

Psychotherapy

A Comparison of Emotion-Focused Therapy and Cognitive-Behavioral Therapy in the Treatment of Generalized Anxiety Disorder: Results of a Feasibility Randomized Controlled Trial

Ladislav Timulak, Daragh Keogh, Craig Chigwedere, Charlotte Wilson, Fiona Ward, David Hevey, Patrick Griffin, Louise Jacobs, Suzanne Hughes, Christina Vaughan, Kea Beckham, and Shona Mahon

Online First Publication, February 3, 2022. <http://dx.doi.org/10.1037/pst0000427>

CITATION

Timulak, L., Keogh, D., Chigwedere, C., Wilson, C., Ward, F., Hevey, D., Griffin, P., Jacobs, L., Hughes, S., Vaughan, C., Beckham, K., & Mahon, S. (2022, February 3). A Comparison of Emotion-Focused Therapy and Cognitive-Behavioral Therapy in the Treatment of Generalized Anxiety Disorder: Results of a Feasibility Randomized Controlled Trial. *Psychotherapy*. Advance online publication. <http://dx.doi.org/10.1037/pst0000427>

A Comparison of Emotion-Focused Therapy and Cognitive-Behavioral Therapy in the Treatment of Generalized Anxiety Disorder: Results of a Feasibility Randomized Controlled Trial

Ladislav Timulak¹, Daragh Keogh¹, Craig Chigwedere¹, Charlotte Wilson¹, Fiona Ward², David Hevey¹, Patrick Griffin², Louise Jacobs², Suzanne Hughes¹, Christina Vaughan¹, Kea Beckham¹, and Shona Mahon¹

¹ School of Psychology, Trinity College Dublin

² HSE National Counselling Service, Dublin, Ireland

Generalized anxiety disorder (GAD) is a chronic mental health difficulty typically present in primary care settings. Cognitive-behavioral therapy (CBT) is the psychological intervention with the best evidence for its efficacy for GAD. The development of other psychological interventions can increase client choice. This feasibility trial examined an initial assessment of the efficacy of EFT in comparison to CBT in the treatment of GAD in the context of an Irish public health service. The trial provided information on recruitment, therapist training/adherence, and client retention relevant for a potential noninferiority trial. A randomized controlled trial compared the efficacy of EFT versus CBT for GAD. Both therapies were offered in a 16–20 sessions format. Therapists ($n = 8$) were trained in both conditions and offered both therapies. Clients were randomly assigned to the two therapies EFT ($n = 29$) and CBT ($n = 29$). Outcomes were assessed using several measures, with the Generalized Anxiety Disorder-7 (GAD-7) being the primary outcome. Clients were assessed at baseline, week 16, end of therapy, and at 6-month follow-up. Therapists were able to learn the two models after a short training and showed moderate levels of adherence. Although not statistically significant, the drop out from treatment was 10% for EFT and 27% for CBT. The two therapies showed large pre–post change and similar outcomes across all measures, with these benefits retained at 6-month follow-up. Results suggest that EFT is a potentially promising treatment for GAD. Further investigation is indicated to establish its potential to expand the available psychological therapies for GAD.

Ladislav Timulak  <https://orcid.org/0000-0003-2785-0753>
Daragh Keogh  <https://orcid.org/0000-0002-9595-4848>
Craig Chigwedere  <https://orcid.org/0000-0003-1081-246X>
Charlotte Wilson  <https://orcid.org/0000-0002-0800-153X>
David Hevey  <https://orcid.org/0000-0003-2844-0449>
Shona Mahon  <https://orcid.org/0000-0003-0983-5154>

We would like to thank our therapists Janet Malone, Owen O'Brien, Isobel O'Flanagan, Catherine Long, Sheila Collins, Rosie Toner, Marty McKenna, Annika Fogarty; adherence raters Chuck Rashleigh, Orla McLoughlin, Ciara Joyce, Katarina Timulakova, Éamonn O Dochartaigh, Eileen Cahill, Judy Moran, Debbie Van Tonder, Ian O'Grady, and trial management members Kevin óg Connolly and Mac MacLachlan and Alice Coyne for sharing syntax for therapists' effects analysis.

The study was funded by an award from the Health Research Board: HRA-POR-2015-1052. Other than funding the study, the HRB has no role in the design of the study; or in the collection, analysis, interpretation, or reporting of data. The study was preregistered in Controlled Trials ISRCTN Registry, ISRCTN52689081, Registered on 24.10.2017. Ladislav Timulak is one of the developers of an adaptation of emotion-focused therapy for the treatment of generalized anxiety. Craig Chigwedere is the director of the MSc in Cognitive-Behavioral Therapy at Trinity College Dublin.

Ladislav Timulak played a lead role in conceptualization, funding acquisition, investigation, methodology, project administration, resources, supervision, validation, writing of original draft, and writing of review and editing, and an equal role in data curation and formal analysis. Daragh Keogh played a lead role in data curation, investigation, and project administration, a supporting role in funding acquisition, and an equal role in conceptualization, methodology, resources, supervision, and writing of review and editing.

Craig Chigwedere played a lead role in project administration and supervision, a supporting role in funding acquisition and investigation, and an equal role in conceptualization resources, validation, and writing of review and editing. Charlotte Wilson played a lead role in project administration and supervision, a supporting role in funding acquisition, resources, and validation, and an equal role in conceptualization, investigation, methodology, and writing of review and editing. Fiona Ward played a lead role in project administration and supervision, a supporting role in conceptualization, funding acquisition, investigation, and methodology, and an equal role in resources and writing of review and editing. David Hevey played a lead role in formal analysis and validation, supporting role in conceptualization, funding acquisition, project administration, and resources, and an equal role in data curation, investigation, methodology, and writing of review and editing. Patrick Griffin played a lead role in supervision, a supporting role in conceptualization, and an equal role in project administration, resources, and writing of review and editing. Louise Jacobs played a lead role in supervision, a supporting role in conceptualization and resources, and an equal role in project administration and writing of review and editing. Suzanne Hughes played a lead role in data curation and supporting role in project administration, resources, and writing of review and editing. Christina Vaughan played a lead role in data curation and supporting role in project administration, resources, and writing of review and editing. Kea Beckham played a lead role in data curation, supporting role in writing of review and editing, and an equal role in project administration and resources. Shona Mahon played a lead role in data curation and supporting role in project administration, resources, and writing of review and editing.

Correspondence concerning this article should be addressed to Ladislav Timulak, School of Psychology, Trinity College Dublin, Dublin 2, Ireland. Email: timulakl@tcd.ie

Clinical Impact Statement

Question: This feasibility study was assessing the tentative relative efficacy of emotion-focused therapy (EFT) for generalized anxiety in comparison to an established cognitive-behavioral treatment. **Findings:** The study showed EFT as a promising treatment for GAD when compared to the established cognitive-behavioral treatment, worthwhile of further exploration. **Meaning:** The adaptation of EFT for generalized anxiety can broaden the range of treatment choices available for this condition. **Next Steps:** The trial offered a number of learnings in terms of planning a larger definitive trial comparing EFT to the established treatment.

Keywords: generalized anxiety disorder, emotion-focused therapy, cognitive-behavioral therapy, primary care

Generalized anxiety disorder (GAD) is one of the most common anxiety disorders with 1-year prevalence around 3% and life-time prevalence around 5% (Kessler, Chiu, et al., 2005; Kessler Berglund, et al., 2005). It has a high comorbidity (e.g., Bruce et al., 2001) and has a negative impact both on the individual and society (Kertz & Woodruff-Borden, 2011; Wittchen, 2002). It is a potentially chronic condition that has propensity for recurrence (Weisberg, 2009). It is a condition that is particularly characteristic of client presentations in primary care settings (Wittchen et al., 2002).

There are currently few forms of treatment available for GAD. Apart from medication (Slee et al., 2019), cognitive-behavioral therapy (CBT) is the best-established intervention (National Institute for Health & Clinical Excellence, 2011). Variants of CBT have been shown to be more effective than waitlist or placebo comparisons (Carpenter et al., 2018; Cuijpers et al., 2014; Hanrahan et al., 2013). However, very few comparisons exist with alternative non-CBT psychological therapies (Carl et al., 2020; Cuijpers et al., 2014) and there have been calls to assess alternative treatments (Hunot et al., 2007). Broadening treatment choice is not only in line with the service-user-centered ethos embraced by public health service providers such as the service where the here presented study took place, but it also has the potential to positively influence outcomes (Swift et al., 2018). The present study, which builds on initial open trials (O'Connell Kent et al., 2021; Timulak et al., 2017), is a step in the development of an alternate psychological treatment for GAD, namely emotion-focused therapy (EFT) for GAD (Timulak & McElvaney, 2018).

EFT (Greenberg, 2015; Greenberg et al., 1993) is a research-informed therapy, which focuses on transforming maladaptive emotions through the generation of adaptive emotions. It has been empirically studied, particularly in the context of depression (Goldman et al., 2006; Watson et al., 2003) and complex trauma (Paivio & Nieuwenhuis, 2001), while recent adaptations have also been examined as to their efficacy for anxiety disorders (Shahar et al., 2017) including GAD (O'Connell Kent et al., 2021; Timulak et al., 2017). As GAD is characterized by sufferers' efforts to prepare (by worrying) for emotionally difficult situations and by the avoidance of potentially painful emotions (Behar et al., 2009; Newman & Llera, 2011). EFT, which focuses on facilitating adaptive emotional processing, represents a potentially useful model for treatment.

