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Transdiagnostic group cognitive behavioural therapy for emotional disorders in primary care: the results of the PsicAP randomized controlled trial

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Abstract

Background. Emotional disorders are highly prevalent in primary care. We aimed to determine whether a transdiagnostic psychological therapy plus treatment-as-usual (TAU) is more efficacious than TAU alone in primary care adult patients.

Methods. A randomized, two-arm, single-blind clinical trial was conducted in 22 primary care centres in Spain. A total of 1061 adult patients with emotional disorders were enrolled. The transdiagnostic protocol ($n = 527$) consisted of seven 90-min sessions (8–10 patients) delivered over a 12–14-week period. TAU ($n = 534$) consisted of regular consultations with a general practitioner. Primary outcome measures were self-reported symptoms of anxiety, depression, and somatizations. Secondary outcome measures were functioning and quality of life. Patients were assessed at baseline, post-treatment, and at 3, 6, and 12 months. Intention-to-treat and per-protocol analyses were performed.

Results. Post-treatment primary outcomes were significantly better in the transdiagnostic group compared to TAU (anxiety: $p < 0.001$; Morris's $d = -0.65$; depression: $p < 0.001$; $d = -0.58$, and somatic symptoms: $p < 0.001$; $d = -0.40$). These effects were sustained at the 12-month follow-up (anxiety: $p < 0.001$; $d = -0.44$; depression: $p < 0.001$; $d = -0.36$ and somatic symptoms: $p < 0.001$; $d = -0.32$). The transdiagnostic group also had significantly better outcomes on functioning ($d = 0.16$–0.33) and quality of life domains ($d = 0.24$–0.42), with sustained improvement at the 12-month follow-up in functioning ($d = 0.25$–0.39) and quality of life ($d = 0.58$–0.72). Reliable recovery rates showed large between-group effect sizes ($d > 0.80$) in favour of the transdiagnostic group after treatment and at the 12-month follow-up.

Conclusions. Adding a brief transdiagnostic psychological intervention to TAU may significantly improve outcomes in emotional disorders treated in primary care.

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Introduction

Emotional disorders – depression, anxiety, and somatoform disorders – are all highly prevalent in the community, imposing an enormous burden on society (Whiteford, Ferrari, Degenhardt, Feigin, & Vos, 2015). In particular, depression and anxiety represent a global burden that is even greater than the impact of chronic physical conditions (Vigo, Thornicroft, & Atun, 2016). Given the large negative consequences of these disorders, it is clear that mental health should be a major priority for all health systems (Patel et al., 2018). One approach to improving access to evidence-based treatments would be to integrate mental health care into the primary care setting (World Health Organization, 2018), where most patients with mild to moderate emotional disorders are treated (Kovess-Masfety et al., 2007).

Many studies have shown that psychological therapy, mainly cognitive behavioural therapy (CBT), is an effective treatment for emotional disorders in primary care (Cuijpers et al., 2019b; Seekles et al., 2013). In recent years, several ambitious health care initiatives, such as the Improving Access to Psychological Therapies (IAPT) project in the UK, have been carried out to expand access to evidence-based psychological treatments for common mental disorders

to a wider population. The results of the IAPT and similar projects show that these initiatives are cost-effective (Layard & Clark, 2015) and highly beneficial for society (Clark, 2018; Wakefield et al., 2020). The pioneering IAPT project provided a model for similar international projects, such as those carried out in Australia (Cromarty, Drummond, Francis, Watson, & Battersby, 2016), Norway (Knapstad et al., 2018, 2020), and Canada (Naeem, Pikard, Rao, Ayub, & Munshi, 2017). Nonetheless, several barriers to dissemination of psychological treatments have been identified (Harvey & Gumport, 2015), including the growing number of disorder-specific treatment guidelines (Newby, McKinnon, Kuyken, Gilbody, & Dalgleish, 2015), which may be particularly relevant in primary care where individuals with emotional disorders frequently present mixed symptoms attributable to different mental health disorders, and primary care providers often are not able to make a precise differential diagnosis due to time and other constraints (Tylee & Walters, 2007).

In the past two decades, there has been a growing effort to develop psychological treatments based on a transdiagnostic approach, supported by evidence showing that many mental disorders share the same psychological processes implicated in the onset and maintenance of psychopathology (Aldao, Nolen-Hoeksema, & Schweizer, 2010; Norton & Hope, 2005; Patel et al., 2018). The available evidence suggests that transdiagnostic psychological therapy can be a highly effective treatment for emotional disorders (Newby et al., 2015). This therapeutic approach focuses on treating the common factors involved in many emotional disorders such as cognitive biases (Beck, 2019; Eysenck & Derakshan, 1997) and dysfunctional emotion regulation strategies (Sakiris & Berle, 2019; Sloan et al., 2017), which are both cognitive and behavioural (Naragon-Gainey, McMahon, & Chacko, 2017). Most recent research has focused on individual treatments – or, in some cases, virtual therapy (i.e. internet-based) – but few studies have tested the efficacy of transdiagnostic group cognitive behavioural therapy (TD-GCBT) (Chamberlain & Norton, 2013; Norton & Barrera, 2012). The available evidence, although limited, suggests that the transdiagnostic group approach might be a particularly useful, cost-effective treatment given the high comorbidity among mental disorders, especially in primary care.

As in many other European countries, the National Health System in Spain (Spanish acronym: *SNS*) is based on the principles of universal coverage, free access, and fairness. The SNS is primarily funded by taxes. The system itself is centred around primary care centres, with the population assigned to a given centre based on geographic proximity. Consequently, in this model, the general practitioners (GP) and nursing staff act as the gatekeepers to the SNS, except for emergency care. Primary care centres are staffed by multidisciplinary teams comprised by GPs, paediatricians, nurses, and administrative staff; some centres also have social workers, midwives, and/or physiotherapists. The core package of primary health care benefits compromises all health care prevention, diagnosis, treatment and rehabilitation services, including mental health. Unfortunately, in Spain, practically none of the regions has mental health professionals on staff at the primary care level. Rather, clinical psychologists working in specialized care can periodically be sent to primary care centres for mental health care issues, but this practice is very uncommon. Therefore, given the minimal presence of clinical psychologists in primary care, the provision of psychological therapy mainly relies on referral to specialized care, for which waiting times are typically long. Thus, most patients with emotional disorders are treated directly by their GPs, and this treatment tends to be medication-centric, despite the recommendations provided by most clinical guidelines. The use of psychotropic drugs (mainly antidepressants, anxiolytics and hypnotics) has been increasing in Spain and their use is currently higher than in many other European countries (OECD, 2015).

