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RESEARCH ARTICLE

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Cognitive evolutionary therapy versus standard cognitive therapy for depression: A single-blinded randomized clinical trial

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Abstract

Objective: To compare the efficacy of cognitive evolutionary therapy (CET) with cognitive therapy (CT) for depression.

Methods: Ninety-seven participants (78 females/19 males) were randomized to a single-blinded controlled trial (CET: $n = 51$ vs. CT: $n = 46$). Assessments were conducted at baseline, Sessions 4 and 8, posttreatment, and 3-month follow-up. Clinical diagnoses were made with Structured Clinical Interview for DSM-IV (SCID) and self-reports for depression and secondary outcomes.

Results: Although both groups showed significant reductions in depressive symptomatology, the overall Time × Treatment group interaction in the intent to treat analysis was not significant ($p = .770$, posttreatment: $d = 0.39$). However, CET was superior to CT at increasing engagement in social and enjoyable activities ($p = .040$, posttreatment: $d = 0.83$, $p = .040$) and showed greater reductions than the CT group in behavioral inhibition/avoidance ($p = .047$, $d = 0.62$). The between-group differences generally diminished at the 3-month follow-up.

Conclusions: CET is a novel therapy for depression that may add therapeutic benefits beyond those of CT.

KEYWORDS
cognitive therapy, Darwinian psychiatry, depression, evolutionary psychopathology, evolutionary therapy, randomized trial

1 | BACKGROUND

Depression is the leading cause of disability worldwide (World Health Organization, 2017). Etiological factors include demographics, prior depression (Lewinsohn, Hoberman, & Rosenbaum, 1988), negative life experiences (Shrout et al., 1989), or past trauma (Maercker, Michael, Fehm, Becker, & Margraf, 2004).

Efficacious interventions for depression include cognitive-behavioral therapy (CBT; Cuijpers, Andersson, Donker, & van Straten, 2011; Cuijpers et al., 2013), interpersonal therapy (Cuijpers et al., 2011; Cuijpers, Donker, Weissman, Ravitz, & Cristea, 2016; Jakobsen, 2011), and antidepressants (Gartlehner et al., 2007). Other possibly efficacious interventions include brief dynamic therapy (BDT) or emotion focused therapy (EFT; Hollon & Ponniah, 2010), as well as Metacognitive Therapy (Jordan et al., 2014; Nordahl, 2009). CBT in particular has been recommended as a front-line treatment for depression by leading institutes of health in Europe and United States (National Institute of Health and Clinical Excellence, 2009; National Institute of Mental Health, 2017). However, although CBT has demonstrated good clinical efficacy (Cuijpers et al., 2013), approximately 40% of patients with moderate to severe depression do not achieve remission (DeRubeis et al., 2005), while relapse is frequent (Amick et al., 2015; Hollon et al., 2005; Hollon & Ponniah, 2010), a limitation that is not unique to CBT or other psychotherapies (Boland & Keller, 2009; Gartlehner et al., 2007; Gilmer et al., 2005).

In summary, despite the merits of current treatments, continued efforts are needed to improve upon existing interventions or create new ones. The present clinical trial was designed to contribute to this agenda by developing and testing an evolutionary-driven cognitive intervention for depression.

Depression has received particular scrutiny in evolutionary psychology because of its high prevalence (World Health Organization, 2017), universality (Nesse & Williams, 2004), and puzzling consequences to fitness (e.g., suicide) in its most severe cases (American Psychiatric Association, 2013; H. E. Fisher & Thomson, 2006). Unlike most of the current explanations of depression, which focus on the proximal causes (e.g., chemical imbalance, dysfunctional thinking), evolutionary explanations focus on the distal, or ultimate causes of the symptoms.

Some evolutionary psychologists have attempted to explain depression through the possible utility of the symptoms. For instance, Leith and Baumeister (1996) argued that depressed mood reduces the likelihood of risk-taking behaviors, which may enhance survivability, thus fitness. Other authors stated that low mood, through its feelings of loss and pessimism, may motivate an individual to seek help, conserve resources, or explore alternative strategies (Nesse, 1998, 2000). Yet other scholars argued that minor depression is the psychic equivalent of physical pain, therefore, it is adaptive, while major depression can be seen as a person's attempt to quit activities that benefit others, but not herself (Hagen, 2003).

