Transdiagnostic cognitive behavioral therapy for the treatment of emotional disorders: A preliminary open trial★

Kelly R. Harris, Peter J. Norton*

Monash University, Australia

ABSTRACT

Background and objectives: To assess the efficacy of a transdiagnostic cognitive behavioral therapy (tCBT) protocol for the treatment of emotional disorders with individuals that have a principal or comorbid depressive diagnosis.

Methods: Treatment-seeking adults meeting diagnostic criteria for a depressive disorder were enrolled in a 12-week tCBT open trial aimed at addressing the underlying core pathology of emotional disorders. Clinician severity ratings (CSRs) regarding principal and comorbid diagnoses, and overall severity as well as clinical global impression-severity (CGI-S) ratings were assessed at pre- and post-treatment and 4-month follow-up. Clinician's provided a clinical global impression–improvement (CGI-I) rating post-treatment and at 4-month follow-up. Depressive and anxiety symptoms were measured at pre-treatment and session-by-session using self-report measures (BDI-II and ADDQ).

Results: Repeated measure ANOVAs indicated a reduction in principal diagnosis severity, overall severity, and CGI-S with large effects observed post-treatment (Cohen's ds = 1.29–1.92) and at 4-month follow-up (Cohen's ds = 0.77–1.04). Mixed-effect regression modelling demonstrated a decrease in depressive and anxiety symptoms over the course of treatment. CGI-I ratings identified 63.64% participants as treatment responders both post-treatment and at 4-month follow-up.

Limitations: The uncontrolled nature of the trial and small sample size are the main limitations to generalizability of the findings.

Conclusions: The findings, although preliminary, provide additional evidence for the utilization of tCBT in the effective treatment of emotional disorders. Further research into the implementation of the tCBT for emotional disorders protocol through a randomized controlled trial involving groups of participants with a range of emotional disorder diagnoses is warranted.

1. Introduction

Depression is the leading cause of disability worldwide (Beyond Blue Ltd, 2015), affecting more than 300 million people globally (World Health Organisation [WHO], February, 2017) and causing impairment across a range of areas including home life, workplace, family and friends. The WHO projects that by 2030, depression will be the number one health concern for both developed and developing countries (Mathers & Loncar, 2006). Like depression, anxiety disorders are highly prevalent, impacting on approximately 264 million people globally (WHO, 2017). Individuals experiencing an anxiety disorder endure varying degrees of interference to a range of facets of their life such as

home, social life, close relationships, work and study (Slade et al., 2009). In terms of economic impact, it is suggested that depression and anxiety cost the global economy US$1 trillion per year (Chisholm et al., 2016). A recent return on investment analysis found investing in treatment for depression and anxiety may actually lead to a fourfold return with each US$1 invested returning US$4 in improved health and engagement with employment (Chisholm et al., 2016).

Cognitive behavioral therapy (CBT) is currently deemed as the gold standard treatment modality for both depressive and anxiety disorders (American Psychiatric Association [APA]), 2010; Australian Psychological Society, 2010, 2016; National Collaborating Centre for Mental Health, 2011; National Institute for Health Care and Excellence,

2009, 2013). Psychotherapy research provides strong evidence supporting the efficacy of diagnosis-specific CBT for many psychological disorders including depression and each of the anxiety disorders (Cuijpers, 2015; Cuijpers et al., 2014; Roth & Fonagy, 2006). However, a range of barriers such as the burden of training clinicians to be competent in the delivery of a range of protocols, impact on access to and effective dissemination of such treatments (Barlow et al., 2017).

Emerging transdiagnostic conceptualizations of depressive and anxiety disorders, coupled with a need to address barriers to dissemination and treatment, has resulted in the development of a transdiagnostic approach to the treatment of emotional disorders. This approach reduces the emphasis placed on the distinct diagnostic categories as defined by the diagnostic and statistical manual of mental disorders (*DSM-5*; APA, 2013) which is often observed within diagnosis-specific protocols. With more similarities than differences, convincing arguments have been presented that suggest that depressive and anxiety disorders are better conceptualized under the one classification of emotional disorders (Barlow, Allen, & Choate, 2004; Norton, Harris, Marker, & Pearl, 2019; Norton & Paulus, 2016, 2017). The commonalities between the different emotional disorders are observed in the aetiology and latent structure (Brown, Chorpita, & Barlow, 1998; Caspi et al., 2014; Krueger, 1999; Norton & Mehta, 2007; Watson, 2005). They share symptoms based on *DSM* (APA, 2013) criteria and have comparable biological bases (Heim & Nemeroff, 2001; McNaughton & Corr, 2004). They also share dispositional traits such as negative affectivity or neuroticism, that increase vulnerability to the development of emotional disorders (Clark & Watson, 1991; Mineka, Watson, & Clark, 1998; Talkovsky & Norton, 2014), and similar cognitive-affective, interpersonal and behavioral maintaining factors (Harvey, Watkins, Mansell, & Shafran, 2004).