In this context, we conducted a randomized controlled trial (RCT) to compare TD-GCBT (7 sessions) plus treatment-as-usual (TAU) to TAU alone in adult patients with emotional disorders in the primary care setting. We hypothesized that TD-GCBT + TAU would be more effective than TAU alone in reducing anxiety, depression, and somatic symptoms, and that these benefits would be sustained 3, 6, and 12 months after treatment finalization. We further hypothesized that TD-GCBT + TAU would, compared to TAU alone, reduce disability, improve quality of life, and increase treatment satisfaction and that these benefits would also be sustained over time.

Subjects and methods

Study design

The PsicAP trial was a multicentre, two-arm, single-blind, RCT. Patients were recruited in the primary care setting within the SNS with symptoms of an emotional disorder (depression, anxiety disorder, or somatization) and randomized to receive either TAU alone (control group) or combined treatment involving TD-GCBT + TAU.

Participants

Patients were recruited from 22 primary care centres in eight different regions in Spain (Andalusia, Basque region, Cantabria, Castilla la Mancha, Galicia, Madrid, Navarra, and Valencia) (Cano-Vindel et al., 2016). All patients who visited their GPs with signs or symptoms of negative or unpleasant emotional problems, moderate depression, anxiety, or somatic symptoms without any clear biological basis were considered candidates for study inclusion. Patients receiving treatment with antidepressants, anxiolytics, and/or hypnotics were also eligible and invited to participate by their treating GP.

Recruitment

The GPs explained the study to potential participants during the course of a routine clinical visit. Patients who agreed to participate were provided with patient information sheet with written details about the study and then asked to sign an informed consent form, after which an initial session with a psychologist was scheduled. At this visit, the study participants completed a battery of electronic questionnaires. The main study inclusion criteria were (1) age between 18 and 65 years and (2) the presence of symptoms suggestive of an emotional disorder, whose presence was initially assessed with the Patient Health Questionnaire (PHQ; Spitzer et al., 1999).

Exclusion criteria included any of the following severe mental disorders: eating disorders; alcohol or substance abuse; bipolar disorder; severe major depressive disorder; recent suicide attempt, or other severe mental disorders diagnosed by the GP. The specific PHQ modules that assess for the presence of eating disorders and alcohol abuse were used to detect these conditions and to exclude patients with these disorders. Participants receiving psychological treatment for any mental disorder were also excluded.

Randomization and masking

A computer-generated allocation sequence was used to randomly assign patients (1:1) to receive either TD-GCBT + TAU or TAU alone. Study participants were contacted by email or phone to inform them of their treatment allocation. A clinical psychologist was assigned to lead a specific TD-GCBT intervention. Patients allocated to TAU were instructed to return to their GPs for treatment. None of the participants or clinicians was blinded to the treatment allocation. However, in accordance with the single-blind study design, the assessors involved in the pre- and post-treatment assessment phases were blinded to the allocation and did not participate in the interventions (TD-GCBT or TAU). The GPs did not receive any information from the researchers regarding baseline assessments, randomization, progress in the intervention, or other outcomes. Medical records and notes were not shared between the intervention team and primary care providers.

Procedures

Interventions

The TD-GCBT protocol (Cano-Vindel et al., 2016; González-Blanch et al., 2018b) was a planned program consisting of seven 90-min therapy sessions held over a 12–14-week period in small groups (8–10 patients) in the primary care centre. These sessions were led by trained clinical psychologists, which were not part of the primary care staff. In order to ensure the fidelity and consistence of the TD-GCBT treatment at all participating sites, all therapists were required to undergo an 8-h training program in the treatment protocol. This training session was led by a senior clinical psychologist. All therapists received a detailed, session-by-session outline of the treatment. The therapeutic approach was based on the transdiagnostic approach to emotional disorders, which assumes that most emotional disorders share several common factors (Aldao et al., 2010; Hofmann & Barlow, 2014), and that the onset and maintenance of emotional disorders are due to dysregulated cognitive-behavioural emotion regulation strategies (Aldao et al., 2010). Any participant who missed a training session was contacted by telephone by an assistant researcher and offered to attend the next session. At the start of each training session, the content of the previous session was briefly reviewed.

The TAU intervention consisted of regular consultations with the treating GP, who assessed the patient's physical and/or psychosocial complaints. GPs were instructed to treat patients in both arms in accordance with their best clinical judgment. In general, these treatments involved the prescription of anxiolytics, antidepressants, or hypnotics, and/or informal counselling/support.

Primary outcomes

The primary outcome measure was the severity of symptoms of emotional disorders (anxiety, depression, and somatic symptoms), which were assessed by the relevant PHQ modules (Spitzer et al., 1999). The PHQ has been validated as a sensitive and specific test to determine the presence of these disorders based on the DSM-IV criteria. In a previous study that included a subset (15%, $n = 178$) of the patients in the current trial, we compared two PHQ modules to assess symptoms of anxiety (Muñoz-Navarro et al., 2017a) and depression (Muñoz-Navarro et al., 2017a) with clinical interviews (the gold standard) to validate these instruments in the present trial.

Symptoms of Anxiety (GAD-7). The presence of anxiety was determined according to the Generalized Anxiety Disorder-7 scale (Spitzer et al., 2006). Total GAD-7 scores range from 0 to 21. For this trial, the cut-off for clinical significance on the GAD-7 was set at ⩾10. Internal consistency of the scale was good ($\alpha = 0.87$). At this cut-off point, both sensitivity (0.87) and specificity (0.78) were acceptable (Muñoz-Navarro et al., 2017a). Mean scores were 12.3 (4.6) and the internal consistency of the scale was good ($\alpha = 0.87$).

Symptoms of Depression (PHQ-9). This PHQ module (Kroenke et al., 2001) was used to detect depression with a cut-off point of ⩾10. Total scores ranged from 10 to 23. Based on a previous study of this cut-off score (Muñoz-Navarro et al., 2017a), participants who scored from 20 to 23 were assigned to undergo a second-order assessment (interview with a clinical psychologist) to confirm the presence of moderate or severe depression disorder. Based on this clinical assessment, the patients were included or not in the trial (Cano-Vindel et al., 2016). The mean score on the PHQ-9 was 13.6 (5.4) and the scale showed a good internal consistency ($\alpha = 0.86$). The most widely used cut-off score in the literature (⩾10) was used as the threshold for caseness, as this cut point presents a reliable balance between sensitivity and specificity (Kroenke et al., 2001).