Drawing from the clinical observation that depression often improves when individuals give up the pursuit of unattainable goals (Price, Sloman, Gardner, Gilbert, & Rohde, 1994), some other evolutionary scholars have argued that depression arises as a result of the inability to reach a critical goal, thus prompting the individual to reassess priorities and focus his/her efforts on other pursuits (Nesse, 2000). Another evolutionary explanation of depression—the Social Competition Hypothesis—conceptualizes it as "involuntary yielding," that is, an adaptation that functions to inhibit aggression toward others of superior rank (Price et al., 1994). Yet other researchers showed that negativity

biases associated with depression lead to an underestimation of personal mate value, which, in turn, is associated to a miscalculation of the mate value of potential partners (Kirsner, Figueredo, & Jacobs, 2003), whereas others linked depression with a fast Life History (Giosan, 2013).

At the core of many evolutionary explanations of depression thus lies the assumption that depression is not a brain disorder, but its symptoms are functional states whose utility is fitness maximization (for a review, see Durisko, Mulsant, & Andrews, 2015). Fitness, from an evolutionary perspective, is defined as the reproductive success of an organism.

Thus, evolutionary theories of depression raise the intriguing possibility that interventions aimed at fitness maximization could come with therapeutic benefits above and beyond the current treatments. Some researchers have already tested some evolutionary-inspired interventions for depression, with promising preliminary results (e.g., Botanov et al., 2012; Giosan, Muresan, & Moldovan, 2014; Jacobson et al., 2007). However, although such interventions do target behaviors associated with improved fitness, to our knowledge, there have been no standardized interventions that integrate evolutionary psychology approaches to treating depression in a comprehensive, multidimensional fashion. Toward this end, the authors of the present study used a protocol for cognitive evolutionary therapy (CET) for depression (Giosan, 2020; Giosan et al., 2014) and compared its efficacy with the widely validated Beck's cognitive therapy (CT) for depression (Beck, Rush, Shaw, & Emery, 1979; Hofmann, Asnaani, Vonk, Sawyer, & Fang, 2012). CET starts with an evaluation of a patient's subjective perception of fitness, realized with the Evolutionary Fitness Scale (Giosan, Wyka, Mogoase, Cobeanu, & Szentagotai, 2018). The EFS includes items tapping in fitness-relevant dimensions, such as social capital, personal and partner's health, physical aspect, quality of children, access to resources and medical care, upward social mobility, fit with the environment, as well as inclusive-fitness factors such as contact with, and investment in relatives. The goal of the fitness evaluation is to identify deficiencies on these biologically relevant dimensions, conceptualized as distal mechanisms contributing to depression, which are then prioritized and targeted in treatment.

Thus, one of the critical differences between CET and CT is that, in CET, the clinical conceptualization includes elements from the evolutionary theories of depression to explain the onset and maintenance of depressive symptoms. Specific areas of interventions needed for a patient are identified in a highly structured and standardized manner, using the comprehensive fitness evaluation conducted at intake. In the absence of a comprehensive fitness evaluation at intake, important areas of intervention may be left out, as they may not be identified during the therapeutic process.

2 | METHODS

2.1 | Design

A randomized, single-blinded design was used to compare CET with CT. Assessments were conducted at baseline, Sessions 4 and 8, posttreatment, and 3-month follow-up. The study was approved by the institutional review board of the institution (a large European university) hosting this project (trial registration: ISRCTN, ISRCTN64664414, http://www.isrctn.com/ISRCTN64664414).

2.2 | Participants

Prospective participants were recruited by licensed clinical psychologists. They were also recruited from private practices and clinics that collaborate with the institution, as well as through posters and various media venues

(e.g., newspapers, radio, social media). Recruitment took place between January 11, 2011 and January 10, 2016, ending within the trial funding envelope and the trial timescale, and achieving 97% of its original target.

The eligibility criteria included adults with Beck Depression Inventory (BDI-II; Beck, Steer, & Brown, 1996) scores > 13, current diagnosis of Major Depressive Disorder or Episode (MDD or MDE), or MDD with Comorbid Dysthymia, as assessed with the *Structured Clinical Interview for DSM-IV* (SCID; First, Spitzer, Gibbon, & Williams, 1997). Participants on medication, or with Panic Disorder, Bipolar Disorder, substance abuse, psychotic symptoms, organic brain disorders, imminent risk of suicide, self-injury or harming others, serious legal or health issues that would prevent from regularly attending, were excluded. Out of the approximately 1,000 individuals who responded to announcements, a total of 97 eligible individuals were randomized and scheduled for the baseline assessments. Six participants (three for each treatment group) did not complete baseline assessments and were not available for rescheduling, thus were considered a case of "no show" and not included in the statistical analyses (see Figure 1). There were no significant differences between treatment groups on the majority of demographic or study variables, except for gender and education level, which were included as covariates in analyses. Treatment groups did not differ in their treatment preference and expectations regarding treatment effectiveness (see Table 1).