Comorbidity literature highlights extremely high levels of overlap between the disorders, with those presenting with a depressive disorder often also having a comorbid anxiety disorder and vice versa (Gorman, 1996; Middeldorp, Cath, Van Dyck, & Boomsma, 2005; Wilamowska et al., 2010). The transdiagnostic model of emotional disorders acknowledges both the commonalities and comorbidity when positing the presence of an underlying core pathology including biological and psychological vulnerabilities that manifests in all emotional disorders (Barrera, Smith, & Norton, 2014). These disorders share underlying temperament factors such as high neuroticism, low extraversion, low distress tolerance and experiential avoidance, that may impact on the development and maintenance of the disorders (Sherman, Tonarely, & Ehrenreich-May, 2018). Transdiagnostic treatment approaches address the core pathology by targeting shared mechanisms (i.e. automatic thoughts, core beliefs, experiential avoidance) that maintain the symptoms (Bullis et al., 2015).

The efficacy of transdiagnostic cognitive behavioral therapy (tCBT) in the treatment of emotional disorders, particularly anxiety disorders, has been demonstrated in meta-analytic reviews (e.g. Newby, McKinnon, Kuyken, Gilbody, & Dalgleish, 2015; Pearl & Norton, 2017), literature reviews (e.g. Craske, 2012; McEvoy, Nathan, & Norton, 2009) and clinical trials (e.g. Barlow et al., 2017; Ellard, Fairholme, Boisseau, Farchione, & Barlow, 2010; Gros, 2014; McEvoy & Nathan, 2007; Norton, 2008, 2012b; Norton & Barrera, 2012). Newby et al. (2015) found that transdiagnostic interventions had a large effect on both anxiety ($g = 0.85$) and depression ($g = 0.92$) but overall they had a larger effect on depression symptoms than anxiety symptoms ($Q = 3.94$, $df = 1$, $p = .047$). Comparisons between transdiagnostic treatments versus disorder-specific treatments indicated that there were no statistical differences between transdiagnostic treatments and disorder-specific treatments for anxiety ($g = 0.15$) however significant differences were observed for depression outcomes with transdiagnostic interventions performing better than diagnosis-specific ($g = 0.58$). These results should be interpreted with caution as only a small number of studies ($n = 4$ for anxiety and $n = 3$ for depression studies) were included in the analyses and therefore replication of results with a larger number of studies is required. Nonetheless, these findings suggest that there may be some advantages in employing transdiagnostic interventions to treat symptoms of depression when comorbid with anxiety symptoms (Newby et al., 2015).

Outcome trials of tCBT for clients with anxiety disorders have shown equivalent outcomes on principal anxiety diagnoses as diagnosis-specific CBT for single anxiety diagnoses (Barlow et al., 2017; Norton & Barrera, 2012). Studies evaluating the effect of tCBT for anxiety on comorbid diagnoses have produced promising results with improvements in comorbid diagnoses larger than those observed in studies of diagnosis-specific CBT for anxiety disorders and significant improvement observed specifically in comorbid depressive diagnoses and symptoms (Ellard et al., 2010; Norton et al., 2013; Talkovsky, Green, Osegueda, & Norton, 2017). Research investigating the delivery of tCBT for emotional disorders via the internet has found encouraging results (e.g. Dear et al., 2015; Hadjistavropoulos et al., 2016; Newby, Mewton, & Andrews, 2017; Proudfoot et al., 2004) with a meta-analytical review reporting efficacy for internet delivered tCBT in the treatment of emotional disorders and comparable outcomes to internet delivered diagnosis-specific treatments (Newby, Twomey, Shi Yuan Li, & Andrews, 2016).

Although there is a growing evidence-base of research into the efficacy of tCBT for emotional disorders, research specifically exploring the efficacy of face-to-face tCBT for the treatment of principal depressive disorders is limited. Previous studies that have investigated the impact of face-to-face tCBT have generally focused on the delivery of protocols to groups consisting of participants with a principal anxiety diagnosis, with limited or no inclusion of participants with a principal depressive diagnosis. Studies that endeavored to expand the focus to include the treatment of all emotional disorders generally continued to have samples predominantly comprised of individuals with a principal anxiety diagnosis (e.g. Bullis et al., 2015; Ehrenreich-May et al., 2017; Ellard et al., 2010; Farchione et al., 2012).

Those protocols and studies that have shifted the focus to individuals with principal depressive disorders have provided promising results. In order to address a need for evidenced-based psychotherapy for veterans within Veterans Affairs Medical Centres with affective disorders, Gros (2014) developed a 12 to 16-session, weekly, individual transdiagnostic program that focuses on exposure techniques for negative emotions with an extra eight optional modules for improving exposure practices and other CBT techniques. The protocol was initially developed as alternative appropriate protocols (i.e. Barlow et al., 2011; Norton, 2012a) were yet to be published. There was also a need for a tCBT protocol more specifically relevant to veterans (Gros, 2014) based on observed differences between veterans and civilians with regards to response to diagnosis-specific treatments. An initial evaluation study consisting of a sample of veterans with a range of principal emotional disorder diagnoses found significant improvements in symptoms of depression ($d = 1.37$) and anxiety ($d = 1.31$) however the sample predominantly consisted of individuals with a principal anxiety related diagnosis (75.9%; $n = 22$ of 29).