Symptoms of somatizations (PHQ-15). On the Spanish version of the PHQ (Spitzer et al., 1999), patients 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). Two items from the depression module (sleep and tiredness) are added and 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 ($\alpha = 0.80$), with a mean score of 14.0 (4.8). Somatic symptoms were assessed according to the PHQ-15 sum score, with a maximum score of 30. Patient inclusion was based on an algorithm with the 13 somatic symptoms (patients with ⩾3 symptoms were classified as 'bothered a lot'). A previous study used this algorithm to determine the sensitivity (78%) and specificity (71%) of the PHQ-15 (Kroenke et al., 2010).

Secondary outcomes

Functional Status. Secondary outcome measures included the level of disability on daily life domains (work, social, and family life) measured with the Sheehan Disability Scale (SDS; Luciano et al., 2010). The internal consistency of this scale was good ($\alpha = 0.80$).

Quality of Life. Quality of life domains (physical, psychological, social, and environmental) was evaluated with the World Health Organization Quality of life Instrument-Abbreviated version (WhoQoL-Bref; Lucas-Carrasco, 2012). Internal consistency for all factors was acceptable ($\alpha > 0.70$): (physical: $\alpha = 0.77$; psychological: $\alpha = 0.79$; social: $\alpha = 0.70$; environmental: $\alpha = 0.79$).

Treatment Satisfaction. Treatment satisfaction for the groups was assessed through a single question ('*Rate your satisfaction with the treatment received*') with responses given on a 10-point scale ranging from 0 (*totally unsatisfied*) and 10 (*totally satisfied*).

Statistical methods

Power and Sample size. To detect a minimally important effect size of ⩾0.2 with an alpha error probability of 0.05 and a power

(1–β) of 0.80 using G*Power 3.1 for SPSS (Faul, Erdfelder, Lang, & Buchner, 2007), a sample size of 394 participants per group would be required. Anticipating a dropout rate of 25%, the necessary sample size would be 525 participants per group. For all results, we applied 95% confidence intervals (CI).

Main Analyses. For primary outcomes, we considered group differences in anxiety (GAD-7), depression (PHQ-9), and somatic symptoms (PHQ-15) comparing baseline and post-treatment scores using a mixed-effect model. A mixed-effects model was computed, including time and treatment group as fixed effects and single participants as a random effect; group differences were analysed after controlling for baseline characteristics: gender, age, and treatment centre. For secondary outcomes, we similarly checked between-group differences in the level of disability on daily life domains (work, social, and family life) and quality of life domains (physical, psychological, social, and environmental). We performed an intention-to-treat (ITT) analysis that included all randomized patients using the chained equations multiple imputation procedure in the SPSS statistical software program, with five imputations. The effect sizes of the treatment on primary and secondary outcomes (mean scores) were calculated by applying Morris's *d* statistic. Morris (2008) described an effect size for the pre-post change (PPC) design, where the standardized effect of the treatment is defined as the difference between groups in mean PPC values, divided by the common standard deviation. The formula for the Morris' effect size is as follow: $[\delta_{PPC} = (\mu_{T2} - \mu_{T1}) - (\mu_{C2} - \mu_{C1})/\sigma]$, where μ_{gt} is the mean of group g at time t, and σ is the standard deviation of the untreated population. The main advantage of this formula is that it takes into account the mean and standard deviation of the sample both at the final assessment and at baseline, leading to a more representative effect size when the values differed from baseline.

Additional analyses: Recovery, reliable recovery, and deterioration rates were calculated. The recovery index was defined as pre-treatment scores above the threshold on any of the three scales and below the threshold on all scales at either the post-treatment or 12-month follow-up assessment. The reliable recovery rate was calculated using a change score based on the standard deviation (S.D.) and Cronbach's alpha of each measure (as described in the IAPT project) to account for scale measurement errors (Clark et al., 2009). Thus, we used a change score of ⩾5 for the GAD-7 and ⩾6 for the PHQ-9 and the PHQ-15. Among the individuals who met the recovery criteria, individuals who scored below the caseness threshold on all three measures after treatment and showed reliable improvement on ⩾ one of the three measures were considered to have achieved a reliable recovery. By contrast, deterioration was defined as an increase in the score on any of the three scales based on the criteria for the scale in question. All statistical analyses were two-tailed; given the multiplicity of comparisons for primary and secondary outcomes, the final alpha level was set at 0.01. Effect sizes for these analyses were calculated using Cohen's *d*. In addition, a per-protocol (PP) analysis for primary and secondary outcomes was performed only in the patients who completed all follow-up measurements.

Results

A total of 1691 patients assessed between 14 January 2014 and 30 July 2018, were considered potential candidates for participation in this trial and were enrolled. Of those, 630 (37.3%) failed to meet all inclusion criteria, leaving a total of 1061 patients (62.7%) who met the trial inclusion criteria. These patients were then randomized to the treatment ($n = 527$) or control ($n = 534$) groups, and this sample ($n = 1061$) was used for the ITT analyses. Of these 1061 patients, 316 in the TAU group and 314 in the TD-GCBT + TAU group completed all post-treatment assessments (drop-out rate: 40.8 and 40.4%, respectively). The final 1-year follow-up assessments were completed by 30 July 2019. The study flow diagram is shown in Fig. 1.

Participants in the experimental group attended a mean of 4.5 (S.D. = 2.6) of the seven sessions; 67.7% of the participants attended 4 or more sessions and were thus considered compliant. The number of TD-GCBT sessions attended was significantly correlated with post-treatment outcome measures: PHQ-9 ($r = -0.14$; $p = 0.022$), GAD-7 ($r = -0.16$; $p = 0.008$), and PHQ-15 ($r = -0.16$; $p = 0.007$), indicating that treatment exposure was associated with better outcomes.

The sociodemographic characteristics of the sample are shown in Table 1. The most common patient profile was a married woman in her early 40s (mean age, 43.6; S.D., 12.3), employed part-time, earning less than €24 000 annually and presenting symptoms of at least three common disorders (depression, anxiety, and somatic). There were no significant between-group differences in TAU in terms of medications or dosage at the 12-month follow-up and visits to the GPs (data not shown, available upon request).

Primary outcomes

Anxiety symptoms (GAD-7)

On the ITT analyses, there were significant between-group differences in anxiety symptoms at all post-treatment time points ($p < 0.001$), with better results in the TD-GCBT + TAU group, with small to medium effect sizes (Morris's $d = -0.38$ to -0.65). On the PP analysis, significant differences were also observed on all measures, but with medium to large effect sizes (Morris's $d = -0.62$ to -1.01). Table 2 and Fig. 2 provide detailed results on these measures.