2.3 | Treatment conditions

The CT and CET therapies, consisting of individual sessions, were each delivered by four CT-trained licensed clinical psychologists, two per condition. The two psychotherapists delivering the CET received an additional 6 weeks of training on the evolutionary components of the CET protocol (Giosan, 2020; Giosan et al., 2014).

2.3.1 | The CT group

The CT group underwent 12 weekly 1-h sessions of CT (Beck et al., 1979) aimed at the correction of dysfunctional, automatic thoughts, and beliefs hypothesized to be responsible for depressive symptoms. Cognitive interventions were paired with behavioral techniques, which were used for cognitive changes, behavioral activation, and positive reinforcements. The patients began the treatment with the identification of negative automatic thoughts, whose validity was subsequently challenged. This has been shown to lead to a more adaptive worldview, which can, in turn, decrease the severity of depressive symptoms (Beck et al., 1979). As the therapy progressed, deeper cognitive structures were targeted (including underlying assumptions/intermediate beliefs and dysfunctional schemas), the goal being a remission of the symptoms and relapse prevention.

2.3.2 | The CET group

The CET group also underwent 12 weekly 1-h sessions of therapy. CET is based on the standard CT methods, with the important distinction that specific goals targeted at increasing an individual's subjective perception of his/her fitness were mainly targeted (Giosan, 2020; Giosan et al., 2014). Briefly, the CET intervention started with the administration of an evolutionary fitness instrument (Evolutionary Fitness Scale [EFS]; Giosan et al., 2018), which gave the CET therapists a comprehensive picture of the fitness areas that needed to be addressed in treatment. In other words, the patients' answers to the EFS at intake primarily guided the intervention elements in this group.