Timulak and McElvaney (2016, 2018) presented an adaptation of EFT for GAD in which they assume that clients suffering from GAD are avoidant of specific triggers that might potentially evoke the client's emotional vulnerability (chronic maladaptive painful

feelings of sadness/loneliness, shame, and/or primary fear/terror). Such clients are cognitively (via worry) preoccupied with actual or potential triggering situations that might elicit this emotional vulnerability. They want to control or avoid these triggering situations and engage in various forms of emotional avoidance while also being unable to process those painful feelings constituting the emotional vulnerability. The therapy is then aimed at transforming this emotional vulnerability through the generation of adaptive experiences that help to restructure problematic emotion schemes and thus lower the propensity for triggering situations to elicit unbearable painful emotions. Therapy also focuses on a more symptomatic level, for instance, it addresses the worry process by highlighting both its function and also the associated experiential cost (for more see below).

Initial studies conducted in primary care and student counseling settings examined the adaptation of EFT for GAD using an open trial format and showed promising results (O'Connell Kent et al., 2021; Timulak et al., 2017). The present study was intended to contribute to the further assessment of EFT as a viable alternative to an established treatment of GAD (CBT) as provided in a public primary care setting. Specifically, we were interested in conducting an initial assessment of *the relative efficacy of EFT in comparison to CBT in the treatment of GAD in the context of an Irish public health service*. Given that this RCT was the first to be conducted in the context of an Irish public health service specialized in delivering psychotherapy in primary care, we also wanted to learn about the feasibility of conducting such a trial, for example, we hoped the trial would provide information about recruitment, therapist adherence, and client retention rates, as well as providing estimates of comparative outcomes that could be used to inform power calculations for a potential definitive noninferiority trial in the same setting (see the pre-stated goals in Timulak et al., 2018).

Method

Trial Design and Setting

The design of the study was a randomized controlled trial (RCT) with two active interventions, EFT and CBT (Timulak et al., 2018). Participants were recruited from a routine national psychotherapy service provided by the public health service in Ireland, the Health Service Executive (HSE). Specifically, the study was hosted by the HSE's Counselling in Primary Care (CIPC) services in the Dublin and North East regions. CIPC is part of a nationwide service which provides psychological therapy to adults who hold a General Medical Card (i.e., individuals eligible to free public health care

on the basis of having a lower income), referred by their General Practitioner (GP; a family doctor), and presenting with mental health difficulties such as anxiety and depression.

Participants/Clients

Participants ($n = 58$) were adults (≥ 18 years) who met criteria for a primary diagnosis of GAD. Clients were first screened for GAD using the Generalized Anxiety Disorder-7 (GAD-7; Spitzer et al., 2006). Clients who scored ≥ 11 , a score suggesting that the client was in the clinical range, were then comprehensively assessed using the Structured Clinical Interview for DSM-5-Research Version (SCID-5-RV; First et al., 2015). To proceed to the study, clients had to meet criteria for GAD as a principal diagnosis. To participate in the study, participants needed to consent to the conditions of the study (e.g., audio recording of sessions, attendance at pre- and posttherapy assessment sessions). Individuals taking psychotropic medication had to agree to be stabilized on that medication for 6 weeks prior to commencing therapy and had to show, with their physician's approval, a willingness to maintain this stability in medication use during the period of therapy. Exclusion criteria included concurrent psychological treatment; substance abuse; psychosis; and organic brain syndrome, as determined during clinical interview and administration of the SCID-5-RV; and suicide risk and risk of harm to others, as defined by scores other than 0 on Item 16 ("I have made plans to end my life") and Item 6 ("I have been physically violent to others") on the Clinical Outcome in Routine Evaluation-Outcome Measure (CORE-OM; Evans et al., 2002).

Therapists

Therapists ($n = 8$) all worked with the CIPC service were psychologists or psychotherapists/counselors, and were, for the purpose of the study, trained in both EFT for GAD and CBT for GAD. All therapists randomly delivered both conditions (see below), thus random allocation was nested within them. Therapists' age at the start of the trial was $M = 48.63$ ($SD = 8.09$) and they had on average $M = 10.25$ ($SD = 4.86$) years of practice. They were all white Irish or European. Therapists saw between 2 and 15 clients ($M = 7.25$; $SD = 3.99$).

Interventions

Emotion-Focused Therapy for GAD (EFT for GAD)

The EFT intervention followed a model described by Timulak and McElvaney (2018; see the introduction) briefly presented in the introduction. Therapy focuses on the restructuring and transformation of problematic emotion schemes centered around the unbearable experiences of chronic emotional vulnerability. Clients are, first, facilitated to tolerate specific painful feelings that they try to avoid or about which they worry. They are then facilitated to articulate the unmet needs embedded in these painful feelings; and to transform these painful feelings through the generation of adaptive emotions such as compassion (e.g., I am here and I care for your pain) and healthy protective anger (e.g., I did not deserve to be exposed to such a pain). Therapy helps clients to regulate their feelings. Core emotional vulnerabilities are typically activated through imaginary dialogues with the triggers of interpersonal

(e.g., experienced hurtful behavior of the other) or intrapersonal (e.g., self-criticism) pain, with the transformation of these vulnerabilities also predominantly occurring through the enactment of adaptive experiences within the same dialogues. Explicit work is also devoted to self-interruptive processes (e.g., an imaginary dialogue is held between the part of the self that wants to avoid pain and the part of the self that is limited by this self-interruption) and to the worry process (e.g., dialogue between the part of the self that prepares for potential triggering scenarios via anxiety-provoking worry and the part of the self that is impacted by this worry process). Clients are facilitated to adopt a more balanced stance where avoidance and worry are less rigidly dominating of the clients' life. Therapists were instructed to aim at having between 16 and 20 sessions as determined by their clinical judgment. Clients attending less than eight sessions were considered to have dropped out from therapy.

Cognitive-Behavioral Therapy for GAD (CBT for GAD)

The CBT intervention was informed by the intolerance of uncertainty model (Dugas & Robichaud, 2007). The model proposes that the ubiquity of uncertainty in all areas of life results in diffuse worry, which occurs in any uncertain situation. Particularly central to the model is the proposition that individuals who develop GAD have a predisposition to be intolerant of uncertainty. This intolerance of uncertainty is then seen to be coupled with positive beliefs about worry (e.g., that worry will help the individual avoid a problematic outcome) and an overall negative problem orientation (e.g., being pessimistic about solving problems). Finally, the model stresses various cognitive avoidance strategies, of which worry is an important part. Treatment involves psychoeducation, particularly focusing on the relationship between intolerance of uncertainty and excessive worrying. The treatment also aims to increase worry awareness through education and worry monitoring, and then through engaging in exposure to real-life worry-provoking situations. Later in the treatment, interventions aimed at the reevaluation of worry beliefs and the learning of helpful problem-solving strategies are introduced, before the introduction of imaginal exposure. In the present study, in vivo exposure was introduced as client's mastered imaginal exposure. Relapse prevention was the focus of the final phase of treatment and included a further focus on problem-solving as well as some mindfulness exercises. As with the EFT condition, therapy lasted between 16 and 20 sessions as per the therapist's clinical judgment. Clients attending less than eight sessions were considered as having dropped out.

Therapists Training and Supervision

Of the eight therapists (6 qualified psychologists and 2 qualified psychotherapists), three had previous experience of EFT during their graduate training and all eight had some previous experience of CBT (with 1 being an accredited CBT therapist). Prior to the trial, therapists declared their theoretical orientation as integrative ($n = 6$), CBT ($n = 1$), and humanistic ($n = 1$). As preparation for participation in the trial all underwent 4 days of general training in EFT with a 5th extra day of training specifically in EFT for GAD (LT, an EFT trainer accredited by the International Society for Emotion-Focused Therapy) and 5 days of training in CBT for GAD (facilitated by CC, course director of a university-based course in CBT, and CW, a

clinical psychologist specialized in CBT). Therapists were also encouraged to attend additional available continuous professional development trainings in EFT and CBT, which some of them availed of (3 therapists did additional EFT and 2 additional CBT workshops). In addition, therapists attended weekly group supervision sessions lasting 1½ hr (1 week in EFT, the next week in CBT) with the trainers in the respective approach, for approximately 8 months before being assessed as adherent to both approaches and thus released to see participants in the trial. The period of time in supervision before achieving adherence and being released to participate in the trial was for two therapists substantially more than 8 months (13 and 14 months) due to personal circumstances that impacted on their ability to regularly attend supervision. To be released to see clients in the trial, therapists had to be deemed adherent to both approaches (as per EFT and CBT trainers' judgment). Supervision then continued throughout the trial, on the same weekly basis for the first 24 months of the trial, and on a fortnightly basis for the last 4 months of the trial. Supervision utilized recordings of training or trial therapy sessions.

