly on maladaptive cognitive emotion regulation strategies and only studied one behavioural strategy (suppression) and one adaptive strategy (reappraisal).
Conclusions: Targeting certain maladaptive emotion regulation strategies (worry, rumination, suppression, negative metacognition) as mediators for treatment with TD-CBT could reduce emotional symptoms and improve well-being. Negative metacognition was the most transdiagnostic strategy, whereas an adaptive strategy such as reappraisal was not a mediator. Thus, maladaptive emotion regulation strategies are key mediators in transdiagnostic therapy for emotional disorders in primary care.

1. Introduction

Cognitive behavioural therapy (CBT) has been shown to be an effective treatment for common mental disorders, including depression (Cuijpers et al., 2019b) and anxiety disorders (Seekles et al., 2013), in the primary care setting. This is important given that these are two of the most prevalent and disabling mental health disorders in the population (Whiteford et al., 2013; 2015). CBT has many benefits. Not only it is

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cost-effective (Chisholm et al., 2016; Layard and Clark, 2015), but it is relatively easy to deliver on a wide scale in public health systems (Clark, 2018). Based on recent data, transdiagnostic therapies represent a highly promising approach for the treatment of mental disorders because the same therapy can be used to treat several different disorders (Cassiello-Robbins et al., 2020), and can be delivered in a group format (Cano-Vindel et al., 2021; Roberge et al., 2020), which makes them even more cost-effective.

Recently, several transdiagnostic perspectives that leveraged two central aims have generated a great deal of interest (Fusar-Poli et al., 2019). First, some perspectives are based on studying the similar effects that certain treatments such as CBT have on different diagnostic groups (Newby et al., 2015; Norton et al., 2013), while others are more focused on the study of the common etiological processes shared by these conditions such as cognitive-affective or behavioural factors (Caspi et al., 2014; Kotov et al., 2021). In recent years, there has been a growing interest in assessing the individual components of CBT, particularly transdiagnostic CBT (TD-CBT), in order to better identify the specific aspects of CBT that are the main drivers of treatment outcomes (Cuijpers et al., 2019a; Holmes et al., 2018). In this line of research, there is a special interest in gaining a better understanding of the role of mediators and mechanisms of change in psychotherapy (Hofmann and Hayes, 2019; Høglend and Hagtvet, 2019). In this context, emotion regulation is a major target of TD-CBT (Sakiris and Berle, 2019; Sloan et al., 2017). This perspective posits that CBT can be used to train patients to improve certain cognitive and behavioural emotion regulation strategies, which in turn may help to reduce symptoms (Naragon-Gainey et al., 2017; Picó-Pérez et al., 2017). Sloan et al. (2017) suggested that effectiveness of transdiagnostic treatments may be attributable to a reduction in some maladaptive emotion regulation strategies (e.g., rumination, worry, and suppression) while simultaneously increasing other, more adaptive strategies (e.g., reappraisal or distraction). Other transdiagnostic approaches have focused more on reducing comorbidity in individuals with anxiety disorders (Norton et al., 2013; Norton and Barrera, 2012); indeed, such strategies have proven effective when delivered in a group format in the primary care setting (Roberge et al., 2020). The available data suggests that the effectiveness of this treatment approach in reducing anxiety is mainly due to its capacity to target mediators such as negative affect and intolerance to uncertainty (Talkovsky and Norton, 2014). Some authors have suggested that metacognition may be a potential mechanism of change in psychotherapy (Misso et al., 2019), while other researchers have focused on behavioral activation (Dimaggio and Shahar, 2017) or other more positive/adaptive strategies such as hope (Gallagher et al., 2020) and cognitive reappraisal (Gross, 2015).

Recently, a large (1061 patients) randomized controlled trial (RCT) conducted in Spain (Cano-Vindel et al., 2021) demonstrated the effectiveness of TD-CBT for emotional disorders (anxiety, depression, and somatization) in the primary care setting. In that trial (the PsicAP study), participants were randomized to either treatment-as-usual (TAU) or group TD-CBT plus TAU. The results showed that TD-CBT plus TAU was highly efficacious in reducing symptoms and improving both quality of life (QoL) and functioning. More than 300 patients were treated in both groups, with 12-month follow-up data available for nearly 200 in each group. TD-CBT significantly reduced emotional symptoms, with medium to large effect sizes (d=−0.65 to −1.01) at the post-treatment evaluation, and these results were sustained over time. Patients in the experimental arm also obtained significant improvements in the secondary outcome measures, with small to medium effect sizes for functioning (d=−0.26 to −0.51) and several QoL domains (d = 0.31 to 0.61); moreover, these effect sizes were even greater at the 12-month follow-up assessment (d = 0.29 to 0.73). In addition, large between-group effect sizes (d >0.80) were observed for reliable recovery rates, which were similar to those achieved in the IAPT program in the United Kingdom (Clark, 2018; Wakefield et al., 2020) and Norway (Knapstad and Nordgreen, 2018; Knapstad et al., 2020). The results of the PsicAP trial are particularly notable given that the group therapy was provided in a transdiagnostic framework with different emotional disorders.

The focus of the PsicAP project was to treat emotion regulation strategies that have been shown to play a transdiagnostic role in emotional disorders (Aldao et al., 2010; Picó-Pérez et al., 2017; Sun et al., 2017). Some of these maladaptive strategies, such as rumination or worry, are closely associated with anxiety and depression disorders (Aldao et al., 2010; Kircanski et al., 2015; McLaughlin and Nolen--Hoeksema, 2011) and with negative metacognition (Sun et al., 2017; Wells, 2008). Also, an adaptive strategy known as cognitive reappraisal, which reflects an effort to change the subjective evaluation of an emotion-generating situation to modify its emotional impact (Gross, 2015), may also help to reduce symptoms and improve wellbeing when patients are trained to use this coping strategy (King and dela Rosa, 2019; Picó-Pérez et al., 2017). Expressive suppression is an emotion regulation strategy first described by Gross (2015) that regulates behavioural or emotional response after an emotion has been generated. This strategy has been associated with anxiety, although the evidence for its role in depression is mixed (Dryman and Heimberg, 2018). Adaptive and maladaptive emotion regulation strategies appear to use different cognitive and neural pathways (Picó-Pérez et al., 2019).