Depression symptoms (PHQ-9)

The ITT analyses revealed significant between-group differences ($p < 0.001$) after treatment finalization and at all follow-up assessments, with better outcomes in the TD-GCBT + TAU group, with small to medium effect sizes (Morris's $d = -0.36$ to -0.58). The PP analyses also showed significant differences between the groups on all measures, with medium to large effect sizes (Morris's $d = -0.60$ to -0.92). See Table 2 and Fig. 2 for more details.

Somatization symptoms (PHQ-15)

Significant between-group differences were detected at all post-treatment time points, indicating a greater reduction in somatic symptoms in the TD-GCBT + TAU group ($p < 0.001$). Effect sizes ranged from small to medium (Morris's $d = -0.31$ to -0.40). The PP analyses showed significant differences between the groups at all time points, with medium effect sizes (Morris's $d = -0.49$ to -0.65). Table 2 and Fig. 2 provide more details.

Recovery, reliable recovery, and deterioration rates

In the ITT analyses (data shown as values and 95% CI), recovery rates for the TAU group at the post-treatment and 12-month

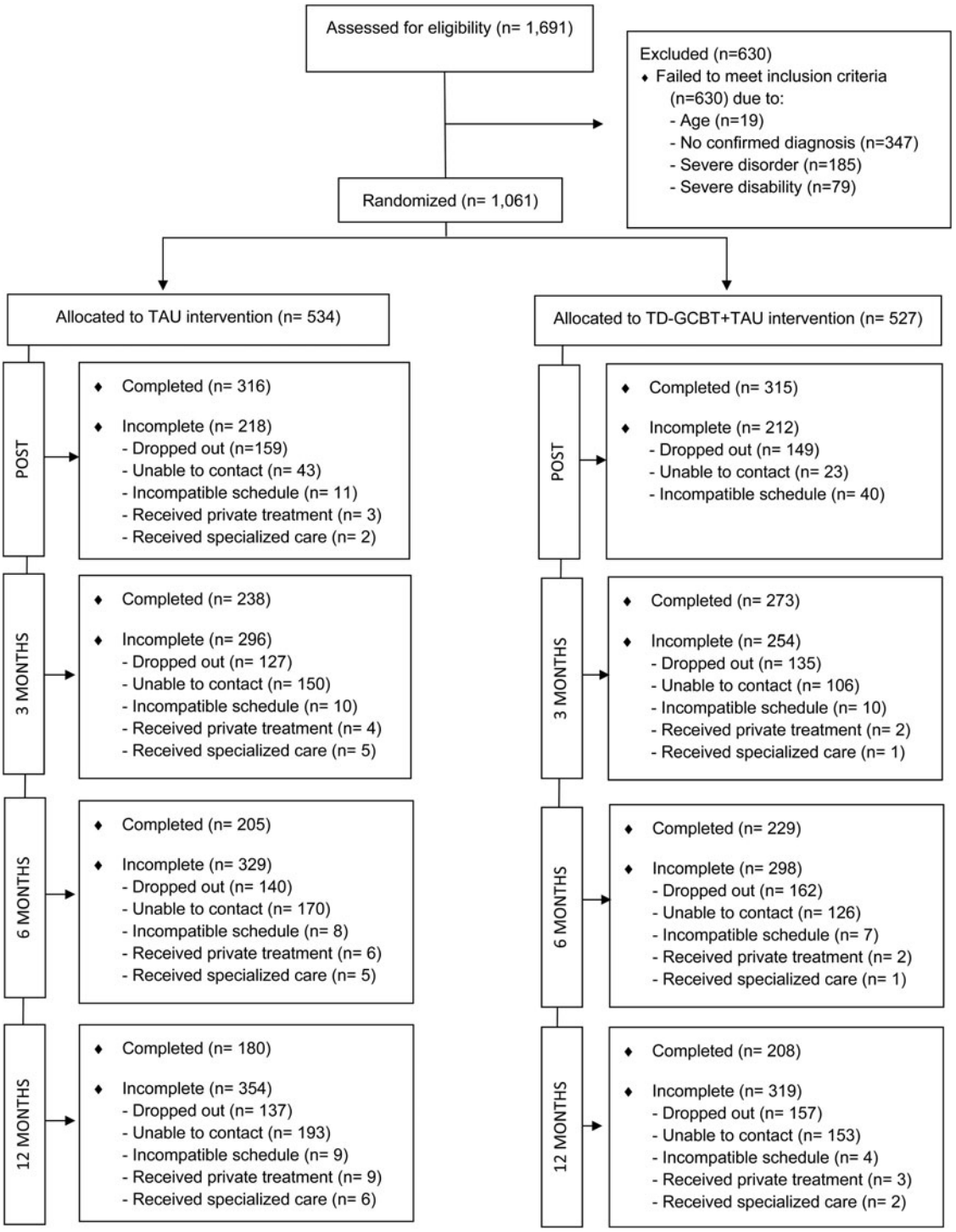

Fig. 1. Flow of participants through the trial.

assessments were 18% (14–22%) and 29% (22–36%), respectively. For the TD-GCBT + TAU group, the recovery rates at those same time points were 51.7% (46–57%) and 52% (45–60%), yielding a between-group effect size of 0.76 (0.60–0.92) and 0.51 (0.36–0.67), respectively. The proportion of individuals considered to have achieved a reliable recovery at the post-treatment and 12-month assessments in the TAU group was 13.3% (9–17%) and 11% (5–16%), respectively; in the TD-GCBT + TAU group, the reliable recovery rates were 49.5% (44–55%) and 45% (37–48%), yielding a between-group effect size of 0.84 (0.68–1.05) and 0.83 (0.67–0.99), respectively. Deterioration rates at the post-treatment and 12-month assessments were 14% (10–17%) and 12% (7−14%) for the TAU group, and 3% (1–5%) and 3% (1–5%) for the TD-GCBT + TAU, yielding a between-group effect size of 0.41 (0.26–0.57) and 0.35 (0.19–0.50), respectively. Similar results were obtained on the PP analysis (data available on request).