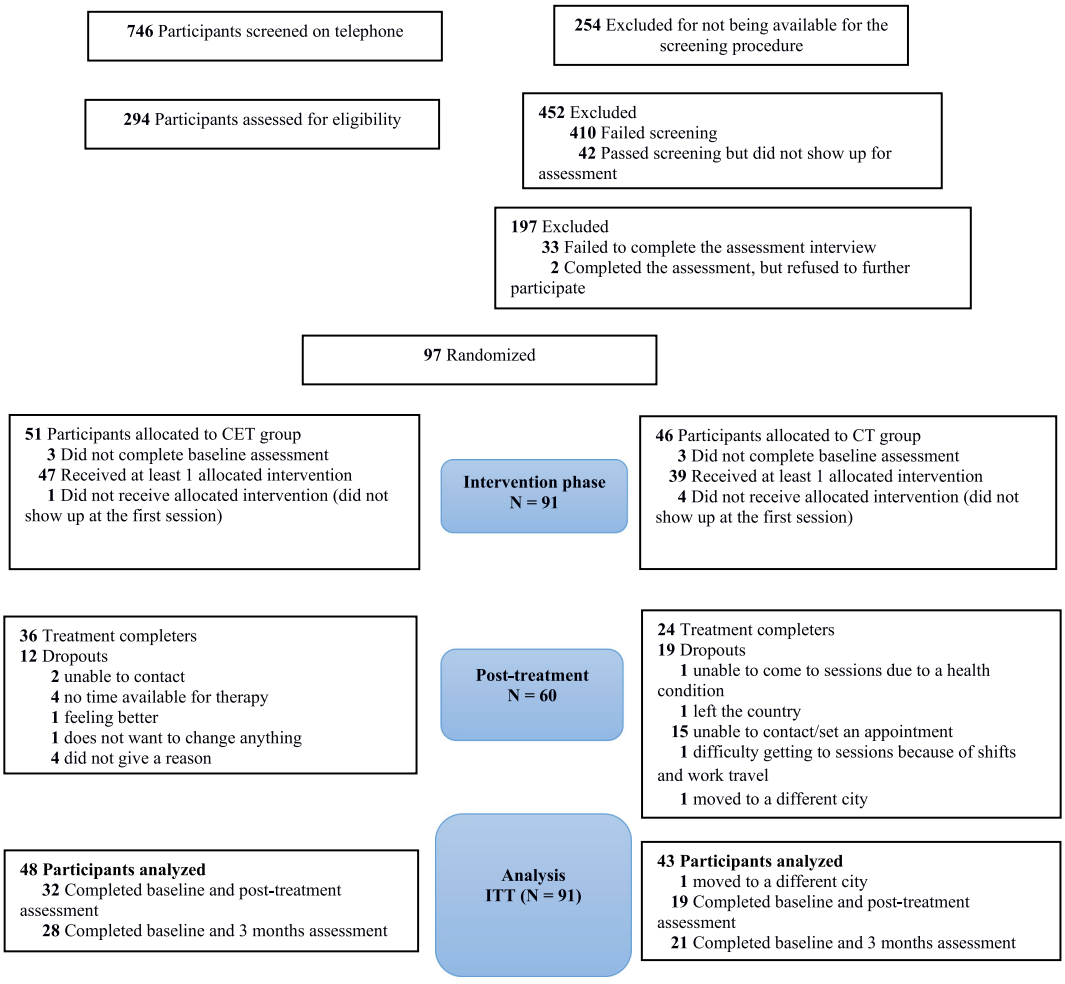

FIGURE 1 Consolidated Standards of Reporting Trials (CONSORT) flow diagram (Schulz, Altman, Moher, & for the CONSORT Group, 2010) showing subjects' allocation to condition. CET, cognitive evolutionary therapy; CT, cognitive therapy; ITT, intention to treat; PP, per protocol [Color figure can be viewed at wileyonlinelibrary.com]

2.4 | Outcomes and measures/variables

The SCID (First et al., 1997) was used for eligibility assessment and diagnosis.

Three sets of outcomes were examined[1]:

1. The primary outcome was level of depressive symptomatology, assessed with the BDI-II (Beck et al., 1996) and a categorical diagnosis of depression after treatment, assessed with the depression module from the SCID (First et al., 1997).
2. The secondary outcomes were (a) quality of life, assessed with *The WHO Quality of Life BREF* (WHOQOL-BREF; World Health Organization, 2012), and (b) social functioning, assessed with *The Social Adjustment Scale* (SAS; Weissman, 1999).

TABLE 1 Participants' characteristics by treatment group

	CET (n = 48)		CT (n = 43)		p values
Age, *M*, *SD*	30.77	10.12	32.33	11.16	.775
Gender, *N*, %					
Male	7	14.6	12	27.9	.118
Female	41	85.4	31	72.1	
Education level, *N*, %					
High school	11	23.4	18	45.0	.020
College degree	19	40.4	17	42.5	
Master's degree or higher	17	36.2	5	12.5	
Marital status, *N*, %					
Single	31	66.0	27	57.4	.981
Married or cohabitating	12	25.5	10	21.3	
Other (divorced or widowed)	4	8.5	3	6.4	
Number of children, *N*, %					
0	35	74.5	30	75.0	.978
1	10	21.3	8	20.0	
2 or 3	2	4.3	2	5.0	
Age of the youngest child, *M*, *SD*	14.36	12.41	17.1	9.52	.580
Treatment preference, *N*, %					
CET	28	65.1	29	78.4	.191
CBT	15	34.9	8	21.6	
Treatment expectancy, *M*, *SD*	22.94	8.58	23.45	6.90	.762

Note: Some demographic data were missing for one participant in the CET group and three participants in the CT group. Baseline comparisons were conducted using two-sided independent t tests for continuous data and χ^2 tests for categorical data.

Abbreviations: CBT, cognitive-behavioral therapy; CET, cognitive evolutionary therapy; CT, cognitive therapy.

3. The tertiary outcomes included: (a) evolutionary fitness, evaluated with the *Evolutionary Fitness Scale* (Giosan et al., 2018), tapping into various dimensions theorized to make up the indicators of fitness; (b) two measures of evaluating mate value (which is a complex of traits and factors that are perceived to be desirable in a mate, such as physical aspect, faithfulness, intelligence, parenting, resource acquisition, etcetera), namely, the *Mate Value Inventory* (MVI; Kirsner et al., 2003), and *Components of Mate Value Survey* (CMVS; M. Fisher, Cox, Bennett, & Gavric, 2008); (c) self-reported physical health, assessed with *The Physical Health Questionnaire* (PHQ; Schat, Kelloway, & Desmarais, 2005); (d) behavioral activation, assessed with the *Behavioral Inhibition System/Behavioral Activation System* (BIS/BAS; Carver & White, 1994); (e) self-reported religiosity, for its potential to influence the efficacy of CET, a Darwinian-inspired intervention, assessed with *The Santa Clara Strength of Religious Faith Questionnaire* (SCSRFQ; Plante, Vallaeys, Sherman, & Wallston, 2002); (f) self-reported coping strategies, assessed with *Brief COPE* (B-COPE; Carver, 1997), measures of positive and negative emotions, assessed with *The Positive and Negative Affect Scale* (PANAS; Watson, Clark, & Tellegen, 1988); (g) maladaptive beliefs measured with *The Attitude and Beliefs Scale II* (ABS II; Macavei, 2002); (h) participants' preferred treatment option; (i) working alliance measured with *The Working Alliance Inventory* (WAI; Horvath & Greenberg, 1986, 1989); (j) treatment outcome expectancies, measured using 10-cm visual analogue scales (VASs); and (k) client satisfaction with therapy measured with the *Client*

Satisfaction Questionnaire (CSQ; Atkinson et al., 2004; Larsen, Attkisson, Hargreaves, & Nguyen, 1979; Nguyen, Attkisson, & Stegner, 1983).