McEvoy and Nathan (2007), used a benchmarking strategy to investigate the effectiveness of CBT for anxiety and depression for diagnostically heterogenous groups. The group CBT protocol employed in the study combines Beck's (1979) depression treatment manual and Barlow and Craske's (1994) anxiety treatment manual and consists of a 10-week, 2-h program including psychoeducation regarding anxiety and depression, calming techniques, behavioral activation tasks, exposure and cognitive restructuring. Results of the study indicated significant improvement in depression ($d = 1.0$) and anxiety ($d = 0.4$) symptoms with diagnostically heterogenous groups comparing positively with diagnosis-specific CBT groups. The exact number of participants with principal diagnoses of depressive disorders is unclear, although 38 were reported to have depression only. Seventy-five participants were described as having comorbid anxiety and depressive diagnoses, but further breakdown (i.e., principal anxiety with comorbid

depression vs. principal depression with comorbid anxiety) was not provided.

Despite these promising early data, the two protocols employed in the aforementioned studies (Gros, 2014; McEvoy & Nathan, 2007) have thus far undergone limited subsequent empirical evaluation. The aim of the current study was therefore to evaluate the efficacy of an extensively evaluated tCBT protocol for anxiety disorders (Norton, 2012a) that has been recently adapted for use broadly across the emotional disorders including individuals with a principal depressive diagnosis. This protocol was selected as it has a broad, established evidence-base regarding treatment for both principal anxiety and comorbid depressive disorders (Norton, 2008, 2012b; Norton & Barrera, 2012; Norton & Hope, 2005), has demonstrated efficacy in the treatment of comorbid diagnoses (Norton et al., 2013; Norton, Hayes, & Hope, 2004) including comorbid depression (Talkovsky et al., 2017), and can effectively be used with diagnostically heterogenous groups (Chamberlain & Norton, 2013). The structure and method of delivery remained consistent with the original protocol with modifications made to language, examples provided, and "exposure" activities in order to make the protocol inclusive of all disorders conceptualized under the emotional disorders classification. The protocol includes elements that are common across other CBT protocols including psychoeducation, self-monitoring, cognitive restructuring, and behavioral activities (often labeled as behavioral activation or exposure in diagnosis-specific CBT protocols). The protocol differs to other emotional disorder protocols such as TBT in terms of number of treatment sessions, length of time for treatment sessions, and treatment format (i.e., individual vs. group). There are also no additional optional modules in the current protocol, it does not include motivational interviewing components, the focus is on emotional engagement (including both exposure practices and behavioral activation) rather than pure exposures, and there is a greater emphasis on cognitive techniques in the current protocol than in other protocols. It was hypothesized that participants would show a significant reduction in clinician severity ratings for depressive and anxiety diagnoses following treatment and at 4-month follow-up.

2. Method

2.1. Participants

Twelve individuals meeting *DSM-5* diagnostic criteria for a principal or comorbid depressive disorder were recruited between June 2016 and December 2017 via a clinic website and social media pages, advertisements, articles and media releases in local newspapers and on social media, referrals from local health professionals, distribution of materials such as pamphlets and speaking appearances on local and national radio. Inclusion criteria for the study were that participants were 18 years or older, had a clinically severe principal or comorbid *DSM-5* diagnosis of a depressive disorder, were adequately proficient in English, displayed no evidence of dementia or other neurocognitive disorders that would impair their ability to provide informed consent or actively engage in treatment, and there was absence of serious suicidality, substance use requiring detoxification, or any other condition that warranted immediate intervention. Participants who were taking prescribed medication were accepted in to the study if they had been on a stable dose for at least the previous 12 weeks. Exclusion criteria included presence of a personality disorder.

2.2. Measures

Anxiety and Related Disorders Interview Schedule for DSM-5. The Anxiety and Related Disorders Interview Schedule for *DSM-5* (ADIS-5; Brown & Barlow, 2014) is a semi-structured, clinician-administered diagnostic interview used to assess the presence, nature and severity of anxiety, mood and somatoform disorders according to *DSM-5* criteria. The interview includes exploration of previous mental health history

and brief screens for alcohol and substance use and psychosis. The previous version, the ADIS-IV, has shown a range of inter-rater agreement for different diagnoses from adequate to excellent, with good to excellent inter-rater reliability for principal diagnoses (Brown, Di Nardo, Lehman, & Campbell, 2001). Unfortunately, no current reliability statistics are available for ADIS-5 however similar analysis to those completed for the ADIS-IV are being completed (Barlow, 2014). In the current sample, two ADIS assessments were assessed by a second blind rater and 100% inter-rater reliability for principal diagnoses was observed. Across the clinic, the inter-rater reliability of ADIS-5 principal is 90.5% agreement.

Clinician Severity Ratings. The provision of a Clinician Severity Rating (CSR) is a component of the ADIS-5. A CSR is a clinician's subjective rating on a scale of 0 (not severe at all) to 8 (extremely severe/distressing) that describes the degree of distress and interference associated with a diagnosis. Clinicians provide a rating for each individual diagnosis as well as an overall severity rating of each client's full psychiatric presentation. A CSR of 4 (moderate impairment) or greater is considered of clinical severity and indicative that a client meets criteria for a particular disorder (Barlow, 2014; Norton & Hope, 2005). CSR of the principal diagnosis was the primary outcome measure.

