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Effectiveness and predictors of group cognitive behaviour therapy outcome for generalised anxiety disorder in an out-patient hospital setting

B. L. Malivoire¹ , K. E. Stewart¹, D. Cameron¹, K. Rowa^{1,2} and R. E. McCabe^{1,2}

¹Anxiety Treatment and Research Clinic, St Joseph's Healthcare Hamilton, Hamilton, Ontario, Canada and ²Department of Psychiatry and Behavioural Neurosciences, McMaster University, Hamilton, Ontario, Canada

Corresponding author: Karen Rowa; Email: krowa@stjoes.ca

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Abstract

Background: Cognitive behavioural therapy (CBT) is an empirically supported treatment for generalized anxiety disorder (GAD). Little is known about the effectiveness of CBT for GAD in real-world treatment settings.

Aim: This study investigated the effectiveness of group CBT and predictors of treatment response in an out-patient hospital clinic.

Method: Participants ($n = 386$) with GAD participated in 12 sessions of group CBT at an out-patient clinic. Of those who provided at least partial data ($n = 326$), 84.5% completed treatment. Most questionnaires were completed at pre- and post-treatment; worry severity was assessed weekly.

Results: Group CBT led to improvements in chronic worry ($d = -0.91$, $n = 118$), depressive symptoms ($d = -1.22$, $n = 172$), GAD symptom severity ($d = -0.65$, $n = 171$), intolerance of uncertainty (IU; $d = -0.46$, $n = 174$) and level of functional impairment ($d = -0.35$, $n = 169$). Greater pre-treatment GAD symptom severity ($d = -0.17$, $n = 293$), chronic worry ($d = -0.20$, $n = 185$), functional impairment ($d = -0.12$, $n = 292$), and number of comorbid diagnoses ($d = -0.13$, $n = 299$) predicted greater improvement in past week worry over treatment. Biological sex, age, depression symptom severity, number of treatment sessions attended, and IU did not predict change in past week worry over time.

Discussion: These findings provide support for the effectiveness of group CBT for GAD and suggest the outcomes are robust and are either not impacted or are slightly positively impacted by several demographic and clinical factors.

Keywords: Cognitive behavioural therapy; Generalized anxiety disorder; Treatment effectiveness; Treatment predictors

Introduction

Generalized anxiety disorder (GAD) is a psychiatric disorder characterized by excessive and uncontrollable worry about a variety of topics, more days than not, over the past 6 months or longer (American Psychiatric Association, 2022). Individuals with GAD also experience associated symptoms such as irritability, muscle tension, restlessness, fatigue, and sleep and concentration difficulties (American Psychiatric Association, 2022). Cognitive behavioural therapy (CBT) is considered the gold standard treatment for GAD (Otte, 2011); however, the majority of research supporting the efficacy of CBT comes from randomized control trials (RCTs). Given that CBT is one of the most recommended and widely used treatments for GAD, it is imperative to continue to examine outcomes of treatment in routine care settings.

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Efficacy of CBT for GAD

CBT is considered the gold standard treatment for GAD because of its robust empirical support (Otte, 2011). Based on systematic reviews and meta-analyses that have compared CBT for GAD with non-specific therapy, waitlist, and placebo conditions, CBT leads to greater reductions in anxiety symptoms with moderate to large effect sizes (Hedges' $g = 0.39$ – 1.01 ; Carpenter *et al.*, 2018; Hunot *et al.*, 2007; van Dis *et al.*, 2020) and greater improvements in chronic worry with a large effect size ($ES = -1.15$; Covin *et al.*, 2008). Furthermore, there is evidence that these gains are maintained at 6- or 12-month follow-up (Covin *et al.*, 2008; Hunot *et al.*, 2007; van Dis *et al.*, 2020). Consistently, cognitive therapy was also found to lead to large reductions in chronic worry compared with non-therapy controls (i.e. waitlist or no intervention; $d = 1.81$) and moderate reductions in the Penn State Worry Questionnaire (PSWQ) compared with other active treatments ($d = 0.63$; Hanrahan *et al.*, 2013). Collectively, there is evidence supporting the efficacy of CBT for GAD with moderate to large effect sizes. However, there are comparatively fewer studies that have investigated the *effectiveness* of CBT for GAD, that is, whether CBT for GAD is effective in real-world treatment settings.

Treatment effectiveness versus efficacy

Researchers and clinicians have expressed concern about the generalizability of RCTs and treatment studies conducted in academic settings to routine practice settings that are less controlled (Butler *et al.*, 2021; Kazdin, 2008; Nelson and Steele, 2007). In RCTs, a number of inclusion/exclusion criteria are commonly used, including absence of co-morbid diagnoses, symptom severity thresholds, and preclusion of psychiatric medication. Given that community treatment seekers are often diagnostically complex and heterogeneous in their presentation, the samples in RCTs are not representative of treatment seekers in the community and consequently the findings may not extend to real-world settings (Shadish *et al.*, 2000; Tolin *et al.*, 2015; Westen *et al.*, 2004). Similarly, the types of participants in academic studies who consent to enter a randomized research study may not be representative of treatment seekers in the community (Tolin *et al.*, 2015). Another concern is that clinical trial therapists are required to strictly adhere to the therapy protocol and often receive more intensive training compared with community therapists (Becker and Stirman, 2011; Weisz *et al.*, 2006;). Lower treatment fidelity in community settings could impact treatment outcomes. As such, it is important to investigate whether the results from RCTs generalize to real-world treatment settings (Tolin *et al.*, 2015).