Clearly, much valuable research has been performed in this area, but we still need to better determine the transdiagnostic strategies that are most effective in reducing symptoms of anxiety, depression and somatizations. We also need to understand how these strategies reduce symptoms and improve measures of wellbeing (e.g., functioning or QoL) in order to gain insights into which approach works best for a given condition/symptom, and how it works. This would provide a better understanding of transdiagnostic treatments. Given this background, we performed a secondary analysis of data from the PsicAP RCT using the measures administered after treatment completion to evaluate, in an exploratory manner, the mediating effects of emotion regulation strategies in primary care patients with emotional disorders who underwent TD-CBT+TAU versus TAU alone.

2. Methods

2.1. Participants and procedure

The PsicAP study (Cano-Vindel et al., 2021) was an RCT conducted at 22 primary care centres within the Spanish National Health System. General practitioners (GP) invited adult patients (ages 18 to 65) with a diagnosis or suspected diagnosis of an emotional disorder to participate in the trial. A total of 1061 participants were included and randomized to TAU delivered by the recruiting GP (controls) or TD-CBT+TAU (experimental arm). Trained clinical psychologists delivered seven group sessions of TD-CBT (groups of 8–10 patients) over a 12–14 week period to train patients in cognitive and behavioural techniques to help regulate emotions (see Cano-Vindel et al., 2016 for more details on the training protocol). The TAU intervention consisted of regular consultations with the GP. Patients in this group with emotional complaints received TAU, which mainly consisted of the prescription of anxiolytics, antidepressants, or hypnotics, and/or informal counselling/support. For the present study, we used the per-protocol sample (see Cano-Vindel et al., 2021), which consisted of 631 patients in the two groups (TAU=316 vs TD-CBT+TAU=315) who completed all pre- and post-treatment measures. The study was conducted in accordance with the principles of the Declaration of Helsinki and following the Spanish Law on Data Protection (EUDRACT: 2013–001,955–11 and Protocol Code: ISRCTN58437086).

2.2. Instruments

2.2.1. Measures of symptoms

Generalized anxiety disorder-7 (GAD-7): The GAD-7 was used to assess symptoms of GAD. On this instrument, participants are asked to rate the frequency of anxiety symptoms during the past 2 weeks (total score

range: 0–21), on a 4-point Likert scale from 0 (*not at all*) to 3 (*nearly every day)*. We used the validated Spanish version of the GAD-7 scale (García-Campayo et al., 2010), which is also valid for Spanish primary care patients and has shown excellent psychometric properties (Moreno et al., 2019; Muñoz-Navarro et al., 2017a). Mean (standard deviation [SD]) scores were 12.3 (4.6) and the internal consistency of the scale was good (α=0.87).

Patient Health Questionnaire-9 (PHQ-9): The PHQ-9 (Kroenke et al., 2001) was used to assess symptoms of depression. This scale contains nine items based on DSM-IV criteria for major depression evaluated on a 4-point Likert scale from 0 (*not at all*) to 3 (*nearly every day)*, with a total score range from 0 to 27. The instrument has good psychometric properties (sensitivity and specificity), and was validated in a sample of participants in the primary care setting in Spain (Muñoz-Navarro et al., 2017b). The mean (SD) score on the PHQ-9 was 13.6 (5.4). The scale showed a good internal consistency (α=0.86).

Patient Health Questionnaire-15 (PHQ-15): The PHQ-15 sum score (maximum score = 30) was used to assess somatic symptoms (Kroenke et al., 2002). We used the Spanish version of the PHQ (Spitzer et al., 1999), which asks patients to rate 13 somatic symptoms on a scale from 0 to 2, as follows: 0 (not bothered), 1 (bothered a little), or 2 (bothered a lot). In addition to those 13 items, the scale also includes two items from the PHQ-9 (sleep and tiredness), scored as follows: 0 (not at all), 1 (several days), or 2 (more than half the days or nearly every day). The reliability of this scale was acceptable (α=0.80), with a mean (SD) score of 14.2 (4.8).

2.2.2. Measures of emotion regulation strategies

Penn State Worry Questionnaire – Abbreviated (PSWQ-A): The PSWQ was developed by Meyer et al. (1990) to assess worry. An abbreviated 8-item version of the PSWQ (PSWQ-A) was developed by Hopko et al. (2003) for use in older adults. We used the Spanish version of the PSWQ-A previously validated in primary care patients by Muñoz-Navarro et al. (2020), who found that the scale has excellent psychometric properties. Patients can response on a 5-point Likert scale ranging from 1 (*it is not typical in me*) to 5 (*it is very typical in me*). Mean (SD) scores were 30.1 (6.8) and the internal consistency obtained in this study was good (α=0.89).

Ruminative Responses Scale – Brooding (RRS-B): The RRS was developed by Nolen-Hoeksema & Morrow (1991) and validated in the Spanish population by Hervás-Torres (2008). This scale is designed to assess different types of rumination. The 5-item subscale corresponding to the "brooding" factor (RRS-B) was validated by Muñoz-Navarro et al. (2020) in primary care patients. The RRS-B uses a four-point Likert-type response scale ranging from 1 (*almost never*) to 4 (*almost always*). Mean (SD) scores were 13.6 (3.6). Internal consistency was adequate (α=0.77).

The Metacognitions Questionnaire–Negative Beliefs (MCQ-NB): The original MCQ-30 was developed by Wells and Cartwright-Hatton (2004). The MCQ-NB is a brief 5-item scale that assesses negative beliefs about uncontrollability/danger. This scale was validated by Muñoz-Navarro et al. (2020) to assess this negative metacognition in primary care patients. Responses to the items are given on a 4-point Likert-type response scale ranging from 1 (*totally disagree*) to 4 (*totally agree*). In our study, the mean (SD) score was 16.4 (4.1) and internal consistency was good (α=0.80).