Clinical Global Impressions. The Clinical Global Impression (CGI; Guy, 1976) rating scales are subjective clinician ratings of symptom severity, treatment response and treatment efficacy. They consist of three scales however only two were utilised in the current study; the Clinical Global Impression – Severity scale (CGI-S) and the Clinical Global Impression – Improvement scale (CGI-I). The CGI-S is a seven-point scale (1 = Normal, not at all ill, to 7 = Among the most extremely ill patients) that involves clinicians indicating the severity of illness in comparison to others with the same diagnosis at the time of assessment. The CGI-I is a seven-point scale (1 = Very much improved, to 7 = Very much worse), requiring clinicians to specify the level of improvement or if a client has worsened in comparison to baseline presentation prior to commencing treatment. Clients receiving a rating of 1 (Very much improved) or 2 (Much improved) were classified as treatment responders.

Beck Depression Inventory – Second Edition. The Beck Depression Inventory – Second Edition (BDI-II; Beck, Steer, & Brown, 1996) is a 21-item self-report measure of depressive symptoms used widely in both research and clinical practice. Each item is scored on a four-point scale ranging from 0 to 3, with higher total scores indicating more severe depression. The BDI-II is positively correlated with the Hamilton Depression Rating Scale and has also demonstrated high one-week test-retest reliability (Beck, Steer, & Brown, 1996). The scale has also shown high internal consistency (α = 0.91) (Beck, Steer, Ball, & Ranieri, 1996), with internal consistency at pre-treatment in the current study α = 0.86.

Anxiety Disorder Diagnostic Questionnaire (ADDQ). The Anxiety Disorder Diagnostic Questionnaire (ADDQ; Norton & Robinson, 2010) is a four section, self-report measure designed to assess for the presence of clinical fear and/or anxiety regardless of diagnoses. High internal consistency, as well as convergent and discriminant validity have been established, and the ADDQ has demonstrated high sensitivity to treatment with pre-post scores correlating strongly with changes in clinician severity ratings following treatment (Smith, Paulus, & Norton, 2017). The internal consistency at pre-treatment for the current sample was α = 0.84.

2.3. Procedure

The study, including all assessment and treatment, was conducted at the FEAR (Fear, Emotions, Anxiety, Research) Clinic, located within the Monash Psychology Centre at Monash University. All methods and procedures for the study were reviewed and approved by Monash University Human Research Ethics Committee. The clinical trial was retrospectively registered on the Australian New Zealand Clinical Trial

Registry (ACTRN12619000337178). Participants who contacted the clinic initially underwent a brief telephone-screening interview in order to ascertain probable suitability for participation in the study. Potential participants were invited to attend the clinic for a comprehensive face-to-face structured diagnostic assessment utilizing the ADIS-5 to evaluate for study eligibility. Prior to assessment, participants were provided with an explanatory statement outlining the study in detail and informed consent was obtained. Assessment was approximately 120–150 min in duration. Assessors were advanced clinical psychology doctoral students and a registered clinical psychologist. All assessors were trained by an expert ADIS-5 interviewer in order to meet rigorous standards for reliability. Reliability training involved observation of three assessment interviews conducted by an experienced ADIS-5 interviewer and agreement with such interviewer on all diagnoses, as well as matching the CSR and CGI within one point for principal diagnosis. Once reliability was achieved, assessors were permitted to independently administer assessments. Although practical constraints prevented diagnostic assessors from being blinded to treatment timepoint (pre- or post-treatment), assessors were not involved in the provision of treatment and naïve to patient progress. Ongoing supervision with a board approved clinical supervisor and transdiagnostic treatment expert was completed throughout the duration of the study. Supervision consisted of review of recorded assessments and treatment sessions coupled with weekly team meetings.

Upon receiving a principal or comorbid diagnosis of a depressive disorder, eligible participants, with assistance from the assessing clinician, developed and rated a *Trigger and Response Hierarchy* of distressing situations or stimuli in preparation for commencing treatment. They also completed pre-treatment self-report measures, the BDI-II and ADDQ. Participants completed the BDI-II and ADDQ prior to the commencement of each of the 12 treatment sessions. Post-treatment assessments commenced after session 12 of treatment and included another face-to-face clinical interview with an assessor blind to treatment progress to re-administer the ADIS-5. Assessors provided updated CSR and CGI ratings and participants were asked to complete the self-report measures. This post-treatment process was also completed at 4-month follow-up.

Participants were assigned to treatment groups based on order that they presented to the clinic, with no consideration given to individual characteristics such as gender, comorbidity, age etc. Once the first four to eight participants had completed pre-treatment assessments, they were designated to begin treatment. As the performance site had only recently commenced clinical services prior to recruitment for the current study, referral pathways were inconsistent and some participants required a small waiting period until enough participants had been recruited to form and commence another group. As the study progressed, due to ongoing difficulties with consistent referrals and recruitment, when there were insufficient numbers to commence a group in a timely fashion, participants were offered individual treatment utilizing the same protocol.