2.5 | Procedure

Potential participants were provided information about the study during their first appointment and consent for the participation in the clinical evaluation was obtained. If the inclusion criteria were met, consent was obtained from those interested in the treatment, and the rest of the baseline assessment was completed. Ineligible participants were referred to outside providers. To verify therapists' adherence to protocols, participants' consent for recording of sessions was obtained. Adherence was assessed by the PI (who was not involved in therapy delivery) or independent clinicians, who listened to a random 25% sample of these recordings.

Randomization into CT or CET was performed a priori using randomizer.org, by a senior researcher, not involved in assessments or therapy. The participants were randomized by a research aid to CET or CT, without being aware at this point of the group allocation (see Figure 1). The clinical psychologists who evaluated them were not involved in therapy.

At the baseline assessment, the participants were assigned unique IDs and completed all the above-mentioned measures, as well as demographic information. The same set of measures, except the demographic information, was administered at posttreatment assessment and 3-month follow-up. Intermediary assessments at Sessions 4 and 8 were completed on a subset of measures, and the BDI-II, CSQ-8, and Intent-to-Attend Scale were administered at each session (Giosan et al., 2014).

2.6 | Statistical approach

An a priori power analysis for a mixed Time × Group analysis of variance (α error probability of .05, two treatment groups, two levels of Time—pre- and posttreatment and correlations among repeated measures), computed with G*Power 3.1.6 (Faul, Erdfelder, Lang, & Buchner, 2007), revealed a need of 50 subjects per condition to detect a medium effect size ($f = 0.247$), power value 0.80.

Analyses were conducted on (1) intent-to-treat sample and on (2) completers. Pretreatment characteristics were compared between treatment groups (CET vs. CT) as well as between completers and dropouts, using independent samples t test and χ^2 tests for differences in means and percentages. These statistics and test were also used for treatment group comparisons on treatment preference and treatment expectancy, as well as therapeutic alliance and treatment satisfaction.

The primary outcome was examined using mixed-effect linear models with a random intercept and slope, fixed effect for time (four assessments: baseline, after Sessions 4 and 8, posttreatment), fixed effect for treatment group (CET and CT), and their interaction. The 3-month follow-up was analyzed in a separate mixed-effect model. All models were adjusted for education level, as treatment groups were not balanced on this characteristic. We used the unstructured covariance matrix and computed between-group effect sizes (d) based on model-predicted BDI-II scores at each assessment point using the LSMeans option in proc mixed procedure in SAS, version 9.4 (SAS Institute Inc.). As no difference between treatment completers and dropouts were found, missing data on study outcomes were handled using the maximum likelihood method. Categorical outcomes (depression severity ranges and diagnostic status) were analyzed using Fisher's exact tests.

The effect of treatment group on all secondary outcomes was examined in an exploratory manner (i.e., no hypotheses were stated in the research protocol and p values were not adjusted for multiple testing), using the same mixed-models methodological approach.

3 | RESULTS

3.1 | Participant retention and session attendance

Ninety-seven participants were enrolled (78 females/19 males, sample mean age = 30.89, SD_{age} = 10.53). Sixty participants completed the protocol (N_{CET} = 36, 75%; N_{CT} = 24, 55.8%; p = .235). The number of treatment sessions received was similar among CET and CT completers (M_{CET} = 10.45, SD_{CET} = 2.35; M_{CT} = 11.56, SD_{CT} = 1.33; p = .238). Thirty-one (34.1%) participants who completed baseline assessments dropped out of the study (CET: n = 12, 25.0%; CT: n = 19, 44.2%; p = .05). Completers and dropouts did not differ in any demographic characteristics or baseline symptom severity. The number of completed treatment sessions was similar among dropout in the CET and CT groups (M_{CET} = 4.64, SD_{CET} = 3.04; M_{CT} = 5.30, SD_{CT} = 2.87; p = .235).