Treatment Fidelity Assessment

In addition to ongoing supervision, we also conducted an independent assessment of the adherence and competence (fidelity) of the delivered treatments. All therapy sessions were audio recorded (with the exception of around 4% of sessions delivered over the phone—see the section on coronavirus disease [COVID-19] Pandemic impact on the trial below). The Person-Centered and Experiential Psychotherapy Scale (EFT version; PCEPS-EFT; Elliott, 2016; Freire et al., 2014—for details of the scale, see below) was used by four EFT experts (EFT certified therapists not otherwise involved in the trial) to assess randomly selected recordings for the EFT condition (one session from the main body of therapy, session four and onwards, per client). The Cognitive Therapy Scale-Revised (CTSR; Blackburn et al., 2001) was used by five CBT experts (CBT certified therapists not otherwise involved in the trial) to assess randomly selected recordings for the CBT condition (one session from the main body of therapy per client). A portion of CBT sessions was added to the sample of EFT sessions rated by EFT experts and a portion of EFT sessions was added to the sample rated by CBT experts. The experts were blind to what therapy sessions they rated were from, so it was possible to assess not just adherence/competence but also appropriate levels of discrimination between the two approaches. A portion of the sessions was rated by at least two independent expert raters, and an average rating was then used. The two adherence/competence scales are presented in more detail below. The actual adherence ratings are presented in the Results section.

Randomization

As the organizational structure of CIPC meant that it was not possible to randomize allocation of clients between therapists (e.g., often only one therapist works in a particular location), the decision was made to randomize within therapists and thus all therapists were trained in both approaches and delivered both therapies. DH, a member of the research team with no allegiance to either intervention and no involvement in the delivery of either training or

supervision, generated the allocation sequence using an online randomizer. A random sequence (of numbers 1 and 2, corresponding to EFT or CBT) was generated for each therapist identified by code. Post SCID-5 assessment (see below), and post allocation to therapist (see the next section on Procedure), a member of the research team (the trial manager) contacted (DH) and requested the assignment (either EFT or CBT) for the next participant.

Procedure

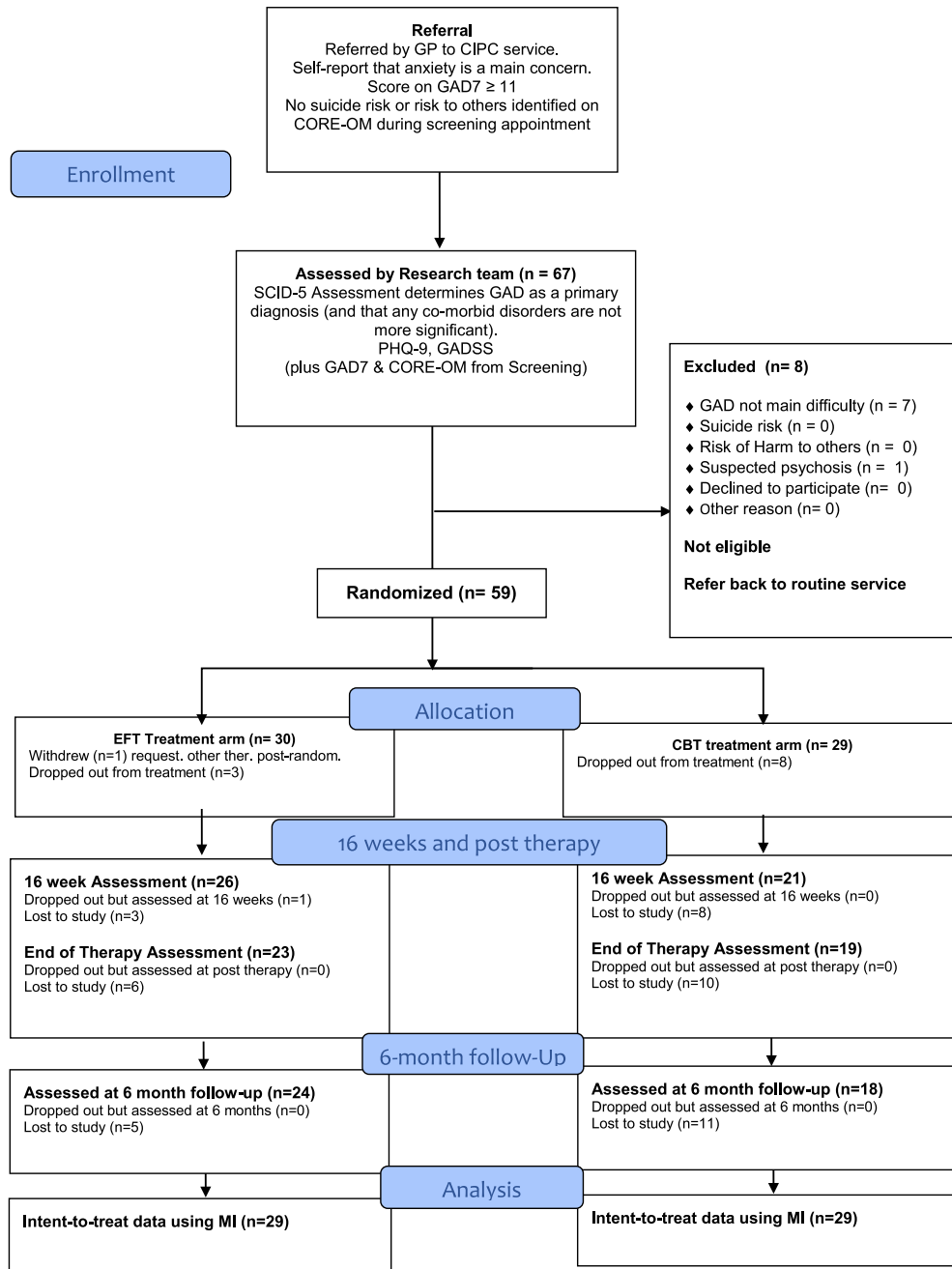
Participants were recruited from clients referred to the CIPC service. Referrals were screened centrally (by CIPC Clinical Coordinators) as per normal service procedure, for suitability for the service, and also as potential participants for the study. When a client presented with anxiety difficulties (as assessed by referral report and/or self-report), had a score of ≥ 11 on the GAD-7, and in the assessing therapist's clinical judgment, potentially met criteria for GAD as a principal diagnosis, the client was given information about the trial. Where the client expressed an interest in participation, met trial inclusion criteria (e.g., stabilized medication regime), and did not meet trial exclusion criteria (e.g., no current risk of suicide or risk of harm to others as measured by the CORE-OM—see above) the assessing therapist sought client consent to refer him or her to the research team for further assessment.

The assessment was performed by a research team member (a doctoral-level psychologist) and included administration of the SCID-5-RV (First et al., 2015) and the Structured Clinical Interview for DSM-5 Personality Disorders (SCID-5-PD; First et al., 2016). In addition, the research team member administered the Generalized Anxiety Disorder Severity Scale (GADSS; Shear et al., 2006), the Patient Health Questionnaire-9 (PHQ-9; Kroenke et al., 2001), and the CORE-OM (Evans et al., 2002). Where assessment indicated GAD as a principal diagnosis, and where inclusion and exclusion criteria were met (see above), the client was invited to participate in the study (for the flow of participants, see the CONSORT Figure 1). During assessment, demographic data (see Table 1) as well as data related to presenting issues were gathered. Further assessments took place at week 16, posttherapy (as close as possible to the date of the last session, where participants finished therapy outside the range of 16 ± 2 weeks) and 6 months post 16 weeks (as close as possible to 42-calendar week from the date of the first session). The study design was prepared in collaboration with the service provider which typically offers 16 sessions of therapy (this can be extended as per clinical judgment and for this study therapists were instructed that they have up to 20 sessions). Thus, a decision was made at the suggestion of the service provider to conduct an assessment at the 16-calendar week time point as well as at the end of therapy as planned by the therapist and at the follow-up.

Ethical Considerations

The study received ethics approval from the School of Psychology Research Ethics Committee and the HSE North East Area Research Ethics Committee. As per ethics committee stipulation, clients were informed that CBT is an established treatment for GAD with good evidence and that EFT is a new treatment in development with promising early results. Clients could withdraw from the study

Figure 1
CONSORT Flow Chart



Note. See the online article for the color version of this figure.

and receive treatment as usual with the CIPC service (one client withdrew from the study postrandomization and requested other treatment; Figure 1). Treatment of all participating clients was closely monitored from a clinical governance perspective according to normal CIPC service guidelines (Counseling Coordinators overseeing any clinical issues that arose) with the option to offer another course of treatment where necessary (e.g., further assessment, hospitalization, acute risk management).

Measures

Diagnostic Measures

Structured Clinical Interview for DSM-5-Research Version (SCID-5-RV). The SCID-5-RV is a semistructured diagnostic interview for assessing the major DSM-5 diagnoses (First et al., 2015). The interview was administered by a psychologist with significant experience using SCID across several research projects.

Table 1
Baseline Demographic and Other Diagnostic Characteristics Across the Two Conditions

Characteristic	EFT (<i>n</i> = 29)	CBT (<i>n</i> = 29)
Age, <i>M</i> (<i>SD</i>)	37.10 (11.09)	32.90 (10.60)
Female gender	25 (86.2%)	24 (82.8%)
Race/Ethnicity		
White Irish/European/American	27 (93.1%)	29 (100%)
White Irish traveler	1 (3.4%)	n/a
Black Irish	1 (3.4%)	n/a
Married/In relationship	17 (58.6%)	18 (64.3%)
College degree	5 (17.2%)	6 (20.7%)
Employed full time	6 (20.7%)	5 (17.2%)
Disability	3 (10.3%)	6 (20.7%)
Prior therapy	21 (72.4%)	23 (79.3%)
Current medication	14 (48.3%)	18 (62.1%)
Comorbid former axis I disorder	24 (82.8%)	26 (89.7%)
Mood disorder	16 (55.2%)	15 (51.7%)
MDD	14 (48.3%)	13 (44.8%)
Anxiety disorder	20 (69%)	22 (75.9%)
Panic disorder	5 (17.2%)	6 (20.7%)
Social anxiety	11 (37.9%)	14 (48.3%)
Agoraphobia	8 (27.6%)	5 (17.2%)
OCD	2 (6.9%)	2 (6.9%)
PTSD	1 (3.4%)	4 (13.8%)
Eating disorder	2 (6.9%)	2 (6.9%)
Comorbid personality disorder	15 (51.7%)	17 (58.6%)
Avoidant	13 (44.8%)	16 (55.2%)
Dependent	1 (3.4%)	4 (13.8%)
Obsessive–Compulsive	1 (3.4%)	3 (10.3%)

Note. None of the differences were statistically significant at $p < .05$; EFT = emotion-focused therapy; CBT = cognitive-behavioral therapy.