Emotion Regulation Questionnaire (ERQ): The ERQ (Gross & John, 2013) is a 10-item self-report tool, validated in Spanish (Cabello et al., 2013), designed to assess cognitive reappraisal (ERQ-R, 6 items)—an adaptive emotion regulation strategy—and expressive suppression (ERQ-S, 4 items), a maladaptive strategy. Responses are given on a 7-point Likert scale ranging from 1 (*strongly disagree*) to 7 (*strongly agree*). Both subscales have demonstrated good levels of internal consistency, reliability, and validity across different samples and cultures (Preece et al., 2020). Mean (SD) scores for these two subscales were 25.6 (7.6) and 15.5 (6.0), respectively. The internal consistency was good for the ERQ-R (α=0.80) and adequate for the ERQ-S (α=0.76).

2.2.3. Measures of functioning

Sheehan Disability Scale (SDS): The participants' overall level of disability was measured with the SDS (Luciano et al., 2010). This instrument asks patients about the extent to which their symptoms interfere with three daily life domains (work, social, and family life). Participants rate the degree of interference on a 10-point Likert scale ranging from 0 (*not at all*) to 10 (*extremely*). The total score is the sum score of the three items. The mean (SD) score was 12.9 (8.2), with good internal consistency (α=0.80).

World Health Organization Quality of life Instrument-Abbreviated version (WhoQoL-Bref): To evaluate overall QoL, we used the single item on the WhoQoL-Bref designed to assess general QoL (Lucas-Carrasco, 2012). Patients respond to the question "*How would you rate your quality of life?"* on a 5-point Likert scale ranging from 1 (*very bad*) to 5 (*very good*). The mean (SD) score was 2.9 (0.8).

2.3. Statistical analyses

Descriptive statistics are provided for pre- and post-treatment symptoms, emotion regulation strategies, functioning, and QoL based

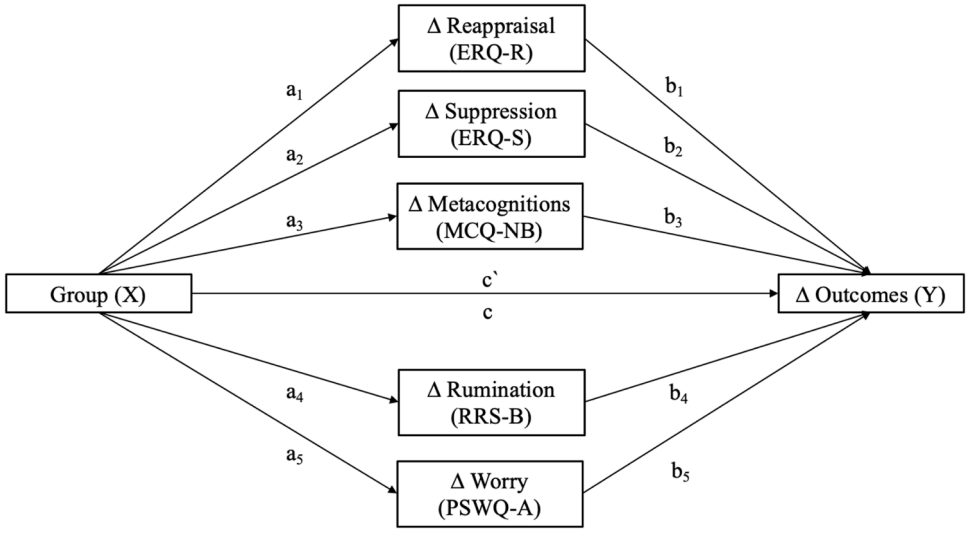

Fig. 1. Hypothetical multiple mediation model of emotion regulation in transdiagnostic cognitive behavioural therapy. Δ represent change scores values from pre- to post-treatment.

on the per-protocol results reported by Cano-Vindel et al. (2021). We performed an analysis of variance (ANOVA) to evaluate treatment efficacy in terms of symptom relief, which were also reported previously in Cano-Vindel et al. (2021). We also added changes in emotion regulation strategies, functioning, and QoL. Within-group effect sizes (pre--to-post-treatment) are provided for each group using the Cohen's effect size measure. Between-group effect sizes were determined using the Morris'd effect size measures, which consider the mean and standard deviation of the sample at the pre- and post-treatment assessments; this technique provides a more representative effect size when the values differ at baseline (Morris, 2008). The IBM-SPSS statistical software program, v. 26, was used to perform all statistical analyses.

We used the SPSS PROCESS macro, v.3.5 (Hayes, 2018) to test the mediation effects under bias-corrected 95% confidence intervals (CI) for the indices using bootstrap calculations based on 10,000 samples. Treatment allocation (TAU or TD-CBT+TAU) was included as an independent variable (X) and symptoms (GAD-7, PHQ-9, or PHQ-15), functioning (SDS) and QoL (WhoQoL-Bref) as dependent variables (Y). We sought to determine whether emotion regulation strategies worked as mediators (M) between the treatment allocation (X) and the dependent variables (Y), and we evaluated both direct and indirect effects (see Fig. 1 for the hypothetical model). We calculated the change scores (pre-to post-treatment) on the mediators and outcomes to test indirect effects of treatment allocation (X) on outcome change scores (ΔY) via mediator change scores (ΔM). To assess the independent association between each of the emotion regulation strategies and the outcome variables, mediators were entered simultaneously to control for intercorrelations among variables. Thus, we conducted five different multivariate mediation analyses to test these effects for each outcome. These mediation analyses were conducted using ordinary least squares regression in path-analytic form (Montoya and Hayes, 2017). For direct effects, we evaluated the multivariate effects of the independent variable to the mediators (a_i) and the effect of the mediators on the dependent variables (b_i). We also tested the total effect of the treatment condition on the outcome (c), which is the sum of the direct effect (c' path) and indirect effect (ab paths) such that $c = c' + (ab)$. Thus, we represented in each triangle figure the following paths: a) the a-path from X to M; b) the b-path from M to Y; c) the c-path from X to Y; d) and the c'-paths from X to Y. Beta regression (β) values are presented as standardized β, with standard deviation (SD) and with asterisks (*$p < 0.05$; **$p < 0.01$, *** $p < 0.001$) to indicate the significant paths. For indirect effects, we provide the point estimate (B values) and both the lower-level (LL) and upper-level (UL) of the CI, which is considered significant when the 0 value does not fall within the 95% CI (Hayes, 2018). If direct effects were significant, this indicates that a direct effect was found from the independent variables to the mediators, and/or from the mediators to the dependent variables. However, if the indirect effects were significant, this indicates that the effects on dependent variables were through the mediators.