2.4. Treatment protocol

Treatment consisted of 12 weekly sessions with two FEAR Clinic clinicians, approximately 2 h in duration. Sessions followed a manualized treatment protocol titled "Transdiagnostic Cognitive Behavioral Therapy (tCBT) for Emotional Disorders". Session one focuses on psychoeducation regarding the nature and components of distress and emotional disorders, and components of treatment and their purpose. Participants are introduced to the concept of self-monitoring and homework including daily monitoring of negative emotions. Session two consists of psychoeducation regarding the adaptive basis of emotional disorders. The concepts of automatic thoughts and cognitive restructuring are introduced to clients. In session three, understanding of cognitive restructuring is further developed. It emphasizes the identification of distress-provoking automatic thoughts and thinking errors

coupled with ways to challenge catastrophic thinking and overestimation of probability of negative outcomes. Assigned homework includes completion of an automatic thought record and cognitive restructuring practice. Sessions four to nine involve participants undertaking emotional engagement exercises in-session based on situations and/or stimuli identified in individual *Trigger and Response Hierarchies*. Further emotional engagement exercises are assigned for homework. Sessions ten and eleven of the protocol shift the focus from specific distress-provoking situations and/or stimuli, and shifts the focus to the concept of underlying core beliefs and how they can influence moods, emotional distress, and behaviors in general. Cognitive techniques are employed by therapists to assist clients with identifying and challenging possible core beliefs regarding a range of themes such as negative affectivity, personal control over events and threat. Homework includes advanced cognitive restructuring, including the identification and challenging of core beliefs (e.g., "If it's not perfect then it's a failure; " see Harris and Norton (2018), for a detailed case example) in daily life. The final session provides psychoeducation regarding maintaining gains and continuing progress. Ways to deal with stressors, lapses and general bad experiences are explored and an action plan is constructed to address relapse prevention.

Clinicians involved in the study were doctoral-level students, under the supervision of the author of the tCBT treatment protocol for anxiety disorders. Clinicians were initially trained in the tCBT treatment protocol for anxiety disorders through observation of previously recorded group treatment sessions followed by supervision. Where possible, new clinicians were paired with more advanced doctoral co-clinicians who had previously delivered the treatment. The supervisor observed recordings of treatment sessions for the purposes of supervision and to ensure treatment fidelity.

3. Results

See Fig. 1 for a flow chart of participants. The sample consisted of seven females (58.3%) and five males (41.7%) aged between 33 and 63 years ($M = 49.92$ years, $SD = 10.99$) and predominantly Caucasian (83.3%). Marital status of the participants was mixed (25% married, 8.3% cohabitating, 33.3% divorced, 8.3% separated, 25% single). The sample was generally well educated (16.7% some undergraduate, 16.7% bachelor's degree or equivalent, 8.3% some professional/graduate school, 33.3% graduate/professional degree). Of the 12 participants, seven (58.3%) reported at the initial assessment interview that they were taking psychotropic medication for depression or anxiety. All participants met criteria for clinically severe diagnoses of both a depressive and an anxiety disorder. The most frequent principal diagnosis was major depressive disorder (MDD; $n = 6$), with other principal diagnoses including persistent depressive disorder (PDD; $n = 3$) and generalised anxiety disorder (GAD; $n = 3$). Significant comorbidity was observed within the sample with 12 (100%) participants meeting *DSM-5* criteria for a secondary diagnosis, five (41.7%) for a third, one (8.3%) for a fourth and one (8.3%) for a fifth comorbid diagnosis. Comorbid diagnoses included GAD ($n = 4$), social anxiety disorder (SAD; $n = 4$), panic disorder (PD; $n = 4$), MDD ($n = 3$), alcohol use disorder (AUD; $n = 2$), posttraumatic stress disorder (PTSD; $n = 1$) and somatic symptom disorder (SSD; $n = 1$).

Ten (83.3%) of the 12 participants completed treatment, seven in a group format and three in an individual format. Participants were considered a drop-out if they failed to attend any of the final three sessions of the treatment program. The two study drop-outs were enrolled in the group treatment format. One study drop-out discontinued treatment after session six however completed post-treatment and 4-month follow-up assessments. Consistent with an intent-to-treat approach, data from the study drop-out participants are included in all outcome analyses. For all participants, the average attendance was 10.25 sessions ($SD = 2.73$).