3.2 | Treatment primary outcome—Main analyses

The treatment groups presented comparable levels of depression (as measured by BDI-II) before the start of the treatment (Figure 2 and Table 2). Both groups showed significant symptoms reduction at posttreatment (CET: $M_{posttreatment\text{-}baseline}$ = −20.33, p < .001; CT: $M_{posttreatment\text{-}baseline}$ = −15.44, p < .001), with gains maintained at the 3-month follow-up. The overall Time × Treatment group interaction was not statistically significant, $F(3, 139) = 0.38$, p = .770; however, the analysis revealed a consistent pattern of larger gains (higher drops in BDI-II scores) in the CET group during the treatment (after Session 4: d = 0.12; after Session 8: d = 0.30; posttreatment: d = 0.39). The effect diminished at the 3-month follow-up (d = 0.20). Furthermore, while none of the participants in either treatment group met SCID criteria for MDD or MDE at posttreatment, fewer CET participants were classified as having moderate or severe depression based on self-reported depressive symptoms over time, with a trend for between-group differences at the posttreatment (CET: 6.3% vs. CT: 26.3%, p = .087), but not at the 3-month follow-up (CET: 10.7% vs. CT: 28.6%, p = .146). Completer analysis yielded a similar pattern of results (data not shown).

3.3 | Treatment secondary and tertiary outcomes—Exploratory analyses

A significant Time × Treatment group interaction, $F(1, 36) = 5.42$, p = .026, was observed in social functioning (as measured by SAS), favoring the CET group at posttreatment (d = 0.67), with gains particularly large in the social and leisure activities, $F(1, 36) = 4.55$, p = .040, d = 0.83. The overall between-group difference in social functioning diminished at the 3-month follow-up (d = 0.13).

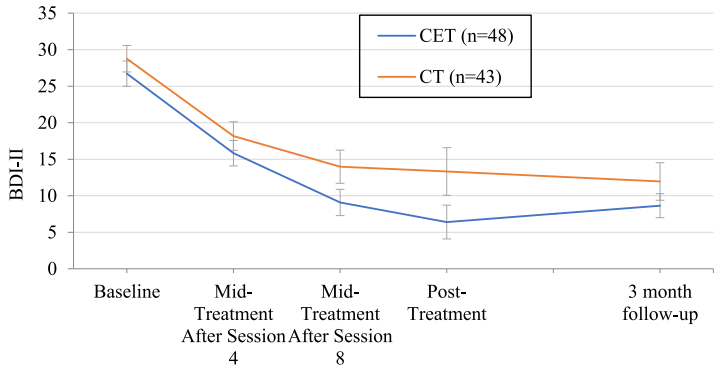

FIGURE 2 Cross-sectional mean scores of BDI-II showing change in depressive symptoms during treatment and follow-up. BDI-II, Beck Depression Inventory; CET, cognitive evolutionary therapy; CT, cognitive therapy [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 2 The effect of treatment (CET vs. CT) on depressive symptomatology (BDI-II) over time

	CET (n = 48)			CT (n = 43)				
	n	*M*	*SE*	*n*	*M*	*SE*	Effect size *d*	*p* value
BDI-II total score								.770*
Baseline	47	29.68	1.56	40	30.83	1.77	_	.630**
Mid-treatment after Session 4	38	18.87	1.62	25	20.10	2.00	0.12	.635**
Mid-treatment after Session 8	35	12.25	1.68	18	15.22	2.39	0.30	.310**
Posttreatment	32	9.58	2.18	19	14.67	3.29	0.39	.200**
3-month follow-up	28	9.23	1.85	21	11.30	2.42	0.20	.501***
	n	%		*n*	%	Group difference (%)		*p* value
Baseline BDI-II severity range								
Low or mild (0–19)		8	17.0	6	15.0	2.0		.914****
Moderate (20–28)		11	23.4	11	27.5	−4.1		
Severe (29–63)		26	55.3	23	57.5	−2.2		
Posttreatment BDI-II severity range								.087****
Low or mild (0–19)		30	93.8	14	73.7	20.1		
Moderate/severe (20–28/29–63)		2	6.3	5	26.3	−20.0		
3-month follow-up BDI-II severity range								.146****
Low or mild (0–19)		25	89.3	15	71.4	17.9		
Moderate/severe (20–28/29/63)		1	10.7	6	28.6	−7.1		

Abbreviations: BDI, Beck Depression Inventory; CET, cognitive evolutionary therapy; CT, cognitive therapy; Effect size *d*, between-group effect sizes based on mixed model estimated means and standard errors at each time point (SAS LSMeans option).

*Overall interaction *p* value for mixed model with fixed effects of time (baseline, after session 4 and 8, posttreatment), group (CET vs. CT), and their interaction.

***p* values for time point comparisons.

***Overall interaction *p* value for mixed model with fixed effects of time (baseline, after Sessions 4 and 8, posttreatment, 3-month follow-up), group (CET vs. CT), and their interaction.