Table 1. Demographics characteristics of sample

Characteristics	Total ($n = 1061$)		Intention to treat sample				Per protocol sample			
			TAU ($n = 534$)		TD-GCBT ($n = 527$)		TAU ($n = 316$)		TD-GCBT ($n = 315$)	
Gender										
Female	861	(81.1)	437	(81.8)	424	(80.5)	261	(82.6)	251	(79.7)
Male	200	(18.9)	97	(18.2)	103	(19.5)	55	(17.4)	64	(20.3)
Age group, years										
⩽19	16	(1.5)	6	(1.1)	10	(1.9)	4	(1.3)	2	(0.6)
20–39	386	(36.4)	197	(36.9)	189	(35.9)	92	(29.1)	102	(32.4)
40–59	581	(54.8)	286	(53.6)	295	(56.0)	186	(58.9)	186	(59.0)
⩾60	78	(7.4)	45	(8.4)	33	(6.3)	34	(10.8)	25	(7.9)
Marital status										
Married	513	(48.4)	248	(46.4)	265	(50.3)	159	(50.3)	177	(56.2)
Divorced	87	(8.2)	34	(6.5)	53	(10.1)	21	(6.6)	28	(8.9)
Widowed	29	(2.7)	14	(2.6)	15	(2.8)	10	(3.2)	6	(1.9)
Separated	58	(5.5)	37	(6.9)	21	(4.0)	18	(5.7)	10	(3.2)
Never married	212	(20.0)	102	(19.1)	110	(20.0)	56	(17.7)	51	(16.2)
Unmarried	162	(15.3)	99	(18.5)	63	(12.0)	52	(16.5)	43	(13.7)
Level of education										
No schooling	11	(1.0)	7	(1.3)	4	(0.8)	3	(0.9)	3	(1.0)
Basic education	267	(25.2)	140	(26.2)	127	(24.1)	87	(27.5)	65	(20.6)
Secondary education	233	(22.0)	122	(22.8)	111	(21.1)	68	(21.5)	59	(18.7)
High School	262	(24.7)	123	(23.0)	139	(26.4)	79	(25.0)	94	(29.8)
Bachelor	242	(22.8)	119	(22.3)	123	(23.3)	70	(22.2)	84	(26.7)
Master/doctorate	46	(4.3)	23	(4.3)	23	(4.4)	9	(2.8)	10	(3.2)
Employment situation										
Employed full-time	248	(14.7)	87	(16.3)	93	(17.6)	44	(13.9)	48	(15.2)
Employed part-time	633	(37.4)	209	(39.1)	183	(34.7)	122	(38.6)	115	(36.5)
Unemployed, in search of work	366	(21.6)	123	(23.0)	107	(20.3)	64	(20.3)	59	(18.7)
Unemployed, not looking for work	202	(11.9)	60	(11.2)	77	(14.6)	40	(12.7)	49	(15.6)
Temporary incapacity to work	129	(7.6)	32	(6.0)	41	(7.8)	25	(7.9)	26	(8.3)
Permanent incapacity to work	37	(2.2)	10	(1.9)	13	(2.5)	9	(2.8)	9	(2.9)
Retired	76	(4.5)	13	(2.4)	13	(2.5)	12	(3.8)	9	(2.9)
Level of income (per year)										
Less than €12 000 euros	670	(39.6)	214	(40.0)	195	(37.0)	118	(37.3)	98	(30.5)
Between €120 000 and €24 000	690	(40.8)	215	(40.2)	218	(41.4)	129	(40.8)	139	(44.6)
Between €240 000 and €36 000	218	(12.9)	74	(13.9)	73	(13.9)	48	(15.2)	48	(15.7)
More than €36 000	113	(6.7)	31	(5.8)	41	(7.8)	21	(6.6)	30	(9.2)

TAU, treatment-as-usual; TD-GCBT, transdiagnostic group cognitive-behavioural therapy.
Results are presented as number and percentages.

Secondary outcomes

We observed (ITT analysis) a significantly greater decrease in the treatment group *v.* controls on all the three disability dimensions (work, social, and family life), with small effect sizes (Morris' $d = -0.16$ to -0.39). These differences were not significant at the 3-month follow-up but were significant at subsequent assessments (months 6 and 12). A similar result was found on the PP analysis, but with greater effect sizes, ranging from small to medium (Morris' $d = -0.26$ to -0.51) (Table 3). Small to medium effect sizes (Morris' $d = 0.17$–0.42) were found on the four quality of life dimensions assessed, with some variations at months 3 and

Table 2. Summary of between-group differences in primary trial outcome

	Intention to treat sample							Per protocol sample						
	TAU			TD-GCBT			Difference	TAU			TD-GCBT			Difference
Outcome measure	No. M (S.D.)			No. M (S.D.)			Morris' *d* *p*	No. M (S.D.)			No. M (S.D.)			Morris' *d* *p*
GAD-7														
Baseline	534		–	527	–	–	–	–	534	12.1	(4.7)	527	12.5	(4.6)	–	0.264
Post-treatment	534	9.5	(5.4)	527	6.8	(4.7)	−0.65	<0.001	316	10.2	(5.5)	315	6.0	(4.3)	−1.01	<0.001
3 months	534	8.7	(5.3)	527	7.3	(5.0)	−0.38	<0.001	238	8.9	(5.4)	273	6.7	(4.9)	−0.62	<0.001
6 months	534	8.6	(5.4)	527	6.9	(5.1)	−0.45	<0.001	204	8.8	(5.7)	229	6.2	(4.9)	−0.78	<0.001
12 months	534	8.3	(5.7)	527	6.6	(5.4)	−0.44	<0.001	180	8.7	(5.8)	208	5.8	(5.3)	−0.91	<0.001
PHQ-9														
Baseline	534	–	–	527	–	–	–	–	534	13.5	(5.4)	527	13.7	(5.3)	–	0.443
Post-treatment	534	10.8	(6.4)	527	8.0	(5.7)	−0.58	<0.001	316	11.5	(6.6)	315	7.0	(5.2)	−0.92	<0.001
3 months	534	10.2	(6.4)	527	8.4	(6.0)	−0.39	<0.001	238	10.3	(6.5)	273	7.8	(6.0)	−0.60	<0.001
6 months	534	9.8	(6.4)	527	7.9	(6.1)	−0.40	<0.001	205	10.0	(6.6)	228	7.3	(6.1)	−0.75	<0.001
12 months	534	9.4	(6.3)	527	7.8	(5.9)	−0.36	<0.001	180	9.7	(6.5)	208	7.1	(6.2)	−0.61	<0.001
PHQ-15														
Baseline	534	–	–	527	–	–	–	–	534	14.0	(4.8)	527	14.3	(4.9)	–	0.388
Post-treatment	534	11.7	(5.2)	527	9.9	(5.4)	−0.40	<0.001	316	12.1	(5.2)	315	9.1	(5.3)	−0.65	<0.001
3 months	534	11.4	(5.1)	527	10.1	(5.3)	−0.32	<0.001	238	11.7	(5.0)	273	9.5	(5.4)	−0.49	<0.001
6 months	534	11.1	(5.3)	527	9.8	(5.6)	−0.31	<0.001	205	11.5	(5.3)	228	9.2	(5.7)	−0.59	<0.001
12 months	534	10.7	(5.6)	527	9.4	(5.6)	−0.32	<0.001	180	11.7	(5.6)	208	8.8	(5.7)	−0.57	<0.001

GAD-7, generalized anxiety disorder-7; M, mean; PHQ-9, Patient Health Questionnaire-9; PHQ-15, Patient Health Questionnaire-15, TAU, treatment-as-usual; TD-GCBT, transdiagnostic group cognitive-behavioural therapy; S.D., standard deviation.