3. Results

3.1. Treatment efficacy

Descriptive statistics are presented in Table 1. Of the 1061 randomized patients, 631 (TAU=316 and TD-CBT+TAU=315) completed the full treatment and all pre- and post-treatment instruments. The between-group's analyses showed that emotional symptoms had large effect sizes for anxiety and depression, and a medium effect size for somatization. All of the emotion regulation strategies—except for suppression (ERQ-S)—were significant, with small to medium between-group effect sizes observed for maladaptive emotion regulation and a positive small effect size for reappraisal. Significant improvements in functioning (medium effect size) and QoL (small effect size) were observed, especially in the TD-CBT+TAU group (Table 1). Within-group effect sizes showed a significantly stronger effect in the TD-CBT+TAU group, with large effect sizes for emotional symptoms and medium effect sizes for worry, rumination, negative metacognition and reappraisal, except for suppression, which was small. In the TAU group, within-group effect sizes were small, with no significant effect on reappraisal and suppression.

3.2. Mediation analysis

When we tested the multivariate mediation analyses, treatment allocation had significant direct effects on change scores for all of the emotion regulation strategies, with larger effects in the TD-CBT+TAU group: reappraisal (β=−2.597; *SE*=0.660; *t*=−3.935; $p = 0.0001$); suppression (β=1.443; *SE*=0.464; $t = 2.468$; $p = 0.014$); negative metacognition (β=2.394; *SE*=0.341; $t = 7.011$; $p<0.0001$); rumination (β=1.422; *SE*=0.281; $t = 5.058$; $p<0.0001$); and worry (β=3.472; *SE*=0.542; $t = 6.405$; $p<0.0001$). Figs. 2 to 6 show the results of the mediation models.

The direct effects of mediators on anxiety were significant for negative metacognition (β=0.299; *SE*=0.022; $t = 6.382$; $p<0.0001$); rumination (β=0.211; *SE*=0.060; $t = 3.486$; $p<0.0001$); and worry (β=0.164; *SE*=0.031; $t = 5.241$; $p<0.0001$), with no significant effects for reappraisal (β=−0.016; *SE*=0.223; *t*=−0.709; $p = 0.479$) or suppression (β=0.056; *SE*=0.033; $t = 1.716$; $p = 0.087$). Indirect effects were significant for negative metacognition, rumination, and worry

Table 1
Means and between- and within-group effect sizes for outcomes and mediators.

Outcomes	Pre-treatment sample						Post-treatment sample				Within-group				Between-group	
	Total ($n = 1061$)		TAU ($n = 316$)		TD-CBT +TAU ($n = 315$)		TAU ($n = 316$)		TD-CBT +TAU ($n = 315$)		TAU		TD-CBT+TAU			
											p	Cohen's *d*	*p*	Cohen's *d*	*p*	Morris' *d*
Symptoms																
Anxiety (0 – 21)	12.3	(4.6)	12.9	(4.6)	12.6	(4.7)	10.2	(5.5)	6.0	(4.3)	<0.001	−0.53	<0.001	−1.47	<0.001	−1.01
Depression (0 – 27)	13.6	(5.4)	13.4	(5.4)	13.8	(5.1)	11.5	(6.6)	7.0	(5.2)	<0.001	−0.32	<0.001	−1.32	<0.001	−0.92
Somatizations (0 – 30)	14.2	(4.8)	14.0	(4.6)	14.1	(4.9)	12.1	(5.2)	9.1	(5.3)	<0.001	−0.39	<0.001	−0.98	<0.001	−0.65
Emotion Regulation Strategies																
Reappraisal (6 – 42)	25.6	(7.6)	24.6	(7.0)	25.8	(7.3)	25.0	(8.4)	28.7	(7.6)	0.42	0.05	<0.001	0.39	<0.001	0.37
Suppression (4 – 28)	15.5	(6.0)	15.3	(6.0)	15.5	(6.0)	15.0	(6.4)	14.0	(6.0)	0.33	−0.05	<0.001	−0.25	0.05	−0.19
Metacognition (6 – 24)	16.4	(4.1)	16.1	(4.1)	16.5	(4.1)	15.5	(4.6)	13.3	(4.1)	0.003	−0.14	<0.001	−0.78	<0.001	−0.59
Rumination (5 – 20)	13.6	(3.6)	13.3	(3.5)	13.5	(3.6)	12.8	(3.9)	11.6	(3.6)	0.018	−0.14	<0.001	−0.53	<0.001	−0.40
Worry (8 – 40)	30.1	(6.8)	29.9	(6.5)	29.7	(7.1)	28.6	(7.2)	24.9	(6.8)	<0.001	−0.19	<0.001	−0.69	<0.001	−0.51
Functioning																
Total (0 – 30)	12.9	(8.2)	12.4	(7.5)	13.2	(7.5)	11.3	(8.2)	8.2	(7.5)	0.022	−0.14	<0.001	−0.67	<0.001	−0.52
Quality of Life																
General (0 – 5)	2.9	(0.8)	2.9	(0.8)	2.9	(0.8)	3.0	(0.8)	3.2	(0.8)	0.024	0.13	<0.001	0.38	<0.001	0.25

Abbreviations: TAU, treatment-as-usual; TD-CBT, transdiagnostic cognitive-behavioural therapy;.