****p* value for Fisher's exact test.

The participants showed similar significant improvements in their perception about the quality of life (measured by WHOQOL-BREF); Time × Treatment group interaction, $F(1, 36) = 0$, $p = .959$ (Table 3).

Significant improvements in each treatment group were observed for most of the additional set of tertiary outcomes (data not shown). Self-reported religiosity (SCSRFQ) had no predictive value over CET's efficacy. Statistically significant Treatment group × Time interaction, $F(1, 36) = 4.64$, $p = .038$, indicated between-group difference in the Behavioral Inhibition/Avoidance subscale at posttreatment ($d = 0.62$). The between-group difference in the Behavioral Inhibition/Avoidance subscale diminished at the 3-month follow-up ($d = -0.25$). There were no improvements in the Mate Value Inventory (MVI) or Brief COPE (B-COPE) in either treatment group.

3.4 | Therapeutic alliance, therapist adherence, and treatment satisfaction

Therapists' adherence to protocol was verified by clinicians not involved in the delivery of the interventions, who reviewed a random sample of recordings of the therapy sessions. Participants in both groups reported high satisfaction with treatment (CSQ CET: $M = 27.28$, $SD = 3.36$, CT: $M = 26.37$, $SD = 3.24$ at Session 1; CET: $M = 31.00$, $SD = 3.66$, CT: $M = 27.90$, $SD = 8.84$ at Session 12, maximum possible score is 32, $p > .05$). Participant perception of

TABLE 3 The effect of treatment (CET vs. CT) on Quality of Life (WHOQOL-BREF), Social Adjustment (SAS), and Behavioral Inhibition Systems (BIS)

	CET (n = 48)			CT (n = 43)				
	n	*M*	*SE*	*n*	*M*	*SE*	Effect size *d*	*p*value
WHOQOL-BREF total score								.959*
Baseline	47	71.24	1.30	41	68.57	1.46	–	.186#
Posttreatment	32	85.87	2.48	19	83.44	3.82	0.16	.598#
3-month follow-up	28	89.02	2.12	21	85.73	2.80	0.28	.354#
SAS total score								.026*
Baseline	47	2.74	0.07	41	2.70	0.08	–	.723#
Posttreatment	27	2.05	0.10	13	2.39	0.14	0.67	.060#
3-month follow-up	19	2.02	0.09	15	2.07	0.11	0.13	.716#
SAS social and leisure activities subscale								.040*
Baseline	48	2.90	0.09	42	2.96	0.10	–	.599#
Posttreatment	27	2.06	0.12	13	2.58	0.18	0.83	.021#
3-month follow-up	19	2.12	0.12	15	2.19	0.15	0.12	.741
BIS avoidance subscale								.047*
Baseline	48	22.64	0.44	40	22.80	0.49	–	.813
Posttreatment	32	19.09	0.67	21	21.69	1.02	0.62	.041
3-month follow-up	27	20.83	0.66	21	19.92	0.82	−0.25	.393

Abbreviations: BIS, Behavioral Inhibition Systems; CET, cognitive evolutionary therapy; CT, cognitive therapy; Effect size *d*, between-group effect sizes based on mixed model estimated means and standard errors at each time point (SAS LSMeans option); SAS, The Social Adjustment Scale; WHOQOL-BREF, The World Health Organization Quality of Life BREF.
*Overall interaction *p* value for mixed model with fixed effects of time (baseline, after Sessions 4 and 8, posttreatment), group (CET vs. CT) and their interaction.
#*p* values for time point comparisons.

therapeutic alliance was also high in each group (WAI Client CET: $M = 68.92$, $SD = 10.63$, CT: $M = 65.44$, $SD = 14.97$ after Session 4; CET: $M = 67.43$, $SD = 13.70$, CT: $M = 65.89$, $SD = 14.75$ after Session 8, maximum possible score is 84, $p > .05$). However, therapist perception of therapeutic alliance was significantly higher among the CET therapists as compared with CT therapists after Session 4 (WAI Therapist CET: $M = 79.08$, $SD = 6.11$, CT: $M = 67.62$, $SD = 10.40$, $p < .001$) and after Session 8 (CET: $M = 79.00$, $SD = 6.86$, CT: $M = 73.91$, $SD = 8.88$, $p = .026$, maximum possible score is 84).

4 | DISCUSSION

To the best of our knowledge, this study is the first attempt to incorporate evolutionary theories of depression into a standardized treatment protocol tested in a randomized clinical trial. Thus, study makes a novel contribution to the body of knowledge of effective interventions for depression.