Structured Clinical Interview for DSM-5 Personality Disorders (SCID-5 for DSM-5-PD). The SCID-5-PD is a semistructured diagnostic interview for assessing the 10 DSM-5 Personality Disorders (First et al., 2016). It was administered with the SCID-5-RV by a psychologist with extensive experience using the SCID.

Primary Outcome Measure

GAD-7. The GAD-7 (Spitzer et al., 2006) is a seven-item self-report questionnaire assessing GAD symptoms over the preceding 2 weeks on a scale from 0 (*not at all*) to 3 (*nearly every day*). The cut-off score is ≥ 10 (Spitzer et al., 2006) with reliable change index 4 (National Health Service, 2014). Cronbach's alphas for the current sample across the four times were .62, .87, .85, and .92. The GAD-7 was used as a primary outcome measure.

Secondary Outcome Measures

GADSS. The Generalized Anxiety Disorder Severity Scale (GADSS; Shear et al., 2006) is an interview-based rating scale designed specifically for assessing symptom severity of GAD. It was administered by members of the research team blind to participants' study allocation. The interview was also recorded. Clients are asked first to identify subjects of worry (e.g., future, health, family, finances, work). They are then asked to rate these target worries in terms of (a) frequency of worry, (b) distress due to worry, (c) frequency of associated symptoms, (d) severity and distress of associated symptoms, (e) impairment in work, and (f) impairment

in social function, on a scale ranging from 0 = *none* to 4 = *very severe*. The scale's internal consistency in the current sample across the four times were .75, .90, .88, and .88.

PHQ-9. This is a nine-item self-report instrument intended to assess the existence and severity of symptoms of depression (Kroenke et al., 2001). Cronbach's alphas for the current sample across the four times were .83, .82, .85, and .80.

CORE-OM. This is a 34-item questionnaire designed to measure distress across four domains: subjective well-being, problems or symptoms, life functioning, and risk (Evans et al., 2002). Items refer to how respondents have been feeling over the past week, and are scored on a 5-point Likert scale ranging between 0 (*not at all*) and 4 (*most or all of the time*). Cronbach's alphas for the current sample across the four times were .90, .95, .95, and .96.

Adherence and Competence Measures

The Person-Centered and Experiential Psychotherapy Scale (EFT Version; PCEPS-EFT). The PCEPS-EFT is a 14-item observer-based measure that assesses the therapist's in-session behavior in terms of its adherence to EFT and its competent delivery (Elliott, 2016; Freire et al., 2014). The first 10 items are generic items common to client-centered and experiential therapies and the last four items are EFT specific (e.g., they focus on EFT tasks such as chair dialogues or EFT case formulation). Each item is scored on a scale from 1 to 6, with four and above adhering to EFT (5 meaning consistently and 6 meaning creatively). For the purpose of this study the scale was used by certified EFT therapists as raters (see above). The interrater agreement as measured by intraclass correlation coefficient (ICC) for raters rating at least four same sessions was on average .77 and Cronbach's α .97.

CTSR. The CTSR is a 12-item observer-based measure that assesses the therapist's in-session behavior in terms of its adherence to CBT and its competent delivery (Blackburn et al., 2001). The items cover core CBT activities, such as use of agenda, homework, work with cognitions, exposure, etc. Each item is scored on a scale from 0 to 6, with a score of 3 indicating that the therapist is competent, a score of 4 indicating minor difficulties, a score of 5 indicating minimal difficulties, and a score of 6 indicating excellence. For the purpose of this study, the scale was used by certified CBT therapists as raters (see above). The interrater agreement for raters (ICC) rating at least four same sessions was on average .76 and Cronbach's α .92.

Sample Size

A participant sample size was determined (using G*Power; Faul et al., 2007) on the basis of a comparison between the two active treatments and pre–post within groups comparison. We used a minimum meaningful comparison (moderate effect size; $f = .25$) with a statistical power of 0.80 and an α level of 0.05 (Timulak et al., 2018).

Data Analysis and Management

Pretherapy, 16 weeks, posttherapy, and 6-month follow-up assessments consisted of administering the GAD-7, GADSS, CORE-OM, and PHQ-9. Data monitoring oversight was provided by DH, a health psychologist and statistician with no direct allegiance to

either of the two compared approaches. The main analysis was performed by DH. As per published protocol (Timulak et al., 2018), the main analysis was run as intent-to-treat analysis (IIT; within- and between-groups comparisons at 16 weeks, the end of treatment, and at 6-month follow-up). Primary (GAD-7) and secondary outcomes (GADSS, PHQ, and CORE) were analyzed using repeated-measures 2×4 ANOVAs for the two active conditions at pretherapy, 16 weeks, the end of treatment, and at 6-month follow-up. Multiple imputation (5 iterations) was performed to replace missing values. Effects were tested at the .05 level. The magnitude of the within-group effects of each of the interventions as well as the magnitude of between-group effects was established (Cohen's d and confidence intervals) using the *Exploratory Software for Confidence Intervals* (Cumming & Calin-Jageman, 2017).

Analysis was conducted to determine the proportion of participants who achieved clinically significant change on the GAD-7 (Jacobson & Truax, 1991). Recovery was defined as pre-post change on the GAD-7 ≥ 4 and postmeasurement score ≤ 9 . Reliable improvement was defined as pre-post change on the GAD-7 ≥ 4 . This was done per IIT with missing data treated as no change. The chi-squared test (χ^2) was used to compare the two treatment groups.

In addition, we checked for any potential therapists' effects. Linear mixed models using restricted maximal likelihood were initially run with a four-level model (time points nested in participant nested in group nested in therapist). Where the therapist by group effect was not statistically significant, following Westra et al. (2016), linear mixed modeling using restricted maximal likelihood fit a four-level model (time points nested within patients nested within therapists) calculated an ICC to determine the therapist main effect for each outcome in terms of variance explained.

Governance and Oversight of the Trial

The Trial Management Group (TMG) was concerned with the running of the trial. Membership consisted of the principal investigator (PI) and EFT trainer and supervisor (LT), the trial manager (DK), CBT trainers and supervisors (CC and CW), and CIPC staff (FW, LJ, and PG). A statistician (DH) was consulted. The group regularly discussed issues such as training and supervision of therapists, recruitment of participants, clinical governance and ethical issues, etc. The TMG also reported to the Trial Steering Committee (TSC). The TSC had an independent chairperson and a representative from the public.

COVID-19 Pandemic Impact

The final weeks of the active phase of the trial were impacted by the COVID-19 pandemic and the resulting nationwide lockdown. During this period, the CIPC service paused face-to-face appointments, with the result that the last few sessions for nine participants in the trial ($n = 5$ in EFT and $n = 4$ in CBT) were conducted via mobile phone (none of these clients dropped out from treatment). Only one client (in the EFT condition) had not yet reached the 16-week time point when lockdown happened. We estimate that approximately 4% of all sessions in the trial happened over mobile phone. The lockdown also meant that we had to seek further ethical approval to conduct the remaining assessments over the phone with measures being emailed to clients and their scores read out to the researcher. This was done for one client at the week 16 assessment time

point (an EFT client), for nine clients at the end of therapy (5 EFT, 4 CBT), and for 18 clients at 6-month follow-up (9 EFT, 9 CBT).

Results

Demographic Data

Table 1 summarizes demographic (e.g., age, gender, race/ethnicity, employment) data across the two conditions. It also contains information on prior therapy, current medication, and comorbid presentations which were present in over 86% of clients. Comorbid personality disorders were present in over 55% of clients. There was no statistical difference in any of the characteristics between the two groups.

Adherence and Competence

The four EFT raters rated the selected EFT sessions ($n = 26$) as adherent to EFT principles. The mean rating for EFT sessions across all items on PCEP-EFT was $M = 4.52$ ($SD = .67$), while the average rating on the EFT subscale was $M = 4.08$ ($SD = 1.00$). These means suggest on average between adequate and good overall person-centered/experiential skills and just about adequate EFT-specific skills. The EFT rater's mean ratings of the subset of CBT sessions ($n = 11$) on the PCEPS-EFT scale and EFT subscale were, respectively, $M = 2.63$ ($SD = .67$) and $M = 1.28$ ($SD = .41$). On average, the raters' ratings of therapist adherence/competence on the PCEPS-EFT scale differentiated between the EFT and CBT sessions to a statistically significant degree on both the overall scale, $t(35) = 6.92$, $p = .00$, and EFT subscale, $t(34) = 8.83$, $p = .00$.