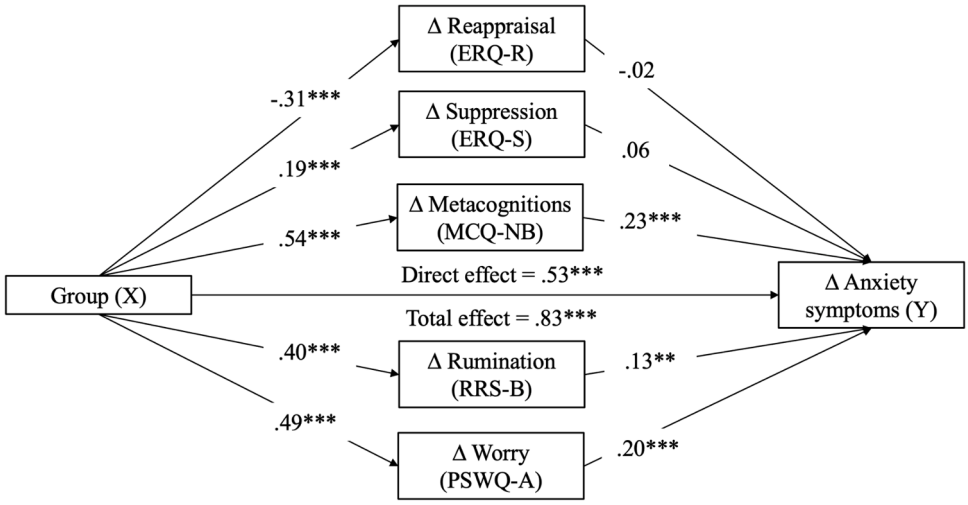

Fig. 2. Multiple mediation model on anxiety symptoms. *Note:* *$p < 0.05$, **$p < 0.01$, *** $p < 0.001$. Δ represent change scores values from pre- to post-treatment.

(Fig. 2 and Table 2).

The direct effects of mediators on depression were significant for suppression (β=0.133; *SE*=0.039; $t = 3.427$; $p<0.001$); negative metacognition (β=0.333; *SE*=0.056; $t = 5.969$; $p<0.0001$); rumination (β=0.205; *SE*=0.072; $t = 2.853$; $p<0.001$); and worry (β=0.120; *SE*=0.037; $t = 3.224$; $p<0.001$), with no significant effects for reappraisal (β=−0.016; *SE*=0.027; $t=-0.605$; $p = 0.545$). Indirect effects were significant for suppression, negative metacognition, rumination and worry (Fig. 3 and Table 2).

For somatization, direct effects of mediators were significant for negative metacognition (β=0.167; *SE*=0.046; $t = 3.615$; $p<0.0001$), rumination (β=0.164; *SE*=0.059; $t = 2.773$; $p<0.001$), and worry (β=0.066; *SE*=0.031; $t = 2.146$; $p<0.05$), with no significant effects for reappraisal (β=0.005; *SE*=0.022; $t = 0.224$; $p = 0.823$) or suppression (β=0.030; *SE*=0.032; $t = 0.927$; $p = 0.354$). Indirect effects were significant for negative metacognition, rumination and worry (Fig. 3 and Table 2).

The direct effects of mediators on functioning were significant for negative metacognition (β=0.379; *SE*=0.081; $t = 4.668$; $p<0.0001$) and rumination (β=0.491; *SE*=0.104; $t = 4.713$; $p<0.0001$) with no significant effects for reappraisal (β=−0.026; *SE*=0.039; $t=-0.674$; $p = 0.501$), suppression (β=0.040; *SE*=0.056; $t = 0.697$; $p = 0.486$), or worry (β=0.085; *SE*=0.054; $t = 1.577$; $p = 0.115$). Indirect effects were significant for negative metacognition and rumination (Fig. 3 and Table 2).

For QoL, direct effects of mediators were significant only for negative metacognition (β=−0.037; *SE*=0.081; $t = 4.533$; $p<0.0001$), with no significant effects for reappraisal (β=0.001; *SE*=0.039; $t=-0.295$; $p = 0.769$), suppression (β=−0.002; *SE*=0.056; $t=-0.300$; $p = 0.764$), rumination (β=−0.011; *SE*=0.011; $t=-1.021$; $p = 0.308$), or worry (β=−0.008; *SE*=0.054; $t=-1.417$; $p = 0.157$). Indirect effects were only significant for negative metacognition (Fig. 3 and Table 2).

Table 2
Estimates of indirect effects of the multivariate mediation analyses .

		Results of multivariate indirect effects		
			95% CI	
Dependent variable	Mediator	Point estimate (SE)	LL	UL
GAD-7				
	Reappraisal	−0.016 (0.023)	−0.060	0.028
	Suppression	0.056 (0.037)	−0.008	0.119
	Metacognition	0.299 (0.047)	**0.207**	**0.392**
	Rumination	0.210 (0.060)	**0.091**	**0.329**
	Worry	0.163 (0.031)	**0.102**	**0.225**
PHQ-9				
	Reappraisal	−0.016 (0.026)	−0.069	0.036
	Suppression	0.132 (0.038)	**0.056**	**0.208**
	Metacognition	0.333 (0.055)	**0.223**	**0.442**
	Rumination	0.204 (0.071)	**0.063**	**0.345**
	Worry	0.119 (0.037)	**0.046**	**0.192**
PHQ-15				
	Reappraisal	0.005 (0.022)	−0.038	0.048
	Suppression	0.029 (0.031)	−0.033	0.092
	Metacognition	0.166 (0.046)	**0.076**	**0.256**
	Rumination	0.164 (0.059)	**0.047**	**0.280**
	Worry	0.065 (0.030)	**0.005**	**0.125**
Functioning				
	Reappraisal	−0.026 (0.039)	−0.102	0.050
	Suppression	0.039 (0.056)	−0.071	0.149
	Metacognition	0.378 (0.081)	**0.219**	**0.537**
	Rumination	0.491 (0.104)	**0.286**	**0.695**
	Worry	0.085 (0.053)	−0.020	0.190
QoL-Gen				
	Reappraisal	0.001 (0.003)	−0.006	0.008
	Suppression	−0.002 (0.005)	−0.012	0.009
	Metacognition	−0.036 (0.008)	**−0.052**	**−0.020**
	Rumination	−0.010 (0.010)	−0.031	0.009
	Worry	−0.007 (0.005)	−0.018	0.003

Note: PHQ-9: patient health questionnaire-9; PHQ-15: patient health questionnaire-15; Generalized anxiety disorder-7; SDS: Sheehan disability scale: QoL-Gen: quality of life - general; WQL-Gen: WHOQOL-Bref-General item; LL: lower limit; UL: upper limit. The indirect effect is statistically significant (in bold formating) if the confidence interval (CI) does not include zero.