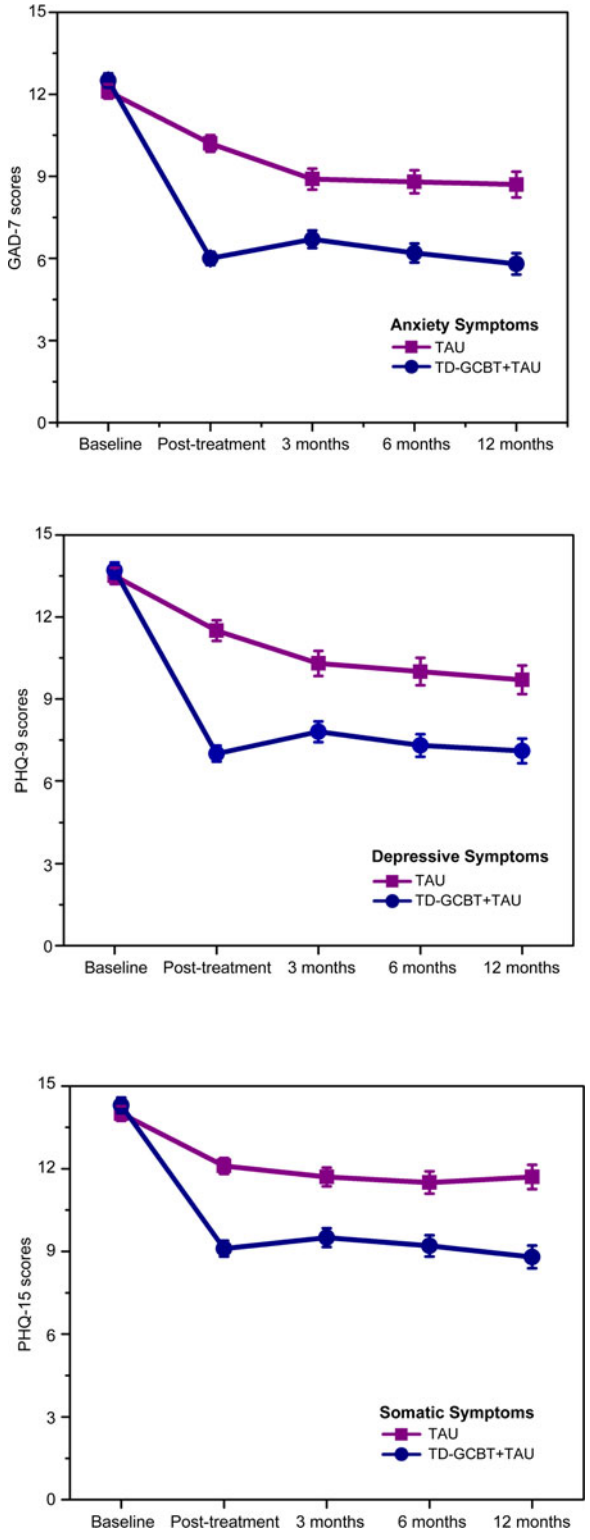

Fig. 2. Primary Outcomes at Baseline and Follow-up. TAU, treatment-as-usual; TD-GCBT, transdiagnostic group cognitive-behavioural therapy. Error bars represent standard errors.

6, and with medium effect sizes (Morris' $d = 0.55–0.72$) at the final assessment (Table 3). The PP results were similar, but with larger effect sizes on almost all measures (Table 3). Overall, patients in the treatment arm were more satisfied than those in the TAU arm [9.75 (1.49) *v.* 7.72 (2.68)], which represents a large effect size (Morris' $d > 0.90$); however, this effect size decreased at subsequent follow-ups from a large to a medium-sized effect (Morris' $d = 0.65$ to 0.51).

Discussion

The main finding of this RCT is that adding TD-GCBT to TAU resulted in a greater reduction in the symptoms of emotional disorders at all post-treatment time points (immediately after treatment finalization, and at months 3, 6, and 12). The effect sizes for the primary outcomes were large for anxiety symptoms and medium for depressive and somatic symptoms. Furthermore, these therapeutic effects were sustained throughout the 12-month follow-up period, with small to large effect sizes. Importantly, the reliable recovery rates showed large effect sizes in favour of the experimental group at the immediate post-treatment assessment and at the 12-month-follow-up. Patients in the treatment group experienced a greater decrease in measures of disability significantly, a greater improvement in the quality of life and – as a consequence – higher treatment satisfaction immediately (scores >9 on a 10-point scale) after treatment completion and at the 12-month follow-up, thus supporting our secondary hypothesis that TD-GCBT + TAU would yield superior results to TAU alone on these measures. Of the patients in the TD-GCBT arm, approximately 70% attended four or more of the seven sessions, a finding that indicates the acceptability of the experimental intervention.

These results are consistent with findings from previous studies, confirming the greater efficacy and effectiveness of adding CBT to TAU in the treatment of emotional disorders (Carpenter et al., 2018; Cuijpers et al., 2019a). Some studies have found that TD-CBT is highly effective in reducing the symptoms of anxiety and depression (Newby et al., 2015), as evidenced by the studies carried out by Norton and Barrera (Norton & Barrera, 2012) and Chamberlain and Norton (Chamberlain & Norton, 2013), both of which reported good results for TD-GCBT (mainly for anxiety disorders). In the primary care setting, however, relatively few studies have been conducted to evaluate individual or group TD-CBT, with the notable exception of a recent pre-post observational study (Kristjánsdóttir et al., 2018) that assessed a 6-week TD-GCBT intervention for adult patients with depression and/or anxiety disorder. Reliable recovery rates in our trial were similar to those reported in other similar projects, such as the IAPT project in the UK, which achieved reliable recovery rates close to 50% on measures of anxiety and depression (Clark, 2018; Wakefield et al., 2020) and slightly lower than those reported in the Norwegian version of the IAPT (58.5%) (Knapstad et al., 2020). However, it is worth noting that we applied stricter, more conservative criteria, as we included three main outcomes (anxiety, depression, and somatizations) *v.* only two (anxiety and depression) in the IAPT programs. In fact, the between-group effect size in our study (>0.80) was larger than that observed in the Norwegian study (0.61). It is also important to emphasize that reliable deterioration rates in the experimental arm in our trial were notably lower than in the control group (3% *v.* 12–14%) as well as lower than the 5–10% deterioration rates commonly found in adult patients participating in clinical trials of psychotherapeutic therapies (Lambert & Ogles, 2004).