The four CBT raters rated the selected CBT sessions ($n = 21$) as adherent to CBT principles. The respective average ratings across all items were $M = 3.60$ ($SD = .78$); for reference, ratings between 3 and 4 on the CTSR scale suggest competent delivery. The CBT raters' rating of the subset of EFT ($n = 10$) sessions on the CTSR scale was $M = 2.46$ ($SD = .59$). On average, the raters' ratings of therapist adherence/competence on the CTSR scale differentiated between CBT and EFT to a statistically significant degree, $t(29) = 4.09$, $p = .00$.

Treatment Drop Out, Number of Sessions, Research Attrition

Drop out was predetermined as constituting attendance at less than eight sessions (Timulak et al., 2018). Three clients dropped out from EFT (i.e., 10.3%) and eight clients dropped out from CBT (i.e., 27.5%). This difference was not statistically significant, although it was nearing the significance level, $X^2(1, N = 58) = 2.80$, $p = .09$. Clients who dropped out from therapy had on average $M = 3.53$ ($SD = 1.44$) sessions. Drop out from treatment typically also meant that clients were lost to the study (only 1 client, in the EFT condition, engaged with the assessment at week 16; in all other cases clients who dropped out from treatment were also lost to the study [research attrition]). Of those who stayed in therapy, clients in the EFT condition had on average $M = 16.69$ ($SD = 2.81$) sessions and clients in the CBT condition had $M = 15.42$ ($SD = 3.09$). This difference was not statistically significant, $t(45) = 1.46$, $p = .15$. Only three clients who stayed in therapy finished therapy by week 16 (2 in the EFT condition and 1 in CBT), so while clients averaged between 15 and 17 sessions, these sessions took place over a longer time period than 16-calendar week.

In terms of research attrition there were, in the CBT condition, $n = 8$ (27.5%) clients' data missing at week 16, $n = 10$ (34.4%) clients' data missing at the end of therapy, and $n = 11$ (37.9%) at 6-month follow-up. For EFT, there were $n = 3$ (10.3%) client data missing at week 16, $n = 6$ (20.6%) at the end of therapy, and $n = 5$ (17.2%) at 6-month follow-up. This difference in research attrition was not statistically significant using chi-square test comparison although it was nearing significance for 16 weeks, $\chi^2(1, N = 58) = 2.80, p = .09$, with $\chi^2(1, N = 58) = 1.38, p = .24$ for end of therapy and $\chi^2(1, N = 58) = 2.08, p = .15$ for the 6-month follow-up.

Main Analyses

As per published trial protocol, the main IIT was run using 2×4 mixed repeated-measures ANOVAs performing multiple imputation to replace missing values. Data distributions were examined using histogram, box-plots, skewness, and kurtosis values. Little's test revealed outcome data were MCAR (missing completely at random), $\chi^2(20) = 20.57, p = .42$. Where data failed to meet the assumption of sphericity for ANOVA, Greenhouse–Geisser corrections were applied. Effect sizes are reported in terms of partial η^2 for the ANOVA model. Table 2 summarizes means and standard deviations across the four time points.

On all measures, there was a main effect of time (improvement from pretherapy to 16 weeks, end of therapy and follow-up with no difference between the three latter time points) and no difference between the two conditions. On the GAD-7, there was a significant effect of time (within-subject comparisons) for pretherapy, 16 weeks, end of therapy, and at the 6-month follow-up, $F(2.25, 126.05) = 169.55, p < .001$; partial $\eta^2 = .75$. There was no significant group-by-time interaction, $F(2.25, 126.05) = 2.18, p = .11$; partial $\eta^2 = .04$, and no significant main effect of group, $F(1, 56) = 1.87, p = .18$, partial $\eta^2 = .03$. On the GADSS, there was a significant effect of time, $F(3, 168) = 148.26, p < .001$; partial $\eta^2 = .73$, and no significant interaction effect, $F(3, 168) = 2.36, p = .08$; partial $\eta^2 = .04$, or main effect of group, $F(1, 56) = 1.26, p = .27$, partial $\eta^2 = .02$. On the PHQ-9, there was a significant effect of time, $F(2.44, 136.79) = 59.36, p < .001$; partial $\eta^2 = .51$. Neither the interaction, $F(2.44, 136.79) = 1.67, p = .19$; partial $\eta^2 = .03$, nor group effect, $F(1, 56) = 0.07, p = .79$, partial $\eta^2 = .001$, were significant. Finally, on the CORE-OM there was a significant effect of time, $F(2.17, 121.19) = 70.79, p < .001$; partial $\eta^2 = .56$; there was no interaction effect, $F(2.17, 121.19) = 2.05, p = .13$; partial $\eta^2 = .04$, or group effect, $F(1, 56) = 1.20, p = .28$, partial $\eta^2 = .02$.

Table 2 summarizes Cohen's d for within-subject comparisons (across time) for all measures. Table 3 presents Cohen's d for between-subject comparisons (between the conditions). To account for the potential differential rate of data attrition that appeared to copy the trend to differential drop out from treatment (see section on Drop Out, Number of Sessions, and Research Attrition) and given that one of the goals of this feasibility trial was to estimate comparative outcomes that can be used to inform power calculations for a definitive noninferiority trial, Table 3 also reports Cohen's d using the last observation carried forward (LOCF) to complement the picture offered by the data using multiple imputation in terms of between-subject estimates.

We also checked for any potential therapists' effects. For each outcome measure, the therapist by group effect was not statistically significant. In addition, the therapists' main effects were not

Table 2
Means and Standard Deviations Across the Four Time Points and Within-Subject Cohen's d Using Imputed Missing Data

Measure condition	Pre M (SD)	16 weeks M (SD)	Within condition Cohen's d (95% CI)		Post M (SD)	Within condition Cohen's d (95% CI)		6 months M (SD)	Within condition Cohen's d (95% CI)	
			Pre-16-week	16-week-Post		Pre-Post	Post-6 months		6 months-Follow-up	
GAD-7										
EFT ($n = 29$)	15.79 (3.13)	9.21 (4.76)	1.63 (1.08, 2.16)		5.45 (3.78)	2.98 (2.10, 3.84)		7.34 (5.56)		-0.40 (-0.68, -0.11)
CBT ($n = 29$)	15.76 (3.17)	6.65 (3.34)	2.79 (1.94, 3.64)		4.72 (3.81)	3.15 (2.22, 4.06)		5.86 (4.75)		-0.27 (-0.56, 0.03)
GADSS										
EFT ($n = 29$)	18.34 (3.17)	11.69 (5.19)	1.54 (0.97, 2.10)		7.41 (4.82)	2.68 (1.81, 3.53)		7.75 (4.66)		-0.07 (-0.43, 0.29)
CBT ($n = 29$)	18.52 (3.04)	8.90 (4.19)	2.62 (1.79, 3.44)		6.55 (4.16)	3.28 (2.27, 4.27)		7.59 (3.92)		-0.26 (-0.61, 0.11)
PHQ-9										
EFT ($n = 29$)	12.97 (5.48)	9.41 (5.75)	0.63 (0.29, 0.96)		6.83 (5.27)	1.14 (0.72, 1.55)		6.07 (4.54)		0.15 (-0.15, 0.45)
CBT ($n = 29$)	13.79 (6.01)	7.79 (4.34)	1.14 (0.70, 1.58)		6.03 (4.62)	1.45 (0.86, 2.02)		6.44 (4.55)		-0.09 (-0.36, 0.18)
CORE-OM										
EFT ($n = 29$)	1.73 (0.49)	1.27 (0.71)	0.74 (0.32, 1.16)		0.87 (0.62)	1.54 (0.99, 2.09)		0.91 (0.73)		-0.06 (-0.26, 0.14)
CBT ($n = 29$)	1.72 (0.58)	0.93 (0.55)	1.41 (0.85, 1.96)		0.76 (0.54)	1.71 (1.10, 2.30)		0.80 (0.56)		-0.06 (-0.30, 0.17)

Note. EFT = emotion-focused therapy; CBT = cognitive-behavioral therapy; GAD-7 = Generalized Anxiety Disorder-7; GADSS = Generalized Anxiety Disorder Severity Scale; PHQ-9 = Physical Health Questionnaire-9; CORE-OM = Clinical Outcomes in Routine Evaluation-Outcome Measure.