Effectiveness of CBT for anxiety disorders

To assess the external validity of empirically supported treatments, Tolin *et al.* (2015) suggested that effectiveness studies are needed that do not involve randomization, that are conducted outside of academic settings with community clinicians, and that include participants with co-morbidities. In general, there is evidence from meta-analyses supporting that CBT for anxiety disorders is effective in routine care settings (Cohen's $d = 0.9$ – 2.6 ; Hans and Hiller, 2013; Stewart and Chambless, 2009; van Ingen *et al.*, 2009). However, only one meta-analysis excluded studies with randomization (Hans and Hiller, 2013), and none included studies investigating the effectiveness of CBT for GAD specifically. In the few studies that have investigated the effectiveness of CBT for GAD in frontline settings, there is promising support that individual CBT leads to moderate to large improvements in chronic worry severity, GAD symptom severity, and depression symptom severity (e.g. Hirsch *et al.*, 2019; Kehle, 2008). Only one study to our knowledge has investigated the effectiveness of *group* CBT for GAD in an out-patient hospital clinic, wherein group CBT led to significant improvements in chronic worry and intolerance of uncertainty (IU) (effect sizes not provided; Torbit and Laposa, 2016). IU is defined as a 'dispositional incapacity to endure the aversive response triggered by the perceived absence of

salient key, or sufficient information, and sustained by the associated perception of uncertainty' (Carleton, 2016; p. 31), and is proposed to be a key maintaining factor in chronic worry (Buhr and Dugas, 2006; Dugas *et al.*, 2004; Freeston *et al.*, 1994). Although the limited research on the effectiveness of CBT for GAD in routine care is promising, more research is needed, especially for *group* treatment, given it is a commonly used cost-effective format in routine practice settings.

Predictors of CBT outcome for GAD

In addition, to improve treatment outcomes, it is necessary to understand which patients are most and least likely to benefit from CBT. In this study, we investigated predictors of treatment outcome, which inform how pre-treatment characteristics interact with treatment outcome (Kraemer *et al.*, 2002). Research on predictors of CBT outcomes is important, as it may inform future research on why treatment is less effective for a particular group of patients and identify areas for further research to refine treatment. This is particularly important for individuals with GAD, as although CBT is generally effective, only 46% of individuals at post-treatment and 57% at 12-month follow-up meet standardized recovery criteria (i.e. a score of 47 or less on the PSWQ) in RCTs (Hanrahan *et al.*, 2013). As a result, there is a need to elucidate factors that predict poorer treatment outcome.

To date, there is limited research investigating for whom CBT for GAD is most and least effective. One factor that would be expected to affect how favourably people will respond to treatment is the severity or duration of their illness. In a study that investigated duration of GAD symptoms as a moderator of outcome for CBT and its components, those who had suffered from GAD longer were found to have better outcomes for CBT components specifically (i.e. cognitive therapy and self-control desensitization; Newman and Fisher, 2013). Consistently, higher clinician-rated symptom severity has been found to predict better outcomes in CBT or its components (Newman and Fisher, 2010). Given that IU is associated with worry severity (e.g. Buhr and Dugas, 2006), it is also possible that IU would influence treatment outcome. As IU is proposed to be a key mechanism underlying GAD and chronic worry, it is plausible that individuals who are highly intolerant of uncertainty would benefit most from CBT treatment.

Another factor that would be expected to influence treatment outcome and that is related to symptom severity is diagnostic co-morbidity. Similar to symptom severity, there is evidence that greater co-morbidity is associated with larger gains in CBT or its components (Newman *et al.*, 2010; Wetherell *et al.*, 2005). Thus, there is preliminary support that the more severe one's GAD symptoms are and the more co-morbid diagnoses they have, the more they will benefit from CBT treatment. However, it is necessary to investigate whether these findings extend to routine care settings.

Other factors that may influence treatment response include the individual's age and sex. Research on the efficacy of CBT for GAD across age generally suggests treatment is less effective for older adults compared with younger adults (Covin *et al.*, 2008; Hanrahan *et al.*, 2013; Kishita and Laidlaw, 2017). It has been speculated that older adults may benefit less from treatment due to factors such as cognitive decline and differences in the clinical expression of GAD symptoms (Covin *et al.*, 2008; Mohlman, 2008; Wolitzky-Taylor *et al.*, 2010; Hall *et al.*, 2016), especially when offered in group format. On the other hand, there are no studies to our knowledge that have investigated sex differences in CBT outcomes for GAD. However, there are differences across sex in somatic complaints, age of onset, co-morbid diagnoses, and level of disability (see Jalnapurkar *et al.*, 2018 for a review) that could influence treatment effectiveness. Furthermore, there is evidence that females with GAD do not respond as well to selective serotonin re-uptake inhibitor (SSRIs) medication treatment compared with males (Simon *et al.*, 2006), which supports the possibility of sex differences in treatment response. Thus, research is needed investigating whether sex influences CBT outcomes, as this could have important treatment implications.