In short, the findings of this large RCT support the efficacy of adding TD-GCBT to TAU in the primary care setting to treat patients with different emotional disorders. Our results show that this combined approach improves symptomatology and

Table 3. Summary of between-group differences of secondary trial outcome

	Intention to treat sample								Per protocol sample							
	TAU			TD-GCBT			Difference		TAU			TD-GCBT			Difference	
Outcome measure	No. M (s.d.)			No. M (s.d.)			Morris' *d* *p*		No. M (s.d.)			No. M (s.d.)			Morris' *d* *p*	
Working life[a]																
Baseline	534	3.5	(3.1)	527	3.6	(3.2)	–	0.600	534	3.5	(3.1)	527	3.6	(3.2)	–	0.604
Post-treatment	534	3.0	(3.1)	527	2.6	(3.0)	−0.16	0.002	316	3.1	(3.1)	315	2.4	(2.9)	−0.26	0.002
3 months	534	2.7	(3.0)	527	2.4	(3.0)	–	0.753	238	2.6	(3.0)	273	2.5	(2.9)	–	0.814
6 months	534	2.7	(83.0)	527	2.1	(2.9)	−0.22	0.001	204	2.8	(3.0)	229	1.9	(2.7)	−0.32	0.001
12 months	534	3.1	(3.3)	527	2.4	(3.2)	−0.25	<0.001	180	3.3	(3.3)	208	2.0	(2.7)	−0.44	<0.001
Social life[a]																
Baseline	534	4.6	(3.0)	527	4.7	(3.0)	–	0.965	534	4.6	(3.0)	527	4.7	(3.0)	–	0.946
Post-treatment	534	4.1	(3.1)	527	3.2	(3.0)	−0.33	<0.001	316	4.1	(3.1)	315	2.9	(2.8)	−0.41	<0.001
3 months	534	3.5	(3.1)	527	3.2	(2.9)	–	0.281	238	3.4	(3.2)	273	3.1	(2.9)	–	0.291
6 months	534	3.4	(3.2)	527	2.7	(3.1)	−0.27	<0.001	205	3.6	(3.2)	228	2.6	(2.8)	−0.36	<0.001
12 months	534	3.8	(3.4)	527	2.9	(3.4)	−0.33	<0.001	180	4.0	(3.3)	208	2.6	(3.1)	−0.48	<0.001
Family life[a]																
Baseline	534	4.6	(3.1)	527	4.8	(3.0)	–	0.437	534	4.6	(3.1)	527	4.8	(3.0)	–	0.430
Post-treatment	534	3.9	(3.1)	527	3.1	(2.9)	−0.33	<0.001	316	4.0	(3.1)	315	2.8	(3.1)	−0.43	<0.001
3 months	534	3.5	(3.1)	527	3.1	(3.1)	–	0.061	238	3.5	(3.1)	273	3.0	(3.0)	–	0.067
6 months	534	3.6	(3.2)	527	2.7	(3.1)	−0.36	<0.001	205	3.6	(3.1)	228	2.6	(2.7)	−0.41	<0.001
12 months	534	3.8	(3.3)	527	2.8	(3.2)	−0.39	<0.001	180	3.9	(3.3)	208	2.5	(2.8)	−0.51	<0.001
Physical[b]																
Baseline	534	22.4	(4.3)	527	22.1	(4.3)	–	0.327	534	22.4	(4.3)	527	22.1	(4.3)	–	0.327
Post-treatment	534	23.2	(4.5)	527	24.7	(4.6)	0.42	<0.001	316	22.7	(4.6)	315	25.1	(4.7)	0.61	<0.001
3 months	534	23.5	(4.6)	527	24.2	(4.8)	0.23	0.017	238	23.2	(4.8)	273	24.4	(4.9)	0.34	0.004
6 months	534	23.6	(4.5)	527	24.3	(4.4)	0.23	0.008	204	23.1	(4.8)	229	24.7	(4.9)	0.44	0.001
12 months	534	24.2	(5.1)	527	26.4	(5.3)	0.58	<0.001	180	22.7	(5.1)	208	25.6	(5.3)	0.73	<0.001
Psychological[b]																
Baseline	534	16.9	(3.8)	527	16.9	(3.8)	–	0.578	534	16.9	(3.8)	527	16.9	(3.8)	–	0.578
Post-treatment	534	17.7	(3.9)	527	19.2	(4.0)	0.39	<0.001	316	17.4	(4.2)	315	19.6	(4.0)	0.61	<0.001
3 months	534	18.1	(3.9)	527	18.9	(4.2)	0.21	0.001	238	18.0	(4.0)	273	19.3	(4.2)	0.38	<0.001
6 months	534	18.5	(3.8)	527	19.1	(3.9)	0.16	0.010	205	18.3	(4.2)	228	19.3	(4.2)	0.31	0.008

12 months	534	18.7	(4.4)	527	20.8	(4.6)	0.55	<0.001	180	18.3	(4.4)	208	20.2	(4.6)	0.54	<0.001
Social[b]																
Baseline	534	9.1	(2.4)	527	9.1	(2.4)	–	0.915	534	9.1	(2.4)	527	9.1	(2.4)	–	0.915
Post-treatment	534	9.4	(3.1)	527	9.8	(3.3)	0.17	0.024	316	9.2	(2.4)	315	10.0	(2.7)	0.31	<0.001
3 months	534	9.5	(2.3)	527	9.7	(2.3)	–	0.110	238	9.3	(2.2)	273	9.8	(2.4)	0.21	0.014
6 months	534	9.5	(2.5)	527	9.7	(2.2)	–	0.263	205	9.6	(2.5)	228	9.8	(2.2)	–	0.467
12 months	534	9.7	(2.2)	527	11.1	(2.6)	0.58	0.005	180	9.3	(2.2)	208	10.0	(2.6)	0.29	0.005
Environment[b]																
Baseline	534	25.3	(4.5)	527	25.7	(4.6)	–	0.143	534	25.3	(4.5)	527	25.7	(4.6)	–	0.143
Post-treatment	534	25.7	(5.3)	527	27.2	(5.6)	0.24	<0.001	316	25.5	(4.7)	315	27.8	(4.8)	0.41	<0.001
3 months	534	26.1	(4.9)	527	26.9	(5.1)	0.09	0.012	238	26.1	(4.8)	273	27.5	(5.2)	0.15	0.001
6 months	534	26.5	(4.8)	527	27.1	(4.8)	–	0.064	205	26.4	(4.8)	228	27.7	(5.0)	0.19	0.008
12 months	534	27.5	(5.0)	527	31.2	(5.3)	0.72	0.001	180	26.6	(5.0)	208	28.3	(5.3)	0.29	0.001