Table 3*Between-Condition (EFT vs. CBT) Effect Sizes for the Respective Times Across All the Measures*

Measure	Pretherapy Between-condition Cohen's <i>d</i> (95% CI) EFT vs. CBT	16 weeks Between-condition Cohen's <i>d</i> (95% CI) EFT vs. CBT	Posttherapy Between-condition Cohen's <i>d</i> (95% CI) EFT vs. CBT	6-month follow-up Between-condition Cohen's <i>d</i> (95% CI) EFT vs. CBT
Between-condition Cohen's <i>d</i> using multiple imputation				
GAD-7	-0.01 (-0.53, 0.50)	-0.62 (-1.14, -0.09)	-0.19 (-0.70, 0.33)	-0.29 (-0.80, 0.23)
GADSS	0.05 (-0.46, 0.57)	-0.59 (-1.12, -0.06)	-0.19 (-0.70, 0.33)	-0.04 (-0.55, 0.48)
PHQ-9	0.14 (-.37, 0.66)	-0.32 (-0.83, 0.20)	-0.16 (-0.67, 0.36)	0.08 (-0.43, 0.60)
CORE-OM	-0.03 (-0.54, 0.49)	-0.55 (-1.07, -0.02)	-0.18 (-0.69, 0.34)	-0.17 (-0.69, 0.34)
Between-condition Cohen's <i>d</i> using LOCF				
GAD-7	-0.01 (-0.53, 0.50)	-0.19 (-0.71, 0.32)	0.05 (-0.46, 0.57)	0.01 (-0.51, 0.52)
GADSS	0.06 (-0.46, 0.57)	-0.29 (-0.80, 0.23)	-0.05 (-0.56, 0.47)	0.10 (-0.41, 0.62)
PHQ-9	0.14 (-0.37, 0.66)	-0.11 (-0.62, 0.41)	0.01 (-0.51, 0.52)	0.22 (-0.30, 0.73)
CORE-OM	-0.03 (-0.54, 0.49)	-0.36 (-0.88, 0.16)	-0.09 (-0.61, 0.42)	0.00 (-0.52, 0.51)

Note. EFT = emotion-focused therapy; CBT = cognitive-behavioral therapy; GAD-7 = Generalized Anxiety Disorder-7; GADSS = Generalized Anxiety Disorder Severity Scale; PHQ-9 = Physical Health Questionnaire-9; CORE-OM = Clinical Outcomes in Routine Evaluation-Outcome Measure. LOCF = last observation carried forward. The negative values for between conditions comparisons in effect sizes suggest the difference being in favor of CBT, the positive values in favor of EFT.

statistically significant and accounted for between 0.011% (PHQ-9) and 0.059% (GADSS) of the variance in outcome measures. Consequently, the analysis suggests that there were no significant therapists' effects across the outcome measures.

Recovery and Improvement Rates

Recovery and improvement rates were also calculated. Reliable improvement was calculated as pre-post change on the GAD-7 ≥ 4 , and if the posttherapy score was also in the nonclinical range ≤ 9 , it was considered to be recovery. These calculations were based on the intent-to-treat sample (missing data were considered as no change). The recovery and reliable improvement rates for the intent-to-treat sample are summarized in Table 4. There were no statistical differences between the groups.

Discussion

This feasibility RCT had several goals. It wanted to assess recruitment processes, therapist adherence/competence, and client retention rates. It also sought to provide estimates of the comparative relative efficacy of EFT in comparison with CBT in the treatment of GAD in the context of an Irish public health service that could then be used to inform power calculations for a potential definitive noninferiority trial (Timulak et al., 2018). In terms of the recruitment process, we were able to recruit 96.6% of our intended sample. In

line with the service focus on medical cardholders (which in the Irish context is a specific socioeconomic group entitled to free medical services), only about 20% of clients were in full-time employment and about the same percentage had a college degree. The sample was almost entirely White, which is characteristic of the broader Irish population that consists of 91.7% White, 0.7% White traveler, 1.4% Black, and 2.1% Asian (Central Statistics Office, 2016). The high comorbidity, inclusive of those personality disorders most commonly found with GAD, such as avoidant and dependent personality disorder, is typical of primary care populations (e.g., Brown et al., 2001). The presence of comorbid personality disorders is notable although not surprising as the rate is common for GAD (Skodol et al., 2014).

In terms of therapist adherence and therapy delivery, our project was quite unique as all therapists were trained in both conditions and randomly delivered the two conditions. This decision was pragmatic as the project was hosted by a public health service with counseling centers spread across multiple locations such that some locations had only one therapist available. If randomization was not nested within the therapist, clients would have had to travel some distance in order to access the service (e.g., to a primary care service located in a different town). This was not feasible from a client accessibility perspective. While this is not a typical design, it has been used previously (Shapiro et al., 1994). It had the benefit of allowing us to test whether we could train available therapists in two interventions in a relatively short period of time (5 training days), albeit supplemented by at least 8

Table 4*Recovery and Reliable Improvement Rates on the Primary Outcome Measure (GAD-7) for Intent-to-Treat Sample*

Condition <i>n</i>	Recovery rate			Reliable improvement rate		
	16 weeks <i>n</i> (%)	Post <i>n</i> (%)	6 months <i>n</i> (%)	16 weeks <i>n</i> (%)	Post <i>n</i> (%)	6 months <i>n</i> (%)
EFT (<i>n</i> = 29)	<i>n</i> = 14 (48.3%)	<i>n</i> = 19 (65.5%)	<i>n</i> = 14 (48.3%)	<i>n</i> = 18 (62.1%)	<i>n</i> = 22 (75.9%)	<i>n</i> = 18 (62.1%)
CBT (<i>n</i> = 29)	<i>n</i> = 18 (62.1%)	<i>n</i> = 17 (58.6%)	<i>n</i> = 15 (51.7%)	<i>n</i> = 19 (65.5%)	<i>n</i> = 18 (62.1%)	<i>n</i> = 15 (51.7%)

Note. EFT = emotion-focused therapy; CBT = cognitive-behavioral therapy; GAD-7 = Generalized Anxiety Disorder-7; Reliable Improvement is calculated as pre-post change on the GAD-7 ≥ 4 ; Recovery is calculated as pre-post change on the GAD-7 ≥ 4 plus the posttherapy score in nonclinical range ≤ 9 . There were no statistical differences between the conditions.

months of fortnightly supervision. This proved possible, although levels of adherence/competence as assessed by external raters were just moderate. While the level of adherence appears to be comparable to that of similar services (Liness et al., 2019), and did distinguish between the two therapies, it could be improved, which is one of the study limitations. Particularly, ratings on the EFT subscale of the PCEPS scale indicated the just about adequate presence of specific EFT skills on average.

To follow up, we are planning a future study that will explore therapists' experiences in more depth as studies suggest that learning EFT in a short format may be a challenge even for experienced therapists (Qiu et al., 2020). The decision regarding the length of training was also a pragmatic decision. Therapists were trained during their work hours and we availed of the period of time that was allocated to us for training purposes by the service. Further discussions are taking place with the hosting service to provide training fully in line with the relevant guidelines (e.g., International Society for Emotion-Focused Therapy; formal certified CBT training) both for service delivery and future research studies.

In terms of drop out, a lower drop-out rate was noted in the EFT condition, although this was not statistically significant. The rate of drop out in the CBT condition (27.5%) was comparable to the drop out from that therapy found in other studies (see meta-analysis by Fernandez et al., 2015). A bigger problem for the study was research attrition (missing data) that copied drop out to the extent that we practically had only per-protocol data (i.e., we only had data from clients who stayed in therapy). This was further compounded by attrition post week 16, leading to overall data attrition in the CBT condition of 34.4% at posttherapy and 37.9% at follow-up. The attrition thus appeared to be skewed and higher in the CBT condition and may thus have impacted on analyses. For this reason, we also provide the LOCF perspective in Table 3. Given that this was a feasibility study, the research attrition problem was one of the major learnings from the project. A definite trial should therefore apply some of the existing strategies for improving retention of participants during data collection (Brueeton et al., 2017). One such option would be to offer assessments via tele-psychology.

Although both protocols were designed to be offered for up to 20 sessions, therapists in the service normally aim to have 16 weekly sessions and go beyond that if there is a clinical need. As already noted, both conditions (exclusive of drop out) had close to 16 sessions on average. Despite this, very few individual courses of therapy ended by calendar week 16. Indeed, only three clients who did not drop out of treatment finished their therapy by calendar week 16 (this was related to scheduling issues such as public holidays and unexpected events which meant therapists had to reschedule planned appointments). This also has implications for the planning of the definitive noninferiority trial. A recent U.K. study conducted in a similar public health setting realized posttherapy assessment at the 24-calendar week time point (Barkham et al., 2021).

In terms of the main analyses and the main goal of the study, that is, to assess the relative efficacy of EFT against a well-established treatment for GAD, CBT, we did not find differences between the conditions. Although the main analyses did not show difference, we did find a trend favoring CBT at week 16. This is interesting as week 16 did not represent an end of therapy point (neither did it represent midtreatment) but rather something like early outcome (only 3 clients ended therapy at that point—2 in EFT and 1 in CBT condition). As explained above, outcomes were measured at this point on the suggestion of the

service provider. It is difficult to make sense of this finding and we need to raise caution that it may be an artifact of the higher research attrition in the CBT condition (assuming that those clients who dropped out from treatment and the study did not improve). As Table 3 shows, much of this trend at week 16 disappears once we calculate the effect size from the LOCF data.

If there was an early response effect, it is difficult to ascertain what might be responsible for it. It may be that EFT first touches on the client's avoided emotional pain and then generates adaptive experiences, such that the process is not necessarily linear and transformative adaptive experiences are more likely to characterize the later stages of therapy. It may be that there is another confound at play, such as the fact that EFT was on average a bit longer (roughly by one session). While this difference was not statistically significant, it may have been that clients were more likely to still be in the working through phase at therapy at week 16. Alternatively, as EFT has less of a direct focus on symptoms compared with CBT, CBT's sustained focus on symptoms might account for early outcomes. In any case, it is a finding that may be interesting to examine, and this might best be achieved by monitoring session-to-session (or week-to-week) changes in client functioning.

Posttherapy and 6-month comparisons erased this possible trend and the two therapies had similar outcomes. Any potential differences seem to be weighing somewhere between 0.00 and 0.30 (no or small effect) of Cohen's *d* (see Table 3). This is further confirmed by intent-to-treat recovery and reliable improvement rates that did not show any difference between EFT and CBT (see Table 4). The implication for a possible definitive trial using a similar design would suggest the need for a sample size larger than 55 participants per group to detect any small effects at the end of treatment and follow-up (Faul et al., 2007). This finding is particularly promising for EFT given that it currently lacks comparative evidence for GAD and anxiety disorders more broadly. The results, together with the retention of clients in therapy, suggest that further development of EFT for GAD is warranted.