Study objectives and hypotheses

The present study had two primary objectives. The first objective was to build on the dearth of research studies on the *real-world effectiveness* of group CBT for GAD by investigating its effectiveness in an out-patient hospital clinic. Based on the efficacy research on CBT for GAD (e.g. Carpenter *et al.*, 2018; Covin *et al.*, 2008; Hanrahan *et al.*, 2013; van Dis *et al.*, 2020), it was predicted that group CBT would lead to moderate to large reductions in GAD symptom severity, chronic worry, intolerance of uncertainty, and depression symptom severity. Given the positive relationship between GAD symptoms and global functional impairment (McKnight *et al.*, 2016), it was also expected that group CBT would lead to improvements in functional impairment. The second objective was to investigate whether demographic and pre-treatment clinical characteristics of individuals with GAD predict treatment outcome. Specifically, we analysed participant sex, age, baseline symptom severity (chronic worry, GAD symptoms, depression symptoms), level of impairment, co-morbidity, and intolerance of uncertainty as predictors. Based on past research, we predicted that age would negatively predict treatment outcome such that worse treatment outcomes would be associated with older age. We also predicted that greater symptom severity, co-morbidity, IU, and related factors including level of impairment and depression, would be associated with better treatment outcomes. Given the lack of research investigating the impact of sex on treatment outcome, no *a priori* hypothesis was made.

Method

Participants

Participants in the current study were patients seeking treatment for GAD at an out-patient hospital clinic that specializes in treatment for anxiety disorders in an urban city in Ontario, Canada. Of those referred to the group ($n = 386$), participants who provided at least two ratings on the PSWQ-PW were included in the analyses ($n = 326$, 84.5%)¹; these were further categorized into completers ($n = 276$; 84.7%), defined as participants who completed at least one of the final three treatment sessions, and drop-outs ($n = 50$; 15.3%) (see Fig. 1). Due to missing data, actual n analysed for each outcome varied from 185 to 326. The mean age of the sample was 39.48 years, and 77.6% of the sample identified as female. For full demographic and clinical characteristics, see Table 1. Participants with other psychiatric co-morbidities were able to take part in the group treatment (see Table 1 for co-morbidity information). Participants were referred to the group by an assessor or a prior treating clinician (e.g. a clinician from a prior CBT group they attended) if GAD was the patient's principal (i.e. most distressing/impairing) concern. The mean Generalized Anxiety Disorder Questionnaire-7 score (12.89) at pre-treatment was above the suggested cut-off score for clinically significant GAD symptoms (10; Spitzer *et al.*, 2006). Treatment completers ($n = 276$) were defined as participants who completed at least one of the final three treatment sessions. Of those who completed treatment, 267 (97%) attended at least eight sessions and only 3% attended less than eight sessions. The average number of attended sessions of those who completed was 10.40 ($SD = 1.49$). Drop-out rate for this sample was 15.3% ($n = 50$).

Measures

Diagnostic measures

Most diagnostic assessments were conducted using the Diagnostic Assessment and Research Tool (DART; McCabe *et al.*, 2017), which is a semi-structured diagnostic tool used to assess for DSM-5 mental disorders. The DART has excellent construct, convergent, and discriminant validity with

¹There was no significant difference between those with and without enough data for analysis on baseline demographics (age and sex), symptoms (PSWQ-T, DASS, IIRS, GAD7, IUS), and number of co-morbid diagnoses.