M, mean; TAU, treatment-as-usual; TD-GCBT, transdiagnostic group cognitive-behavioural therapy; S.D., standard deviation.
[a]Disability domains measured with the Sheehan Disability Scale.
[b]Quality of Life domains measured with the World Health Organization Quality of life Instrument-Abbreviated.

helps a large proportion of patients to recover while minimizing the risk of deterioration. The brief group psychological intervention applied in this study significantly improved several aspects of functional impairment as well as the quality of life. This finding is important given the growing demand among clinicians for treatments that do not focus solely on symptom reduction (Gladis, Gosch, Dishuk, & Crits-Christoph, 1999). The effect sizes of these secondary outcomes were within the ranges reported in published meta-analyses in terms of the effects of psychological treatments on functioning and quality of life in patients with emotional disorders (Kamenov, Twomey, Cabello, Prina, & Ayuso-Mateos, 2016), with medium effect sizes for quality of life, and small to medium effects for functioning. The modest effects on these outcomes are consistent with the findings reported in the meta-analysis conducted by Kamenov et al. (2016), who concluded that psychological interventions appear to have a greater positive effect on symptom severity than on functioning and quality of life. Interestingly, we found that some of the positive effects of treatment were not significant at the 3- and 6-month follow-up assessments, suggesting that changes in these variables may fluctuate after treatment. It is reasonable to expect that changes in functioning and quality of life take more time to take root than changes in symptoms, which are more immediate. Nonetheless, it is important to emphasize that the benefits observed in this trial for all dimensions of quality of life and functioning were sustained 12 months after completion of the therapeutic intervention.

Limitations

First, the effects of treatment were assessed with self-reported measures, with the limitations inherent to such instruments. Nevertheless, we employed only instruments that have been validated in the primary care setting. In addition, we also conducted validity studies of these instruments in a subsample of our patients (15% of the full sample) using semi-structured interviews (the gold standard) for comparison to obtain the optimal cut-off score for these tools (Muñoz-Navarro et al., 2017a, 2017b). We also studied the validity of the PHQ modules in our primary care sample, which showed excellent psychometric properties (Cano-García et al., 2020; González-Blanch et al., 2018a; Moreno et al., 2019). Another potential limitation is the high attrition rate. Similar high attrition rates have also been reported in other RCTs comparing psychological interventions with TAU in primary care (Bortolotti, Menchetti, Bellini, Montaguti, & Berardi, 2008). However, the high treatment compliance and high level of treatment satisfaction support the feasibility and acceptability of the TD-GCBT in this population. Besides the primary context, it seems likely that the high attrition rate was due to the lack of sufficient research staff needed to implement a clinical trial of this size, leading to a high rate of missing cases in both groups. Even though this limitation may have affected the study's power to detect small effect sizes, the overall effect sizes for the primary outcomes ranged from medium to large. Moreover, despite the high dropout rate, no relevant clinical differences were observed between the individuals who completed all assessments and those who did not. Furthermore, the large number of GPs involved in patient recruitment (>120 GPs from 22 centres) also supports the value of the intervention for primary care providers. Another limitation is the use of TAU rather than sham treatment to control for unspecific therapeutic factors, such as therapist contact and expectancy effects. However, we purposely selected TAU for the control arm to enhance the external validity of the findings, as this reflects real-world clinical practice in Spanish primary care settings. Although satisfaction with TAU (7.7) was high and similar to that found in national surveys (7.3) (Bernal-Delgado et al., 2018), future studies should compare TD-GCBT to other group interventions such as relaxation therapy. Finally, we do not have detailed information on the specific interventions provided in the TAU arm for all participants; however, to prevent differences in TAU treatment, the GPs were blinded to the treatment allocation and participants in the TD-GCBT arm were specifically asked to avoid sharing any information regarding the psychological therapy with their GPs. Importantly, there were no significant between-group differences in the number of GP visits or medications prescribed. Likewise, a cost-efficacy and cost-utility study based on a subsample ($n = 487$) of participants (Ruiz-Rodríguez, 2019) found no significant differences at the 12-month follow-up in terms of costs associated with GP visits ($t = -0.21$, $p = 0.83$), primary care nurse visits ($t = 0.63$, $p = 0.53$), and medications ($t = -0.27$, $p = 0.78$). All these data suggest that TAU was similar in the two groups during the course of the study.

Conclusion

The PsicAP project is the largest mental health care clinical trial ever conducted in Spain. Our findings provide compelling evidence to support adding a brief TD-GCBT intervention to usual care for the treatment of emotional disorders in primary care. Importantly, the observed therapeutic benefits – symptom reduction and better functioning and quality of life – were sustained 1 year after treatment finalization. We believe this cost-effective approach has the potential to dramatically improve the clinical treatment of emotional disorders and could revolutionize current models of care in the primary care setting in Spain. Ultimately, our hope is that these findings will prompt health authorities in Spain (and elsewhere) to consider the broad-based implementation of this approach, expanding access to all primary care centres, in line with the initiatives undertaken in other countries to improve access to psychological therapies.

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Authors contributions. ACV planned and developed the study design, managed the trial as Principal Investigator, got the main research funds and revised the manuscript. RMN drafted the manuscript, collected and analysed data, and coordinated the study. JAM collected data, was involved in patient care, revised and corrected the manuscript, and obtained research funds. PRR collected data, was involved in patient care, and revised and corrected the manuscript. LAM analysed data, revised the methodology and corrected the manuscript. CGB collected data, contributed to the manuscript writing and revisions, revised and corrected the manuscript, and obtained research funds.

Conflict of interest. The authors have no conflicts of interest to declare.

Ethical standards. The study was approved by the National Scientific Research Ethics Committee in Spain, and conducted in accordance with the Declaration of Helsinki (EUDRACT: 2013-001955-11) and the study protocol was registered (ISRCTN58437086). All participants gave their written informed consent.

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