The promising EFT results can be seen also in the context of how the outcome was measured in the study, with all instruments being mainstream symptom-focused instruments. This is despite the primary focus in EFT not being on symptoms (such as worry and anxiety) per se, but rather on the central emotional vulnerability (e.g., chronic loneliness/sadness, shame, and fear) that clients with GAD difficulties want to avoid. The primary EFT focus is to help clients become capable of staying with vulnerable emotions, overcoming avoidance in order that it is possible to generate adaptive experiences of compassion and protective anger in response to the emotional needs embedded in core emotional vulnerability (Timulak & McElvaney, 2018). To that effect, it would be important to include in any further definitive trial, instruments that can evaluate adaptive connection with vulnerable emotions and the capacity for generating adaptive emotional experiences (e.g., the Strathclyde Inventory, Zech et al., 2018).

The efficacy of EFT should also be considered in the context of the very good results achieved by the CBT condition. The CBT results in the here presented trial are comparable to the results reported in studies conducted in similar public health settings using the same measure GAD-7 (Hirsch et al., 2019). The CBT condition thus represented a good standard of an established treatment for GAD in the Irish context. The condition involved standard CBT interventions for GAD such as psychoeducation, worry monitoring

and reevaluation, problem-solving, and both imaginal and in vivo exposure. The training, albeit brief, and supervision was provided by experienced CBT trainers/supervisors.

Conclusions

This feasibility trial was the first trial assessing the relative efficacy of EFT in comparison to an established treatment for GAD. It was conducted within a routine Irish public primary care health setting where this condition is typically treated. The trial showed that it is worthwhile to further explore the provision of an EFT adaptation for GAD in order to broaden the range of treatment choice available to the public. This feasibility trial also offered a number of learnings in terms of planning a larger trial. Namely, that it is important to adopt strategies to mitigate research attrition (e.g., using tele-psychology for assessment); that it is important to further enhance training of therapists so that they can deliver highly adherent good quality treatment; that therapy in these routine conditions is not necessarily delivered on a weekly basis so the predetermined assessment points need to take this into account (e.g., extending out the initial assessment point to 24 weeks); that it may be worthwhile to measure outcome on a weekly or sessional basis in order to track improvement and potential early responses to treatment; that it may be useful to add an outcome measure theoretically specific to EFT; and that any more definite comparison needs to be calibrated for small comparative effects and should thus include a corresponding sample size.

References

- Barkham, M., Saxon, D., Hardy, G. E., Bradburn, M., Galloway, D., Wickramasekera, N., Keetharuth, A. D., Bower, P., King, M., Elliott, R., Gabriel, L., Kellett, S., Shaw, S., Wilkinson, T., Connell, J., Harrison, P., Ardern, K., Bishop-Edwards, L., Ashley, K., . . . Brazier, J. E. (2021). Person-centred experiential therapy versus cognitive behavioural therapy delivered in the English Improving Access to Psychological Therapies service for the treatment of moderate or severe depression (PRaCTICED): A pragmatic, randomised, non-inferiority trial. *The Lancet Psychiatry*, 8(6), 487–499. [https://doi.org/10.1016/S2215-0366\(21\)00083-3](https://doi.org/10.1016/S2215-0366(21)00083-3)
- Behar, E., DiMarco, I. D., Hekler, E. B., Mohlman, J., & Staples, A. M. (2009). Current theoretical models of generalized anxiety disorder (GAD): Conceptual review and treatment implications. *Journal of Anxiety Disorders*, 23(8), 1011–1023. <https://doi.org/10.1016/j.janxdis.2009.07.006>
- Blackburn, I. M., James, I. A., Milne, D. L., Baker, C., Standart, S., Garland, A., & Reichelt, F. K. (2001). The revised cognitive therapy scale (CTS-R): Psychometric properties. *Behavioural and Cognitive Psychotherapy*, 29(4), 431–446. <https://doi.org/10.1017/S1352465801004040>
- Brown, T. A., Campbell, L. A., Lehman, C. L., Grisham, J. R., & Mancill, R. B. (2001). Current and lifetime comorbidity of the DSM-IV anxiety and mood disorders in a large clinical sample. *Journal of Abnormal Psychology*, 110(4), 585–599. <https://doi.org/10.1037/0021-843X.110.4.585>
- Bruce, S. E., Machan, J. T., Dyck, I., & Keller, M. B. (2001). Infrequency of “pure” GAD: Impact of psychiatric comorbidity on clinical course. *Depression and Anxiety*, 14(4), 219–225. <https://doi.org/10.1002/da.1070>
- Brueton, V., Stenning, S. P., Stevenson, F., Tierney, J., & Rait, G. (2017). Best practice guidance for the use of strategies to improve retention in randomized trials developed from two consensus workshops. *Journal of Clinical Epidemiology*, 88(1), 122–132. <https://doi.org/10.1016/j.jclinepi.2017.05.010>
- Carl, J. R., Miller, C. B., Henry, A. L., Davis, M. L., Stott, R., Smits, J. A. J., Emsley, R., Gu, J., Shin, O., Otto, M. W., Craske, M. G., Saunders, K. E. A., Goodwin, G. M., & Espie, C. A. (2020). Efficacy of digital cognitive behavioral therapy for moderate-to-severe symptoms of generalized anxiety disorder: A randomized controlled trial. *Depression and Anxiety*, 37(12), 1168–1178. <https://doi.org/10.1002/da.23079>
- Carpenter, J. K., Andrews, L. A., Witcraft, S. M., Powers, M. B., Smits, J. A. J., & Hofmann, S. G. (2018). Cognitive behavioral therapy for anxiety and related disorders: A meta-analysis of randomized placebo-controlled trials. *Depression and Anxiety*, 35(6), 502–514. <https://doi.org/10.1002/da.22728>
- Central Statistics Office. (2016). *Census 2016*.
- Cuijpers, P., Sijbrandij, M., Koole, S., Huibers, M., Berking, M., & Andersson, G. (2014). Psychological treatment of generalized anxiety disorder: A meta-analysis. *Clinical Psychology Review*, 34(2), 130–140. <https://doi.org/10.1016/j.cpr.2014.01.002>
- Cummings, G., & Calin-Jageman, R. (2017, June 13). Accompanying exploratory software for confidence intervals intro. *Introduction to the new statistics: Estimation, open science, and beyond*. Routledge. <http://routledge.com/textbooks/9781138825529/student.php>
- Dugas, M. J., & Robichaud, M. (2007). *Cognitive-behavioral treatment for generalized anxiety disorder: From science to practice*. Routledge/Taylor & Francis.
- Elliott, R. (2016). *Person-Centred & Experiential Psychotherapy Scale-EFT supplement*. University of Strathclyde, Department of Psychology. Unpublished scale available from the author.
- Evans, C., Connell, J., Barkham, M., Margison, F., McGrath, G., Mellor-Clark, J., & Audin, K. (2002). Towards a standardised brief outcome measure: Psychometric properties and utility of the CORE-OM. *The British Journal of Psychiatry*, 180(1), 51–60. <https://doi.org/10.1192/bjp.180.1.51>
- Faul, F., Erdfelder, E., Lang, A. G., & Buchner, A. (2007). G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behavior Research Methods*, 39(2), 175–191. <https://doi.org/10.3758/BF03193146>
- Fernandez, E., Salem, D., Swift, J. K., & Ramtahal, N. (2015). Meta-analysis of dropout from cognitive behavioral therapy: Magnitude, timing, and moderators. *Journal of Consulting and Clinical Psychology*, 83(6), 1108–1122. <https://doi.org/10.1037/ccp0000044>
- First, M. B., Williams, J. B. W., Benjamin, L. S., & Spitzer, R. L. (2016). *Structured clinical interview for DSM-5 personality disorders (SCID-5 for DSM-5-PD)*. American Psychiatric Association.
- First, M. B., Williams, J. B. W., & Karg, R. S. (2015). *Structured clinical interview for DSM-5—research version (SCID-5 for DSM-5, research version; SCID-5-RV, Version 1.0.0)*. American Psychiatric Association.
- Freire, E., Elliott, R., & Westwell, G. (2014). Person-Centred and Experiential Psychotherapy Scale: Development and reliability of an adherence/competence measure for person-centred and experiential psychotherapies. *Counselling & Psychotherapy Research*, 14(3), 220–226. <https://doi.org/10.1080/14733145.2013.808682>
- Goldman, R. N., Greenberg, L. S., & Angus, L. (2006). The effects of adding emotion-focused interventions to the client-centered relationship conditions in the treatment of depression. *Psychotherapy Research*, 16(5), 537–549. <https://doi.org/10.1080/10503300600589456>
- Greenberg, L. S. (2015). *Emotion-focused therapy*. American Psychological Association.
- Greenberg, L. S., Rice, L. N., & Elliott, R. (1993). *Facilitating emotional change: The moment by moment process*. Guilford Press.
- Hanrahan, F., Field, A. P., Jones, F. W., & Davey, G. C. (2013). A meta-analysis of cognitive therapy for worry in generalized anxiety disorder. *Clinical Psychology Review*, 33(1), 120–132. <https://doi.org/10.1016/j.cpr.2012.10.008>
- Hirsch, C. R., Beale, S., Grey, N., & Liness, S. (2019). Approaching cognitive behavior therapy for generalized anxiety disorder from a cognitive process perspective. *Frontiers in Psychiatry*, 10, Article 796. <https://doi.org/10.3389/fpsy.2019.00796>
- Hunot, V., Churchill, R., Silva de Lima, M., & Teixeira, V. (2007). Psychological therapies for generalised anxiety disorder. *The Cochrane*