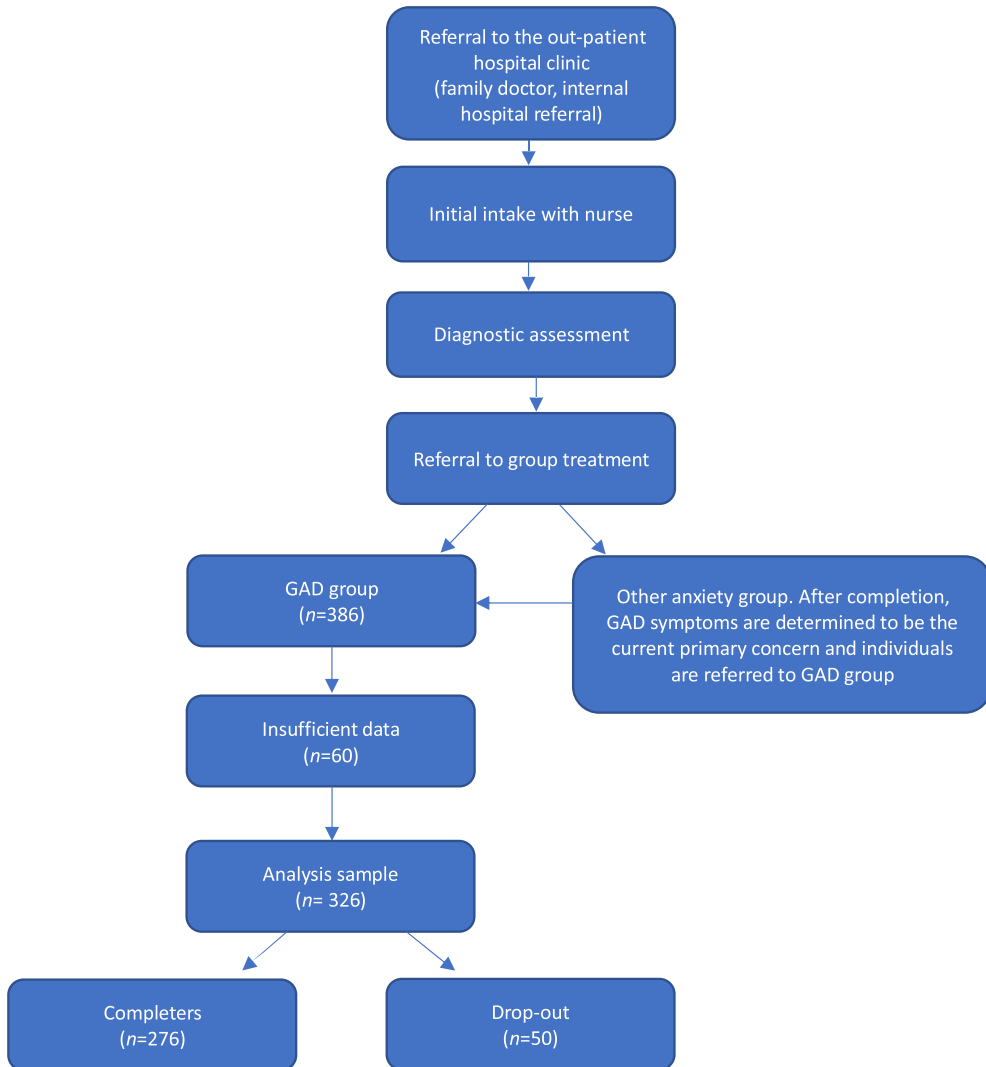


Figure 1. Study procedure and participant flow diagram. GAD group n includes all people who consented to treatment. Insufficient data: participants who had two or fewer PSWQ time points. Analysis sample: sample with enough data for analysis. Completers: participants who had attended at least one of the three final sessions. Drop-out: participants did not attend any of the final three sessions.

relevant self-report symptom measures (Schneider *et al.*, 2022). One assessment was conducted using the MINI International Neuropsychiatric Interview 7.0 (MINI; Sheehan, 2015) and one was conducted using the Structured Clinical Interview for *DSM-5* (First *et al.*, 2016), both of which are reliable and valid instruments for assessing *DSM-5* psychopathology (First *et al.*, 2016; Sheehan, 2015).

Symptom measures

Penn State Worry Questionnaire-Past Week (PSWQ-PW). The PSWQ-PW (Stöber and Bittencourt, 1998) assesses experiences of pathological worry over the past week. The PSWQ-PW has strong reliability and good convergent validity with other measures of weekly worry (Puccinelli *et al.*, 2022; Stöber and Bittencourt, 1998). The PSWQ-PW has been demonstrated to be able to capture

Table 1. Demographics and clinical characteristics at pre-treatment

| Variable | <i>n</i> | Frequency |
|---|----------|---------------|
| Demographic variables | | |
| Age, mean (<i>SD</i>) | 326 | 39.48 (12.86) |
| Sex, % female | 326 | 77.6% |
| Relationship status, % in relationship | 268 | 69.8% |
| Ethnicity | 263 | |
| White | | 93.9% |
| Indigenous | | 0.8% |
| Black | | 1.1% |
| Hispanic/Latin American | | 0.8% |
| Asian | | 2.3% |
| Multi-racial | | 0.4% |
| Other | | 1.5% |
| Employment status, % employed full-time | 272 | 24.3% |
| Education, % completed college/university | 265 | 67.9% |
| Clinical variables | | |
| DASS-21 Depression, mean (<i>SD</i>) | 293 | 18.36 (10.58) |
| DASS-21 Anxiety, mean (<i>SD</i>) | 293 | 15.00 (9.52) |
| DASS-21 Stress, mean (<i>SD</i>) | 293 | 22.94 (9.35) |
| GAD-7, mean (<i>SD</i>) | 293 | 12.82 (5.07) |
| IIRS Relationships and Personal Development, mean (<i>SD</i>) | 292 | 3.87 (1.27) |
| IIRS Intimacy, mean (<i>SD</i>) | 292 | 4.36 (1.87) |
| IIRS Instrumental, mean (<i>SD</i>) | 292 | 4.61 (1.47) |
| IIRS Total, mean (<i>SD</i>) | 292 | 55.35 (15.34) |
| IUS-12, mean (<i>SD</i>) | 294 | 41.87 (9.15) |
| PSWQ-PW, mean (<i>SD</i>) | 265 | 65.12 (14.75) |
| PSWQ Total Score, mean (<i>SD</i>) | 185 | 67.37 (9.83) |
| Co-morbid diagnoses | 299 | |
| Social anxiety disorder | | 21.4% |
| Major depressive disorder | | 20.7% |
| Persistent depressive disorder | | 10.7% |
| Panic disorder | | 9.4% |
| Obsessive-compulsive disorder | | 6.0% |
| Post-traumatic stress disorder | | 4.3% |
| Alcohol use disorder | | 3.0% |
| Cannabis use disorder | | 2.7% |

Data for some demographic variables were only available for a subset of the full sample (participants may have chosen not to complete demographic forms); sample sizes for available data are provided for each variable. DASS, Depression, Anxiety and Stress Scales-21-item version; IIRS, Illness Intrusiveness Rating Scale; IUS, Intolerance of Uncertainty Scale-12-item version; PSWQ, Penn State Worry Questionnaire (PW, past week version).

changes in weekly worry over the course of treatment (Puccinelli *et al.*, 2022; Stöber and Bittencourt, 1998). In the current study, Cronbach's alpha was .90. Of note, the PSWQ trait version (PSWQ-T; Meyer *et al.*, 1990) was used as a predictor of treatment outcome, to assess the number of participants who scored at or above the established cut-off of 65 (Fresco *et al.*, 2003), and to calculate a reliable change index (Jacobson and Traux, 1991). The PSWQ-T version has good to excellent internal consistency (Dear *et al.*, 2011; Molina and Borkovec, 1994) and has demonstrated both content and construct validity (Stöber and Bittencourt, 1998).