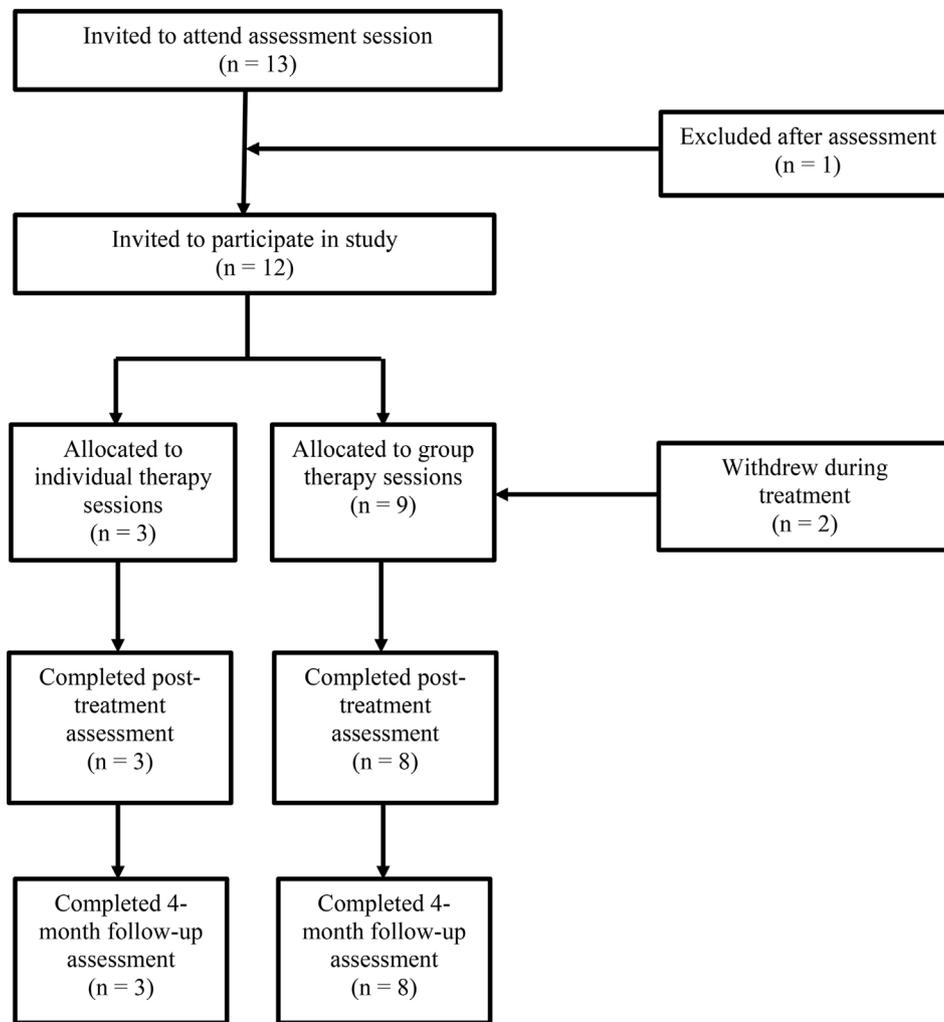Table 1 provides a description of means and standard deviations for

Fig. 1. Participant flowchart.

Table 1
Means and standard deviations for outcome measures.

Measure	Pre-treatment	Post-treatment	4-month follow-up
Principal diagnosis CSR	5.25 (0.75)	3.08 (2.02)[a] [b]	3.17 (2.12)[a] [b]
Overall CSR	5.17 (0.83)	3.25 (1.36)[a] [b]	3.41 (1.78)[a] [b]
CGI-S	4.67 (0.49)	3.08 (1.44)[a]	3.17 (1.53)[a]
CGI-I		2.27 (0.90)	2.73 (1.49)
BDI-II	31.53 (9.05)	23.55 (13.39)[a]	
ADDQ	34.90 (8.13)	25.18 (10.41)[a]	

Note. CSR = Clinician Severity Rating; CGI−S = Clinical Global Impressions – Severity Rating; CGI−I – Clinical Global Impressions – Improvement Rating; BDI−II = Beck Depression Inventory – Second Edition; ADDQ = Anxiety Disorder Diagnostic Questionnaire.

[a] Significant reduction in severity or symptoms.

[b] Clinically significant change in severity/diagnosis.

outcome measures of interest. Repeated measure ANOVAs were employed to analyze clinician rated measures from pre-to post-treatment and 4-month follow-up. For principal diagnosis CSR, large effects were observed across participants post-treatment, $F(1,11) = 22.40$, $p = .001$, Cohen's $d = 1.37$, and at 4-month follow-up, $F(1,11) = 17.41$, $p = .002$, Cohen's $d = 1.04$. Similarly, a reduction in participant overall CSR was observed from pre-to post-treatment, $F(1,11) = 44.42$, $p < .001$, Cohen's $d = 1.92$, and 4-month follow-up, $F(1,11) = 12.54$, $p = .005$, Cohen's $d = 0.85$, with large effects that reached significance. The same pattern was observed for CGI-S ratings with large effects indicating a reduction in severity ratings post-treatment, F

$(1,11) = 19.56$, $p = .001$, Cohen's $d = 1.29$, and at 4-month follow-up, $F(1,11) = 11$, $p = .007$, Cohen's $d = 0.77$.