4. Discussion

Transdiagnostic treatments are a highly promising approach for emotional disorders such as depression and anxiety (Cassiello-Robbins et al., 2020), with the available data suggesting that the treatment has effects, at least partially, through certain mediators such as emotion regulation strategies (Sakiris and Berle, 2019; Sloan et al., 2017). In the present study, we evaluated data from a large RCT to determine the mediating role of emotion regulation strategies (according to treatment allocation) on symptoms of anxiety, depression and somatization, as well as on functioning and QoL (Cano-Vindel et al., 2021). We found significant indirect effects for most of the maladaptive emotion regulation strategies (negative metacognition, rumination and worry) on the three emotional symptoms as well as for suppression in depression, with better results in all cases in the TD-CBT+TAU group. For functioning, significant indirect effects were observed for negative metacognition and rumination; by contrast, the only mediator of QoL was negative metacognition. Cognitive reappraisal was never significant. This implies that the greatest improvement in emotional symptoms, functioning and

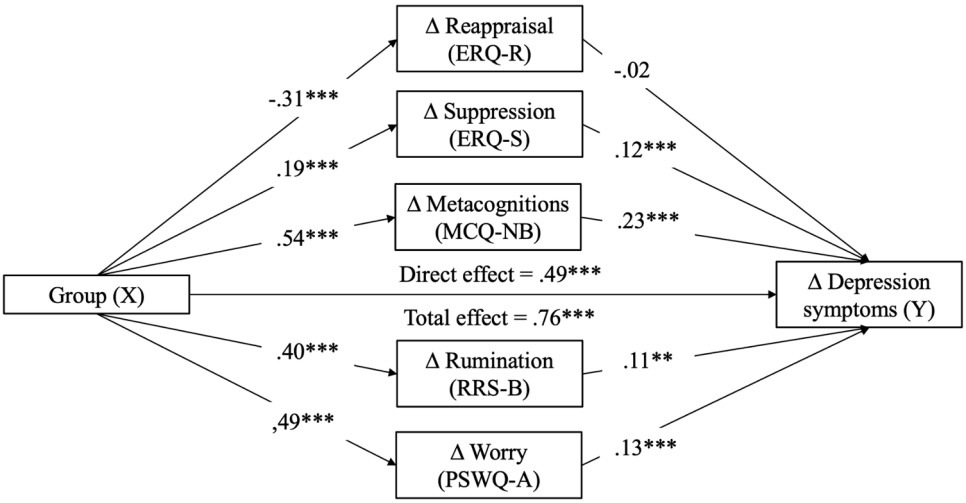

Fig. 3. Multiple mediation model on depression symptoms.
Note: *$p < 0.05$, **$p < 0.01$, *** $p < 0.001$. represent change scores values from pre- to post-treatment.

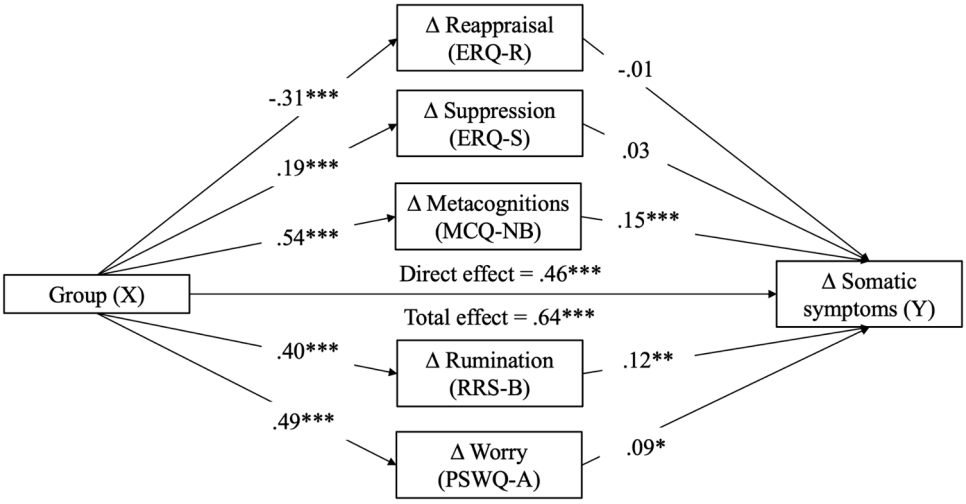

Fig. 4. Multiple mediation model on somatic symptoms.
Note: *$p < 0.05$, **$p < 0.01$, *** $p < 0.001$. represent change scores values from pre- to post-treatment.

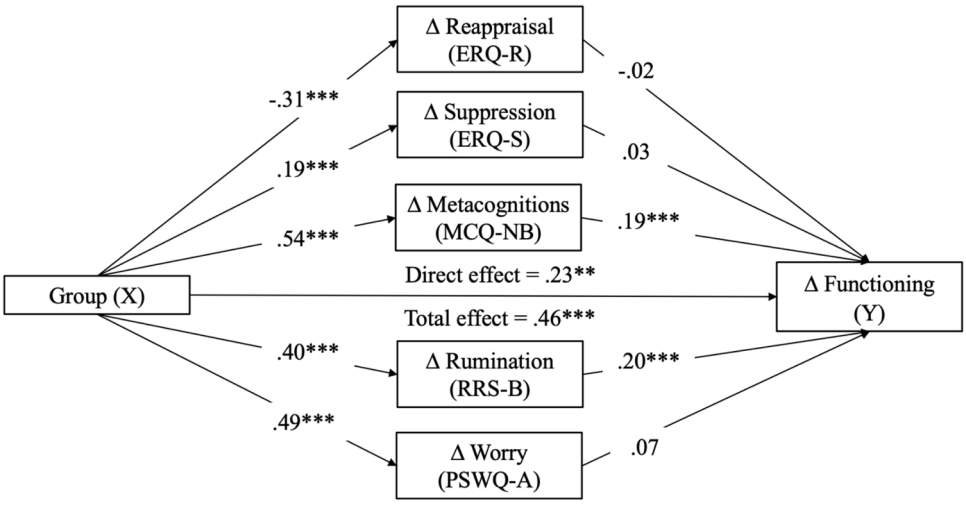

Fig. 5. Multiple mediation model on functioning.
Note: *$p < 0.05$, **$p < 0.01$, *** $p < 0.001$. represent change scores values from pre- to post-treatment.