CET and CT showed similar reductions in symptoms of depression at posttreatment and 3-month follow up. Although CET was not statistically superior to CT, it is noteworthy that fewer CET participants were classified as having moderate or severe depression over time, with between-group analyses showing trend differences at posttreatment. However, while large, the difference in the percentages was not statically significant (CET: $n = 2$,

6.3%, CT: $n = 5$, 26.3%). CET was superior to CT in increasing engagement in social and enjoyable activities at posttreatment and, to a lesser extent, at 3-month follow up. Indeed, we found evidence that in the participants receiving CET, but not in those receiving CT, engagement in these activities was directly related to decreased symptoms of depression, suggesting that CET may lead to richer social reach, which, in turn, may have positive therapeutic effects. Moreover, participants in the CET group showed significantly greater reductions in Behavioral Inhibition/Avoidance at both posttreatment and follow-up, compared with the CT group. Although we did not assess the impact of depression on significant others in this study, increased engagement in social and other activities would likely have a positive effect on attachments that could, in turn, help to maintain treatment gains over time.

Perceptions of quality of life, perceived fitness, mate value (as measured with the CMVS, but not with the MVI), perceptions of physical health, positive and negative affect, and behavioral activation improved significantly in both groups over time and the protocols were similarly efficacious in these respects. There was a trend for fewer maladaptive beliefs in the CET group at posttreatment and 3 months, but it was not significant. Patient perception of therapeutic alliance and treatment satisfaction was high and similar in both groups. However, therapist perception of therapeutic alliance was significantly higher among the CET therapists as compared with CT, which may suggest, according to the literature on working alliance (e.g., Hersoug, Høglend, Monsen, & Havik, 2001), higher confidence in their own professional skills for the CET therapists, although the link between it and outcomes is heterogeneous (Horvath, Del Re, Flückiger, & Symonds, 2011) or negligible when controlling for effect of prior symptoms (Zilcha-Mano et al., 2015).

Despite the promising results of this study, there are several caveats that need to be acknowledged. As with any clinical trial testing psychotherapeutic interventions, therapist blinding was not possible. To minimize possible biases, the principal investigator and the statistician were blind to the study conditions, and the principal investigator was not involved in the actual delivery of the interventions. Furthermore, the present study lacked a no-treatment control group (i.e., waitlist). Hence, a study design with an active comparator (standard CT for depression) was implemented, which generally requires a large sample size to reach statistical significance, given that both treatment groups are expected to improve during the treatment. A relatively small sample size of this study design ($n = 97$), determined by our power analysis based on medium effect size, coupled with an expected, yet high dropout (28.6%) may have had the limited statistical power to detect the treatment effects and introduced bias in the study results. However, the fact that the completers did not differ from the participants who dropped out in any characteristics, coupled with the use of mixed models methodology for data analysis with factors likely related to dropout (time and Time × Treatment interaction) may have mitigated some of the bias (Gueorguieva & Krystal, 2004). Future studies investigating the efficacy of this therapeutic approach should collect detailed information about dropout reasons and continue assessments for participants who chose to leave the study. These studies should also consider a clinical noninferiority trial approach, to better establish the merits of CET versus CT for depression.

The study also employed strict inclusion criteria, which limited the heterogeneity of the sample. Better generalizability of the findings will require future replications in larger trials. Furthermore, because clinician-rated and self-report measures of depression often differ considerably, future studies should use clinician-rated measures of depression to further examine the efficacy of CET. Last, but not least, future studies should examine whether the special training required of the CET therapists may potentially make them more persuasive, leading to lower endorsement of depressive symptomatology in their patients.

However, despite these caveats, this randomized trial is an auspicious first step in the development of a standardized, evidence-based, evolutionary-driven cognitive intervention for depression, laying the groundwork for further testing of the merits of such an approach. Whereas there were no significant differences in the depression outcomes between the two conditions, CET was better on some of the secondary outcomes, namely, social and leisure activities. Notably, given the fact that CET was compared with an active arm that represents one of the most widely validated protocols for depression (CT), the effect sizes obtained were not negligible (small to moderate for

the primary outcomes and large on the secondary outcomes) showing that, on certain clinically relevant dimensions, CET may be superior to CT. The results of this study warrant future research to further examine the efficacy of this approach, particularly whether it may be comparable or superior to medication and/or other types of depression treatments, as well as whether it is beneficial in reducing relapse. Our encouraging findings provide preliminary evidence that CET is a novel, effective therapy for mild to moderate depression that may be offered to patients for whom other types of treatment either are not appealing or have not been effective.

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ENDNOTE

[1]For more detailed descriptions of the measures and the rationale for their inclusion, please see Giosan et al. (2014).

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