Generalized Anxiety Disorder-7 (GAD-7). The GAD-7 is a brief, 7-item questionnaire of GAD symptoms (Spitzer *et al.*, 2006). The measure has good reliability as well as good criterion and construct validity (Spitzer *et al.*, 2006). A cut-score of 10 identifies people with GAD with a sensitivity of 89% and a specificity of 82% (Spitzer *et al.*, 2006). In the current study, Cronbach's alpha was .88.

Depression, Anxiety Stress Scale (DASS-21). The DASS-21 is a 21-item self-report measure of symptoms of depression, anxiety, and stress (Lovibond and Lovibond, 1995). The Depression subscale was used in the present study, containing 7 items. The scale has good psychometric

properties (Antony *et al.*, 1998). In the current study, Cronbach's alpha for the depression subscale was .89.

Illness Intrusiveness Rating Scale (IIRS). The IIRS is a 13-item measure of the degree to which illness (or the treatment of an illness) interferes with quality of life in different domains (Devins *et al.*, 1983). It has been shown to be reliable (internal consistency and test-retest) and has construct, criterion and discriminant validity (Devins, 2010). In addition, it has been shown to be sensitive to change during treatment (Devins, 2010). In the current study, Cronbach's alpha was .76 for the relationship subscale, .70 for the intimacy subscale, .73 for the instrumental subscale, and .86 for the total subscale. The mean IIRS score in the current study (55.42) is consistent with norms for anxiety disorder populations (55.30; Devins, 2010) and people with GAD (54.60; Gros *et al.*, 2009).

Intolerance of Uncertainty Scale (IUS-12). The IUS-12 is a 12-item measure of intolerance of uncertainty (Carleton *et al.*, 2007). The IUS-12 has good internal consistency and test-retest reliability over 12 weeks, as well as good construct validity (Carleton *et al.*, 2007; Wilson *et al.*, 2020). The IUS-12 is sensitive to changes in IU during treatment in people with GAD (Wilson *et al.*, 2020). A cut-off score of 28 has been demonstrated to discriminate individuals with GAD from those without (the average score in the current sample was 42.01). In the current study, Cronbach's alpha was .91.

Procedure

The current data were collected as part of an ongoing program evaluation examining outcomes of out-patient CBT treatment for GAD. The procedures and measures used in this study were approved by the local institutional review board (ref. no. 07-2955) and incorporated standard practices in the clinic. Participants who were referred to the clinic completed a diagnostic assessment (see measures above) and a demographic questionnaire.² Assessments were completed by trained clinicians who were either registered clinical psychologists or who were being supervised by clinical psychologists (e.g. psychotherapists, social workers, graduate students).

Following the assessment, participants were referred for group CBT for GAD. At the time of the initial diagnostic assessment, the majority (78%) of the analysed sample had a primary diagnosis of GAD. The other most common primary diagnoses at the time of initial assessment in this sample were major depressive disorder (5%) and panic disorder (2%). However, all individuals who entered group CBT for GAD were deemed as having clinically significant GAD symptoms. Individuals could be referred by a treating clinician to the GAD group following treatment for another disorder, if the clinician deemed that GAD was the primary concern *at that time*.

The treatment was based upon the work of Borkovec and Costello (1993), Dugas *et al.* (2004), Gyoerkoe and Wiegartz (2006), Heimberg *et al.* (2004), and Waters and Craske (2005). Patients received 12 weeks of group psychotherapy, consisting of 2-hour sessions. Treatment sessions would typically begin with homework review, followed by practice of new skills. The following components were included in treatment: (1) psychoeducation about GAD (sessions 1–2), (2) cognitive restructuring (sessions 3–4), (3) problem solving (sessions 5–6), (4) behavioural experiments for intolerance of uncertainty (sessions 7–8), (5) progressive muscle relaxation (session 9), (6) attentional distraction and scheduled worry time (session 10), and (7) relapse prevention (sessions 11–12). The treatment was delivered by registered clinical psychologists, other professionals (e.g. social workers, psychotherapists, nurses), or graduate students (who were

²Given that there could be a delay between initial assessment and the start of treatment, age at the time of treatment was verified prior to data analysis using medical charts.

supervised by registered clinical psychologists). Typically, two to three group therapists were involved per group.

At the beginning and end of the 12-week treatment, patients were asked to complete a questionnaire package that included all the measures. At each weekly treatment session, participants were asked to complete the PSWQ-PW sent by a secure email link. Questionnaire completion was encouraged but was not monitored.

Data analysis

A series of paired-samples *t*-tests were used to evaluate treatment efficacy for treatment completers for chronic worry (PSWQ-T), GAD symptoms (GAD-7), depression symptoms (DASS-21 Depression subscale), intolerance of uncertainty (IUS-12), and functional impairment (IIRS total score), at pre- and post-treatment. Reliable change indices (RCI; Jacobson and Traux, 1991) were calculated for PSWQ-T as a primary outcome measure, with a test-retest $r = .92$ (Meyer *et al.*, 1990).