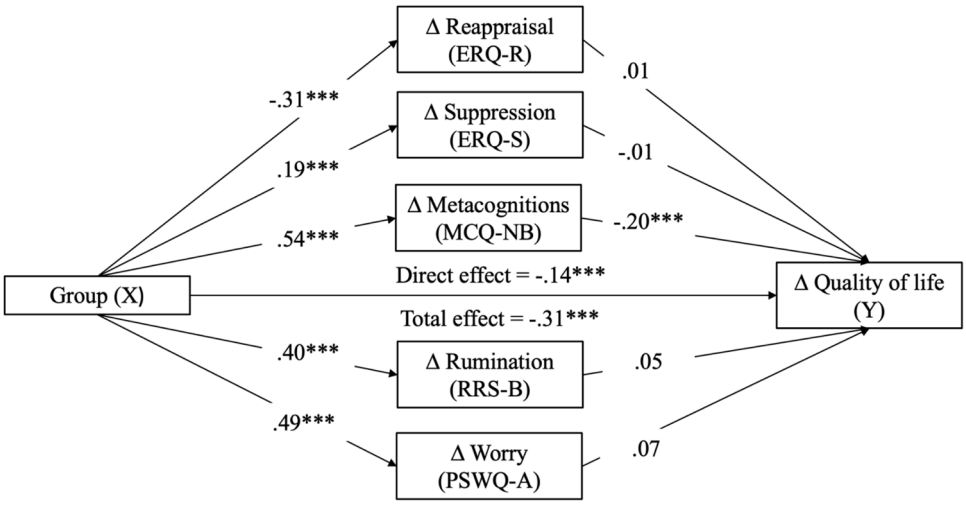

Fig. 6. Multiple mediation model on quality of life. Note: *$p < 0.05$, **$p < 0.01$, *** $p < 0.001$. represent change scores values from pre- to post-treatment.

QoL was achieved by targeting these mechanisms of change through TD-CBT+TAU, especially with the three maladaptive emotion regulation strategies. Finally, negative metacognition could be considered the most transdiagnostic emotion regulation strategy, not only for emotional symptoms, but also for functioning and QoL.

Interestingly, the transdiagnostic group therapy tested in this study may represent an efficient approach to providing evidence-based psychological therapy for people suffering from anxiety, depression, and somatization, all of which commonly present with high comorbidity (Cassiello-Robbins et al., 2020; Sakiris and Berle, 2019). The large sample evaluated in this RCT makes these findings quite robust, providing valuable insights into the mediating role of emotion regulation as the core aspect of transdiagnostic therapy and revealing the processes and mechanisms of psychotherapy underlying the changes (Hofmann and Hayes, 2019). In this regard, the treatment of maladaptive emotion regulation strategies, especially cognitive strategies (worry, rumination and negative metacognition), but also a behavioural strategy like suppression, can yield positive results. By contrast, reappraisal (an adaptive strategy) did not reduce symptoms nor improve wellbeing, suggesting that it may not be a good transdiagnostic target. However, this finding contradicts previous research showing that targeting adaptive strategies could help to prevent anxiety and depression (Arango et al., 2018; Moreno-Peral et al., 2020). Accordingly, helping primary care patients to manage emotions by providing them with cognitive and behavioural resources through psychoeducational and psychological interventions may greatly reduce the enormous burden of these disorders (Megías-Robles et al., 2019; Moreno-Peral et al., 2020).

As Cano-Vindel et al. reported (2021), TD-CBT significantly reduced symptoms of anxiety, depression, and somatization, with a large effect size for anxiety and depression, and a medium effect size for somatization. In the present work, significant reductions (medium effect sizes) in these symptoms were found for all of the maladaptive emotion regulation strategies studied except for suppression, which had no significant effect. The adaptive cognitive reappraisal strategy also had a significant positive effect, although the effect size was small. These results are consistent with previous reports on the effects of transdiagnostic treatments on emotion regulation strategies (Sakiris and Berle, 2019; Sloan et al., 2017), which found medium effect sizes for maladaptive strategies and small effect sizes for adaptive strategies. These findings are also in line with other studies, which have found that the treatment of maladaptive emotion regulation strategies is efficacious for reducing common psychopathologies such as anxiety and depression (Aldao et al., 2010; Sakiris and Berle, 2019). Thus, transdiagnostic treatments appear to have a more positive impact on emotion regulation than TAU, underscoring the importance of targeting maladaptive strategies such as rumination, worry, or negative metacognition through psychotherapy (Aldao and Nolen-Hoeksema, 2010; Hsu et al., 2015; Kircanski et al., 2015; Muñoz-Navarro et al., 2020). Finally, the improvement in functioning and QoL was significant but with small effect sizes, as expected (Cano-Vindel et al., 2021). When we evaluated the within-group effect sizes, we found large effect sizes for emotional symptoms in the TD-CBT+TAU group, but medium effect sizes for anxiety and small effect sizes for depression and somatization in the TAU group. An important finding in the TAU group was that neither cognitive reappraisal nor suppression were significant and the effect sizes were very small for the three maladaptive strategies. By contrast, in the transdiagnostic group, these effect sizes were large for negative metacognition, small for suppression and medium for the rest, and the effects were significant on all analyses. These effects could explain why transdiagnostic therapy could be more efficacious than TAU with regard to outcomes, as there may be a learning effect, with potential mediators of treatment outcomes.