- Database of Systematic Reviews*, Article CD001848. Advance online publication. <https://doi.org/10.1002/14651858.CD001848>
- Jacobson, N. S., & Truax, P. (1991). Clinical significance: A statistical approach to defining meaningful change in psychotherapy research. *Journal of Consulting and Clinical Psychology, 59*(1), 12–19. <https://doi.org/10.1037/0022-006X.59.1.12>
- Kertz, S. J., & Woodruff-Borden, J. (2011). Human and economic burden of GAD, subthreshold GAD, and worry in a primary care sample. *Journal of Clinical Psychology in Medical Settings, 18*(3), 281–290. <https://doi.org/10.1007/s10880-011-9248-1>
- Kessler, R. C., Berglund, P., Demler, O., Jin, R., Merikangas, K. R., & Walters, E. E. (2005). Lifetime prevalence and age-of-onset distributions of DSM-IV disorders in the National Comorbidity Survey Replication. *Archives of General Psychiatry, 62*(6), 593–602. <https://doi.org/10.1001/archpsyc.62.6.593>
- Kessler, R. C., Chiu, W. T., Demler, O., Merikangas, K. R., & Walters, E. E. (2005). Prevalence, severity, and comorbidity of 12-month DSM-IV disorders in the National Comorbidity Survey Replication. *Archives of General Psychiatry, 62*(6), 617–627. <https://doi.org/10.1001/archpsyc.62.6.617>
- Kroenke, K., Spitzer, R. L., & Williams, J. B. W. (2001). The PHQ-9: Validity of a brief depression severity measure. *Journal of General Internal Medicine, 16*(9), 606–613. <https://doi.org/10.1046/j.1525-1497.2001.016009606.x>
- Liness, S., Beale, S., Lea, S., Byrne, S., Hirsch, C. R., & Clark, D. M. (2019). Multi-professional IAPT CBT training: Clinical competence and patient outcomes. *Behavioural and Cognitive Psychotherapy, 47*(6), 672–685. <https://doi.org/10.1017/S1352465819000201>
- National Health Service. (2014). *Improving access to psychological therapies: Measuring improvement and recovery in adult services. Version 2*. NHS England.
- National Institute for Health and Clinical Excellence. (2011). Generalised anxiety disorder and panic disorder (with or without agoraphobia) in adults: Management in primary, secondary and community care. *Clinical Guidelines, 113*. <https://www.nice.org.uk/guidance/cg113/resources/generalised-anxiety-disorder-and-panic-disorder-in-adults-management-pdf-35109387756997>
- Newman, M. G., & Llera, S. J. (2011). A novel theory of experiential avoidance in generalized anxiety disorder: A review and synthesis of research supporting a contrast avoidance model of worry. *Clinical Psychology Review, 31*(3), 371–382. <https://doi.org/10.1016/j.cpr.2011.01.008>
- O'Connell Kent, J. A., Jackson, A., Robinson, M., Rashleigh, C., & Timulak, L. (2021). Emotion-focused therapy for symptoms of generalised anxiety in a student population: An exploratory study. *Counselling & Psychotherapy Research, 21*(2), 260–268. <https://doi.org/10.1002/capr.12346>
- Paivio, S. C., & Nieuwenhuis, J. A. (2001). Efficacy of emotion-focused therapy for adult survivors of child sexual abuse: A preliminary study. *Journal of Traumatic Stress, 14*, 115–134. <https://doi.org/10.1023/A:1007891716593>
- Qiu, S., Hannigan, B., Keogh, D., & Timulak, L. (2020). Learning emotion-focused therapy: Certified emotion-focused therapists' perspectives. *Person-Centered and Experiential Psychotherapies, 19*(4), 310–330. <https://doi.org/10.1080/14779757.2020.1717989>
- Shahar, B., Bar-Kalifa, E., & Alon, E. (2017). Emotion-focused therapy for social anxiety disorder: Results from a multiple-baseline study. *Journal of Consulting and Clinical Psychology, 85*, 238–249. <https://doi.org/10.1037/ccp0000166>
- Shapiro, D. A., Barkham, M., Rees, A., Hardy, G. E., Reynolds, S., & Startup, M. (1994). Effects of treatment duration and severity of depression on the effectiveness of cognitive-behavioral and psychodynamic-interpersonal psychotherapy. *Journal of Consulting and Clinical Psychology, 62*(3), 522–534. <https://doi.org/10.1037/0022-006X.62.3.522>
- Shear, K., Belnap, B. H., Mazumdar, S., Houck, P., & Rollman, B. L. (2006). Generalized anxiety disorder severity scale (GADSS): A preliminary validation study. *Depression and Anxiety, 23*, 77–82. <https://doi.org/10.1002/da.20149>
- Skodol, A. E., Geier, T., Grant, B. F., & Hasin, D. S. (2014). Personality disorders and the persistence of anxiety disorders in a nationally representative sample. *Depression and Anxiety, 31*(9), 721–728. <https://doi.org/10.1002/da.22287>
- Slee, A., Nazareth, I., Bondaronek, P., Liu, Y., Cheng, Z., & Freemantle, N. (2019). Pharmacological treatments for generalised anxiety disorder: A systematic review and network meta-analysis. *Lancet, 393*(10173), 768–777. [https://doi.org/10.1016/S0140-6736\(18\)31793-8](https://doi.org/10.1016/S0140-6736(18)31793-8)
- Spitzer, R. L., Kroenke, K., Williams, J. B., & Löwe, B. (2006). A brief measure for assessing generalized anxiety disorder: The GAD-7. *Archives of Internal Medicine, 166*, 1092–1097. <https://doi.org/10.1001/archinte.166.10.1092>
- Swift, J. K., Callahan, J. L., Cooper, M., & Parkin, S. R. (2018). The impact of accommodating client preference in psychotherapy: A meta-analysis. *Journal of Clinical Psychology, 74*(11), 1924–1937. <https://doi.org/10.1002/jclp.22680>
- Timulak, L., Keogh, D., Chigwedere, C., Wilson, C., Ward, F., Hevey, D., Griffin, P., Jacobs, L., & Irwin, B. (2018). A comparison of emotion-focused therapy and cognitive-behavioural therapy in the treatment of generalised anxiety disorder: Study protocol for a randomised controlled trial. *Trials, 19*(1), Article 506. <https://doi.org/10.1186/s13063-018-2892-0>
- Timulak, L., & McElvaney, J. (2016). Emotion-focused therapy for generalised anxiety disorder: An overview of the model. *Journal of Contemporary Psychotherapy, 46*(1), 41–52. <https://doi.org/10.1007/s10879-015-9310-7>
- Timulak, L., & McElvaney, J. (2018). *Transforming generalized anxiety: An emotion-focused approach*. Routledge.
- Timulak, L., McElvaney, J., Keogh, D., Martin, E., Clare, P., Chepukova, E., & Greenberg, L. S. (2017). Emotion-focused therapy for generalized anxiety disorder: An exploratory study. *Psychotherapy: Theory, Research, & Practice, 54*(4), 361–366. <https://doi.org/10.1037/pst0000128>
- Watson, J. C., Gordon, L. B., Stermac, L., Kalogerakos, F., & Steckley, P. (2003). Comparing the effectiveness of process-experiential with cognitive-behavioral psychotherapy in the treatment of depression. *Journal of Consulting and Clinical Psychology, 71*(4), 773–781. <https://doi.org/10.1037/0022-006X.71.4.773>
- Weisberg, R. B. (2009). Overview of generalized anxiety disorder: Epidemiology, presentation, and course. *Journal of Clinical Psychiatry, 70*(Suppl 2), 4–9.
- Westra, H. A., Constantino, M. J., & Antony, M. M. (2016). Integrating motivational interviewing with cognitive-behavioral therapy for severe generalized anxiety disorder: An allegiance-controlled randomized clinical trial. *Journal of Consulting and Clinical Psychology, 84*(9), 768–782. <https://doi.org/10.1037/ccp0000098>
- Wittchen, H. U. (2002). Generalized anxiety disorder: Prevalence, burden, and cost to society. *Depression and Anxiety, 16*, 162–171. <https://doi.org/10.1002/da.10065>
- Wittchen, H.-U., Kessler, R. C., Beesdo, K., Krause, P., Höfler, M., & Hoyer, J. (2002). Generalized anxiety and depression in primary care: Prevalence, recognition, and management. *The Journal of Clinical Psychiatry, 63*(Suppl. 8), 24–34. <https://www.psychiatrist.com/jcp/medical/primary-care/generalized-anxiety-depression-primary-care-prevalence/>
- Zech, E., Brison, C., Elliott, R., Rodgers, B., & Cornelius-White, J. H. (2018). Measuring Rogers' conception of personality development: Validation of the Strathclyde Inventory-French version. *Person-Centered and Experiential Psychotherapies, 17*(2), 160–184. <https://doi.org/10.1080/14779757.2018.1473788>

Received September 21, 2021

Revision received December 30, 2021

Accepted December 30, 2021 ■