Hierarchical linear modelling (HLM; Raudenbush and Bryk, 2002) was used to evaluate effectiveness of the treatment, as well as the impact of pre-treatment variables on the trajectory of change in past week worry over the course of group treatment for GAD. HLM is appropriate for use with datasets that have a multi-level structure and is also able to account for missing data using restricted maximum likelihood as the estimation method (Raudenbush and Bryk, 2002). Missing data for the primary outcome, PSWQ-PW, ranged from 13.2% (at treatment week 1) to 35.9% (at treatment week 10). Missing data were not imputed for Level-2 predictors. Effect size is calculated for all HLM analyses as Cohen's *d* (small = 0.20, medium = 0.50, and large = 0.80; Cohen, 2013). The analysis included participants who dropped out from treatment ($n = 50$, or 15.3% of the sample). There was no significant difference on baseline demographics (age, sex), symptom measures (PSWQ-T, DASS, IIRS, GAD-7, IUS), or number of co-morbid diagnoses, between those who completed and those who dropped out of treatment.

The primary outcome variable for all analyses was the PSWQ-PW, and Time (coded weekly over 11 weeks of treatment as 0 to 10) was included at Level-1. Level-2 predictor variables included age, biological sex (sex assigned at birth), DASS Depression subscale, GAD-7, IIRS total score, IUS total score, PSWQ-PW, and total number of co-morbid diagnoses, all collected at pre-treatment. Examples of the models are shown below, with (1) representing Level-1; (2) and (3) representing Level-2 at the intercepts and slope for a single respective variable score; and (4) showing the mixed model. Continuous Level-2 variables were centred around the grand mean.

$$PSWQ - PW_{ti} = \pi_{0i} + \pi_{1i} * (TIME_{ti}) + e_{ti} \quad (1)$$

$$\pi_{0i} = \beta_{00} + \beta_{01} * (VAR_i) + r_{0i} \quad (2)$$

$$\pi_{1i} = \beta_{10} + \beta_{11} * (VAR_i) + r_{1i} \quad (3)$$

$$PSWQ - PW_{ti} = \beta_{00} + \beta_{01} * VAR_i + \beta_{10} * TIME_{ti} + \beta_{11} * VAR_i * TIME_{ti} + r_{0i} + r_{1i} * TIME_{ti} + e_{ti} \quad (4)$$

Results

Treatment outcomes

Trait worry ($d = -0.91$, 95% CI [0.80, -1.03], RCI = 3.15), GAD symptoms ($d = -0.65$, 95% CI [-0.54, -0.76]), depression ($d = -1.22$, 95% CI [-1.12, -1.34]), and intolerance of uncertainty ($d = -0.46$, 95% CI [-0.35, -0.57]), all significantly reduced from pre- to post-treatment, while

Table 2. Results of hierarchical linear modelling of treatment outcomes

| Effect | PSWQ | | | | | |
|---|----------|-----------|----------|------|----------|----------------------|
| | <i>b</i> | <i>SE</i> | <i>t</i> | d.f. | <i>p</i> | <i>d</i> (95% CI) |
| Initial PSWQ Trait severity (intercept) | 64.99 | 0.80 | 80.80 | 325 | <.001 | |
| PSWQ Trait severity over time (slope) | -1.42 | 0.09 | -15.43 | 325 | <.001 | -0.91 (-0.80, -1.03) |
| GAD-7 | | | | | | |
| Initial GAD-7 severity (intercept) | 12.88 | 0.30 | 43.48 | 301 | <.001 | |
| GAD-7 severity over time (slope) | -4.11 | 0.37 | -11.21 | 301 | <.001 | -0.65 (-0.54, -0.76) |
| DASS Depression subscale | | | | | | |
| Initial DASS severity (intercept) | 18.45 | 0.62 | 30.00 | 302 | <.001 | |
| DASS severity over time (slope) | -11.74 | 0.55 | -21.25 | 302 | <.001 | -1.22 (-1.12, -1.34) |
| IIRS | | | | | | |
| Initial IIRS severity (intercept) | 55.38 | 0.89 | 62.01 | 301 | <.001 | |
| IIRS severity over time (slope) | -6.68 | 1.07 | -6.22 | 301 | <.001 | -0.35 (-0.24, -0.47) |
| IUS | | | | | | |
| Initial IUS severity (intercept) | 41.97 | 0.53 | 79.03 | 302 | <.001 | |
| IUS severity over time (slope) | -5.02 | 0.64 | -7.89 | 302 | <.001 | -0.46 (-0.35, -0.57) |

functioning significantly improved with a small effect size ($d = -0.35$, 95% CI [-0.24, -0.47]). Analyses are presented in Table 2.

Predictors of treatment outcome

A correlation matrix of predictors of treatment outcome is presented in Table 3. Detailed results of primary outcome analyses are presented in the Supplementary material (Table S1). Baseline GAD-7 total score ($b = -0.06$, $SE = 0.02$, $t = -2.85$, d.f. = 291, $p = .005$, $d = -0.17$, 95% CI [-0.06, -0.29]), IIRS total score ($b = -0.01$, $SE = 0.01$, $t = -2.06$, d.f. = 290, $p = .040$, $d = -0.12$, 95% CI [-0.01, -0.24]), worry severity at the start of treatment ($b = -0.03$, $SE = 0.01$, $t = -2.73$, d.f. = 183, $p = .007$, $d = -0.20$, 95% CI [-0.08, -0.37]), and total number of diagnoses ($b = -0.21$, $SE = 0.10$, $t = -2.19$, d.f. = 297, $p = 0.03$, $d = -0.13$, 95% CI [-0.01, -0.24]) all significantly impacted change in past week worry over the course of group treatment for GAD. These results indicate that greater levels of pre-treatment trait worry and anxiety, as well as greater illness-related impairment and more co-morbid diagnoses each predict slightly greater improvement in chronic worry (see Fig. 2). Neither age nor biological sex were significant predictors of treatment outcome. Furthermore, DASS-21 Depression, and IUS-12 total score did not significantly predict trajectory of change in PSWQ-PW ($p > .05$), indicating that baseline depression and intolerance of uncertainty do not impact improvement in worry over time.