To fully utilize the entire sample of treatment initiators, session-by-session BDI-II and ADDQ self-report measures were assessed using mixed-effect regression modelling (MRM). Using a restricted maximum likelihood (REML) estimator, the data were fitted to a random intercepts and slopes model. Due to a number of participants failing to complete and return outcome questionnaires provided at 4-month follow-up, insufficient data was available to complete analyses of self-report measures at this time point. Thus, only pre-to post-treatment analyses were completed and reported. First, session-by-session BDI-II scores were modeled with time as a predictor to establish the extent to which depressive symptoms changed over the course of treatment. Results indicated that the intercept of the BDI-II scores (i.e. prior to Session 1) was within the clinical range, maximum likelihood estimate (MLE) = 28.87, Wald $z = 12.89$, $p < .001$, and decreasing BDI-II scores were observed throughout treatment, $MLE = -0.69$, Wald $z = -2.70$, $p = .007$. Second, session-by-session ADDQ scores were modeled with time as a predictor to establish the extent to which anxiety symptoms changed over the course of treatment. Results indicated that the intercept of the ADDQ scores (i.e. prior to Session 1) was within the clinical range, $MLE = 33.83$, Wald $z = 19.42$, $p < .001$, and decreasing ADDQ scores were observed throughout treatment, $MLE = -0.86$, Wald $z = -4.30$, $p < .001$.

In order to assess the clinical significance of change from pre-treatment to post-treatment and 4-month follow-up, the clinician rated

outcome measures of principal diagnosis CSR and CGI-I were examined. Seven of 11 (63.64%) participants who returned for post-treatment assessment had a principal diagnosis CSR score below the cut-off for clinical severity (CSR < 4; Barlow, 2014; Norton & Hope, 2005). More specifically, six of nine (66.67%) participants with a principal depressive diagnosis no longer met the full criteria for a depressive diagnosis and one of three (33.33%) participants with a principal anxiety diagnosis no longer met full criteria for the anxiety diagnosis. Seven of 11 (63.64%) participants who returned for 4-month follow-up assessments had a principal diagnosis below the cut-off for clinical severity. This included five of nine (55.55%) participants with a principal depressive diagnosis and two of three (66.67%) participants with a principal anxiety diagnosis. At post-treatment CGI-I ratings ranged from 1 (very much improved) to 4 (no change), $M = 2.27$, $SD = 0.90$. Seven of 11 (63.64%) participants were identified as treatment responders (CGI-I < 3) at post-treatment. After 4-month follow-up assessments, CGI-I ratings ranged from 1 (very much improved) to 6 (much worse), $M = 2.73$, $SD = 1.49$. Seven of 11 (63.64%) participants were identified as treatment responders at 4-month follow-up.

In terms of comorbid diagnoses, 18 comorbid diagnoses of clinical severity were initially assigned to the 11 participants who returned for post-treatment assessment. Of those 18 diagnoses, 14 (77.78%) were assigned a CSR of a subclinical level by assessors at post-treatment. For those that had a comorbid depressive diagnosis ($n = 3$), two (66.67%) participants were assigned a subclinical level of diagnosis at post-treatment. Treatment gains remained relatively stable at 4-month follow-up with 13 of the initial 18 (72.22%) comorbid diagnoses remaining at subclinical levels. Two of the three (66.67%) participants with a comorbid depressive diagnosis at pre-treatment were assigned subclinical CSRs at 4-month follow-up.

4. Discussion

The findings of this open trial offer initial support for the efficacy of tCBT for the treatment of emotional disorders. More specifically tCBT for emotional disorders may be an effective treatment option for individuals with a principal or comorbid depressive diagnosis. In this trial, all participants evidenced meaningful improvements in overall diagnoses and symptom severity, with large effect sizes observed on all clinician rated outcome measures post-treatment (Cohen's $ds = 1.29–1.92$) and at 4-month follow-up (Cohen's $ds = 0.77–1.04$). The post-treatment effect sizes observed here are consistent with those reported by Gros (2014) in a sample also comprised of principal diagnoses of both depressive and anxiety disorders. Post-treatment CSRs of principal diagnosis for the overall sample ($M = 3.08$) were highly similar to those reported in other transdiagnostic trials (e.g. Ellard et al., 2010; Norton & Barrera, 2012). These treatment gains were maintained at 4-month follow-up with mean principal diagnosis CSR ($M = 3.17$) and mean overall CSR ($M = 3.41$) below clinical cut-off points.

Improvements were also observed in self-report outcome measures. Using MRM procedures, the data showed a negative slope across sessions that reached statistical significance, suggesting that participants experienced significant declines in BDI-II and ADDQ scores over time during treatment. With respect to depressive symptoms, on average, participants showed a 0.69-point decline in BDI-II scores per session, or an average decrease of more than 8 points over the course of the 12-week treatment. Despite this, and incongruent with the results from the clinician ratings, BDI scores at post-treatment remained on average in the moderately severe range. The reasons for this are unclear, but it is possible that residual depressive symptoms may continue to exist following treatment despite no longer meeting criteria for a depressive diagnosis. For anxiety symptoms, on average participants showed a 0.86-point decline in ADDQ scores per session, or an average decrease of more than 10 points over the course of treatment.

The issue of comorbid disorders and their impact is of importance to the understanding and treatment of mental health disorders (Norton

et al., 2013; Talkovsky et al., 2017). Whilst the traditional approach to treatment has previously been to initially treat the principal diagnosis and then target any remaining comorbid diagnoses (Norton & Hope, 2005), this treatment was designed to shift the focus from the hierarchy of diagnoses to the underlying core pathology found in all emotional disorders and the mechanisms that maintain the symptoms. Thus, the aim was to address comorbidity through the treatment of all emotional disorder diagnoses simultaneously. Clinician severity ratings of all principal diagnoses, both depression and anxiety, decreased over the course of treatment and at 4-month follow-up. Improvement was observed for comorbid diagnoses, with a large proportion of comorbid diagnoses deemed as below the clinical cut-off at post-treatment (77.78%) and at 4-month follow-up (72.22%).