Analysis of direct effects showed that treatment allocation had a significant effect on all strategies, with large standardized beta values—particularly for worry, rumination, and negative metacognition—and with slightly smaller values for reappraisal and very small values for suppression. These findings were expected and in accordance with previous studies (Sakiris and Berle, 2019; Sloan et al., 2017). These direct effects on dependent variables such as anxiety, depression, and somatization presented significant and positive effects in three maladaptive emotion regulation strategies (negative metacognition, rumination and worry). In this case, suppression had an indirect effect only for depressive symptoms while reappraisal had no effect at any emotional symptoms. For functioning, two maladaptive strategies (negative metacognition and rumination) had a significant effect but only negative metacognition were significant for QoL. Finally, reappraisal was not significant for any outcomes, which was an unexpected finding given that previous studies have reported an association between these adaptive strategies and both anxiety and depression (Hsu et al., 2015; Picó-Pérez et al., 2017), which has also been found to be more closely associated with improved wellbeing than reduction of distress and unpleasant feelings (King and dela Rosa, 2019).

Finally, indirect effects were evaluated using multivariate mediation analyses, which showed that three maladaptive emotion regulation strategies (worry, negative metacognition, and rumination) could be considered mediators for treatment of emotional symptoms. Suppression had an indirect effect only for depressive symptoms. For QoL, only negative metacognition was a significant mediator. For functioning, the only significant mediators were rumination and negative metacognition. Again, reappraisal was not significant for any outcome, which was

unexpected given the findings reported by other authors. In this regard, Enrique et al. (2021) conducted a similar study to ours as a secondary analysis of an RCT in which participants received internet-based CBT. In that study, mediation analyses of emotion regulation on depression and anxiety symptoms showed that reappraisal was the only significant mediator, but not suppression nor worry, findings that differ from our data. These results could be explained by the fact that we performed the multivariate mediation analyses by introducing the mediating variables simultaneously, which allowed us to study the intercorrelations within the mediators, thus leaving out the strategies with less variance on indirect effects. Given these findings, we can deduce that worry, rumination-brooding type, and negative metacognition such as negative beliefs about uncontrollability and danger are clear candidates to be considered transdiagnostic mediators for the treatment of emotional disorders (Aldao and Nolen-Hoeksema, 2010; Hsu et al., 2015; Kircanski et al., 2015; Muñoz-Navarro et al., 2020). Moreover, negative metacognition was the most transdiagnostic strategy, which supports the effect of metacognitive therapy for emotional disorders, functioning and well-being (Sun et al., 2017; Wells, 2008). Thus, even though suppression and reappraisal were not transdiagnostic, these strategies may be worth targeting based on previous evidence indicating a positive role for these strategies in anxiety and depression (Enrique et al., 2021). As we showed in a study published recently (Muñoz-Navarro et al., 2020), even though these strategies are theoretically unidimensional, they may be highly correlated. In this regard, future studies could seek to determine if there is a latent factor within these emotion regulation strategies that could explain the transdiagnostic effect of psychological therapy using transdiagnostic processes such as emotion regulation training.

This study has several strengths and limitations. First, we focused mainly on cognitive emotion regulation strategies and only studied one behavioural strategy (suppression). It would be interesting in the future to evaluate additional strategies such as behavioural avoidance, distraction, intolerance to uncertainty and/or other strategies that play a role in anxiety and depression (Naragon-Gainey et al., 2017). In addition, negative metacognition could be not considered properly as an emotion regulation strategy. However, it is worth emphasizing that the strategies that we studied in the present work had been validated in a previous study (Muñoz-Navarro et al., 2020), which demonstrated that brief scales can detect the presence of these emotion regulation strategies, which is important in the primary care setting. Another limitation is that we only evaluated one adaptive strategy (reappraisal), which had no effect on any outcomes. Future studies should assess other adaptive cognitive and behavioural emotion regulation strategies, which could provide a deeper understanding of the role of adaptive strategies in constructs related to wellbeing (e.g., functioning and QoL). Future lines for research should assess the mediating role of these strategies on other functioning domains, particularly QoL. It would also be necessary to study this effect over time (e.g., from 6 to 12 months after treatment) to help understand the substantial improvement in QoL observed over the long term in a previous study (Cano-Vindel et al., 2021). Also, the use of change scores in the mediators and outcome variables has some limitations. First, they do not adequately control for baseline imbalances between groups (Vickers and Altman, 2001). This is because participants with low scores at the beginning of the study tend to improve more than those with high scores (regression to the mean). In addition, these scores do not allow us to analyze accurately the correlation between the pre-test measures and the outcome measures or to investigate their role as moderators of the mediators. Future research could focus on analysing the role of baseline measures as moderators of mediators (Igartua, and Hayes, 2021). Finally, it would be interesting to study, in serial mediation models, how working on different strategies could potentially reduce symptoms and improve wellbeing. Despite these limitations, an important strength of this study is that it is based on data from a large RCT conducted in the primary care setting within a public national health system. Moreover, we evaluated diverse emotion regulation strategies, including maladaptive and adaptive strategies, both cognitive and behavioural. This analysis provides powerful insights into the treatment of emotional disorders in primary care, which is the first point of contact for all patients with mental health problems and where most are treated.

5. Conclusions

The results of this study show that certain maladaptive emotion regulation strategies—worry, rumination-brooding type, and negative metacognition—may be potential targets for transdiagnostic therapy due to their mediating role in the treatment of emotional disorders. Suppression may also be a mediator for depression. Negative metacognition could be considered the most transdiagnostic strategy. Our data suggest that reappraisal is not a significant mediator. The findings presented in this work suggest that emotion regulation strategies should be considered mediators of transdiagnostic therapy delivered in primary care for the treatment of emotional disorders.

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CRediT authorship contribution statement

Roger Muñoz-Navarro: Conceptualization, Methodology, Formal analysis, Writing – original draft, Project administration. **Leonardo Adrián Medrano:** Validation, Methodology, Visualization, Writing – review & editing. **Joaquín T. Limonero:** Validation, Writing – review & editing. **César González-Blanch:** Validation, Writing – review & editing, Funding acquisition. **Juan A. Moriana:** Writing – review & editing, Supervision, Funding acquisition. **Paloma Ruiz-Rodríguez:** Data curation, Writing – review & editing. **Antonio Cano-Vindel:** Project administration, Supervision, Writing – review & editing, Funding acquisition.

Declaration of Competing Interest

The authors declare no conflict of interest

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