In a *post-hoc* analysis, total number of sessions attended was investigated as a predictor of treatment outcome.³ The total number of treatment sessions attended, however, did not predict change in PSWQ-PW ($b = 0.01$, $SE = 0.42$, $t = .033$, d.f. = 324, $p = .740$, $d = -0.02$, 95% CI [.13, -0.10]).

Post-hoc completer analysis

To further shed light on treatment effectiveness, clinical cut-offs on the GAD-7 (10; Spitzer *et al.*, 2006) and the PSWQ-T (65; Fresco *et al.*, 2003) were used to assess the number of participants

³We thank the anonymous reviewer for their suggestion to include this *post-hoc* analysis.

Table 3. Correlation matrix of predictors of treatment at baseline

| | Age | Biological sex | Co-morbidities | DASS Depression | GAD-7 | IIRS total | IUS | PSWQ |
|---------------------|-------|----------------|----------------|-----------------|-------|------------|-------|------|
| Age | 1 | | | | | | | |
| Biological sex | -.11* | 1 | | | | | | |
| Co-morbid diagnoses | -.08 | .01 | 1 | | | | | |
| DASS Depression | .02 | -.03 | .27** | 1 | | | | |
| GAD-7 | -.11 | .11 | .18** | .54** | 1 | | | |
| IIRS total | -.07 | .05 | .33** | .56** | .60** | 1 | | |
| IUS | -.07 | .03 | .21** | .45** | .56** | .53** | 1 | |
| PSWQ-T | -.10 | .17* | .18* | .29** | .63** | .44** | .59** | 1 |

* $p < .05$, ** $p < .01$.

who met these cut-offs at pre- and post-treatment. Scoring at or above these cutoffs is suggestive of GAD. At pre-treatment, 72% of the sample who completed the GAD-7 scored above the cut-off for GAD, while only 39% of those who completed the GAD-7 were above the threshold at post-treatment. Stated differently, 61% scored *below* the diagnostic threshold for GAD symptoms at post-treatment.⁴ For the PSWQ-T, 66% of people were above the cut-off of 65 at pre-treatment. At post-treatment, only 26% of those who completed the measure were above the cut-off, meaning 74% were below the threshold.⁵

Discussion

Although CBT has been found to lead to improvements in chronic worry and GAD symptoms with moderate to large effect sizes in RCTs (e.g. Carpenter *et al.*, 2018; Covin *et al.*, 2008; van Dis *et al.*, 2020), there have been few studies that have investigated the effectiveness of CBT in community settings. Furthermore, little is known about who will respond more or less favourably to treatment. This study sought to address these gaps by investigating the effectiveness of group CBT for GAD in an out-patient hospital clinic. Consistent with recommendations for effectiveness studies, participants were not randomized to treatment, treatment was provided by community clinicians, and participants were not excluded based on co-morbidities or medication use (Tolin *et al.*, 2015).

In line with our predictions, CBT was found to lead to medium to large reductions in GAD symptom severity ($d = -0.65$) and chronic worry severity ($d = -0.91$) from pre- to post-treatment. This is consistent with research conducted in more controlled research trials and suggests that the promising results from RCTs extend to community settings. Furthermore, the reliable change index of 3.51 for the PSWQ-T is indicative of reliable change. By the end of treatment, 61% of participants who completed the GAD-7 at post-treatment were now below the threshold for GAD symptoms (Spitzer *et al.*, 2006), compared with only 28% of the sample at the beginning of treatment. Furthermore, 74% of those who completed the PSWQ-T at post-treatment fell below a cut-off score of 65 on the PSWQ-T (Fresco *et al.*, 2003), compared with only 34% at the beginning of treatment.

In addition to GAD symptoms, IU was found to significantly decrease from pre- to post-treatment ($d = -0.46$), which is consistent with another study that investigated the effectiveness of group CBT for GAD in an out-patient hospital setting (Torbit and Laposa, 2016). The significant reduction in IU is encouraging as IU is proposed to be one of the key factors that exacerbates and maintains chronic worry (Buhr and Dugas, 2006; Dugas *et al.*, 2004).

⁴Patients that completed the GAD-7 at post-treatment = 171.

⁵Patients that completed the PSWQ-T at post-treatment = 118.