One advantage of the current trial is that it is more reflective of the complexities and comorbidities that clinicians may face in the real-world. Whilst clinical trials have often been criticized for not replicating real-world settings (Rothwell, 2005, 2006), the current trial allows for greater generalizability with high heterogeneity observed among participants and with each of the participants included in the trial having comorbid diagnoses and at least one depressive and one anxiety disorder diagnosis. This suggests that it may be possible to use one tCBT protocol, instead of sequential disorder-specific protocols, to treat individuals with comorbid depressive and anxiety disorders.

4.1. Limitations

Results from this trial should be interpreted in the context of its limitations. First, the sample utilised in this study was small. Caution needs to be taken when interpreting the results, as due to the small numbers available for analysis, it is unclear as to whether the format of treatment delivery (i.e., individual vs. group format) or principal diagnosis (i.e., depression vs. anxiety) impacted on the results. In the current study, the reassignment of participants to individual treatment was an artefact of recruitment issues due to the newness of the research clinic; however this highlights the need for further research which assesses delivery format and associated potential clinical implications. Although the protocol was designed to be delivered in a group format, it would be beneficial to have a stronger understanding of the efficacy of the protocol when delivered in an individual format as recruitment difficulties can present in both research and real-world settings. Although the aim of the current study was not to compare the reduction of symptoms based on principal diagnosis, examination of such data would also provide further information regarding the efficacy and appropriateness of treating individuals with an emotional disorder within a diagnostically heterogeneous tCBT protocol. Thus, replication of the results achieved in this study are warranted.

Second, due to the uncontrolled nature of the trial, the results should be interpreted with caution, as causal attributions regarding the effect of the treatment protocol cannot be directly assumed. It is possible that the reductions in both anxiety and depression observed in the sample could be due, in whole or in part, to spontaneous recovery. However, when considering the large effect sizes and the high percentage of participants classified as treatment responders, it appears improbable that the effects are purely just a function of unrelated improvement over the course of time. Nevertheless, in order to offer more definite conclusions, a randomized controlled trial, comparing tCBT with a waitlist or attention placebo control condition using adequate controls and blinds is necessary to rule out this possibility.

Third, all of the measures used in the study were either based on direct client report (i.e. self-report questionnaires) or clinician ratings based on participant interviews. To some extent data could have been influenced by factors such as over- or under-reporting symptom severity, and biased or distorted recall. Exacerbating this was the fact that diagnostic assessors could not be held blind to assessment period, raising issues related to potential assessor bias, although none of the assessors were involved in the provision of treatment and were kept

naïve to patient progress in treatment. Future studies of the treatment approach could consider the use of other measures of anxiety and depressive symptoms and avoidance or behavioral coping such as behavioral tests, physiological measures and measures of cognitive interference. It may also be beneficial to administer a second self-report measure of the symptoms of interest (i.e. Centre for Epidemiologic Studies Depression Scale for depressive symptoms and the Beck Anxiety Inventory for anxiety symptoms) at regular intervals to compare consistency of self-report measures. In order to reduce assessor bias, assessors should be kept naïve to treatment condition and assessment period in future trials. Unfortunately, in the current trial assessment of the long-term effectiveness of the treatment is limited as follow-up data was only based on clinician rated outcome measures as participants often failed to return questionnaires provided at post-treatment assessment. Future trials should aim to collect follow-up data from a range of perspectives.

4.2. Conclusion and future considerations

This study highlights that a transdiagnostic treatment approach to emotional disorders can effectively reduce both depression and anxiety diagnoses and symptoms in individuals with principal and comorbid depressive diagnoses. These findings, although preliminary, provide further evidence to support the transdiagnostic model of emotional disorders and the treatment of individuals with an emotional disorder diagnosis within a heterogeneous group. Although speculative and requiring confirmation, the utilization of tCBT for emotional disorders may provide various benefits for both clients and clinicians. Most importantly for clients is a potential increase in access to evidence-based treatments, a reduction in wait-times and also a reduction in costs (Norton & Hope, 2005). Transdiagnostic treatments also have the potential to improve dissemination of evidence-based treatment, by reducing training time and costs for clinicians (Hollon et al., 2002) and accommodate comorbidity (Norton et al., 2013) without the need to treat multiple diagnoses sequentially (Chamberlain & Norton, 2013). Although preliminary and based on a small sample, the results obtained here provide support for the continued investigation of tCBT for emotional disorders. In order to improve generalizability of the findings of this study further research such as a randomized controlled trial utilizing the current intervention is recommended and required.

Conflicts of interest

Peter J Norton, Ph.D. receives royalties from Guilford Press for the published treatment manual used in the current study. Kelly Harris declares that she has no conflicts of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jbtep.2019.101487.

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