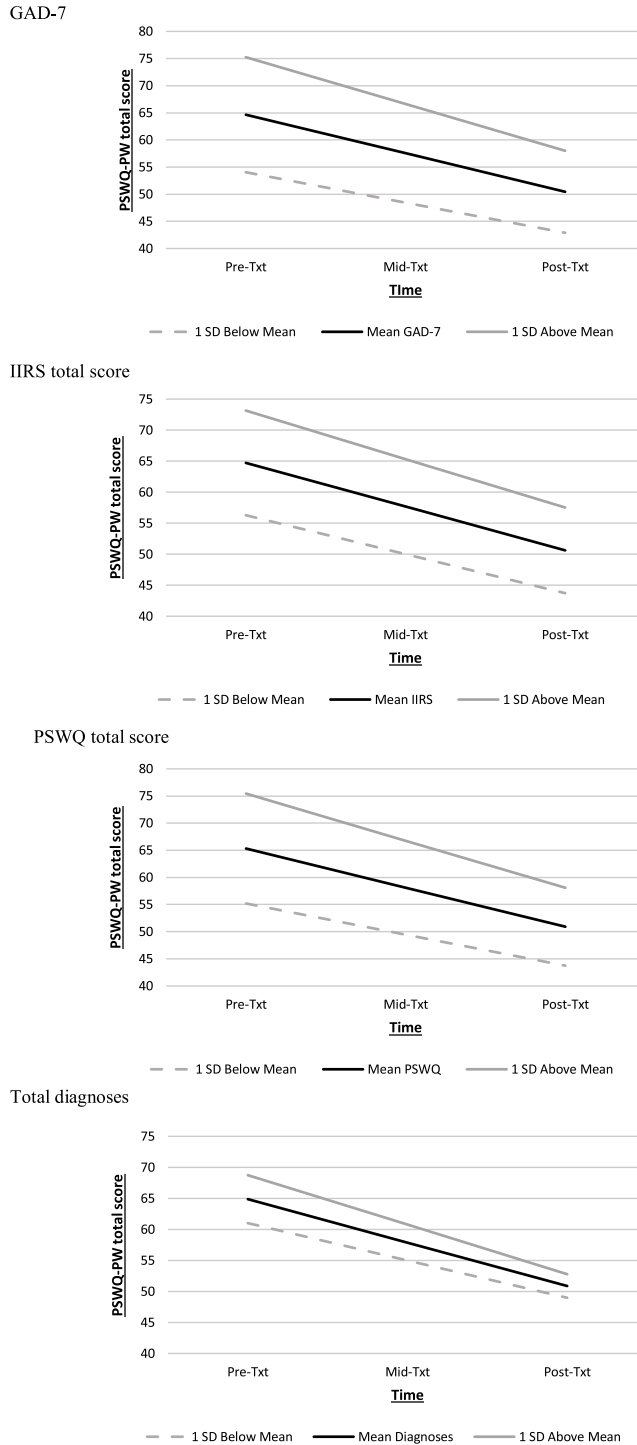


Figure 2. Results of hierarchical linear modelling for significant ($p < .05$) analyses predicting change in PSWQ-PW over time.

Furthermore, the treatment protocol used in this community hospital setting included many CBT skills and was not an IU-centred CBT protocol (see Robichaud *et al.*, 2019). In the present study treatment, only two out of the 12 sessions focused on the concept of IU and challenging the need for certainty through exposures, which is less than the IU-centred protocol (Robichaud *et al.*, 2019). As such, it is possible that a couple of sessions focusing on reducing IU is sufficient to see meaningful improvements in this area.

We also found significant improvements in depression symptoms ($d = -1.22$) and functional impairment ($d = -0.35$) from pre- to post-treatment. These findings are promising as they suggest that CBT for GAD can lead to improvements in both GAD and depressive symptoms, and better quality of life (although improvements in functioning were small). In this sample, approximately 32% of patients met diagnostic criteria for a co-morbid depressive disorder and consequently it is encouraging that patients could see large improvements in their depressive symptoms following GAD treatment.

Although group CBT was found to lead to improvements in anxiety and depressive symptoms, IU, and quality of life pre- to post-treatment, 39% of participants did not meet the cut-off suggestive of recovery on the GAD-7. Consequently, it is important to investigate why treatment is less effective for some individuals. We investigated whether baseline demographic and clinical factors predicted treatment outcome. Consistent with our predictions and past research (e.g. Newman and Fisher 2010; Wetherell *et al.*, 2005), greater GAD ($d = -0.17$) and chronic worry severity ($d = -0.20$), and greater number of co-morbid diagnoses ($d = -0.13$) were associated with greater improvements in chronic worry over the course of treatment. Furthermore, greater levels of symptom interference (i.e. poorer quality of life as measured by the IIRS) at the start of treatment was also associated with greater improvements in chronic worry over the course of treatment with a small effect size ($d = -0.12$). Collectively, these findings provide preliminary evidence that individuals with GAD with more severe symptoms and complex presentations are more likely to recover following treatment. As such, it is possible that treatment may not need to be adapted for more severe clinical presentations. This may be due to a variety of factors. First, there may be more 'room to grow' for patients who are experiencing the most severe symptoms and more restricted functioning. These patients are likely to have more distorted thinking or maladaptive behaviours, such as avoidance, contributing to worry and anxiety, and thus small shifts in thinking or changes in behaviour could have profound effects on their well-being. It is of course possible this effect could be partially explained by regression to the mean, whereby extreme scores will naturally regress towards the mean over time, irrespective of intervention (Davis, 1976). However, this is not to discount the effect of GAD treatment for those individuals who have more mild or moderate symptoms, as they may still benefit greatly from treatment. It is important to consider that some degree of worry and IU, for example, is normative, and there may be only so much improvement we would expect to see in these individuals.

It is worth noting that all effect sizes for significant predictors were small ($d = 0.12$ to 0.20). This suggests that GAD symptoms, functional impairment, and number of co-morbid diagnoses may have limited influence on treatment outcomes. These findings suggest that variability in treatment response is likely to be influenced by other factors, and further investigation of treatment predictors and interactions between predictors of treatment for GAD is needed.

Despite the differences in GAD presentations across sex and the lifespan (see Jalnapurkar *et al.*, 2018 and Wolitzky-Taylor *et al.*, 2010 for reviews), participants' age and biological sex did not significantly predict trajectory of change in chronic worry. This is consistent with meta-analyses showing that few studies find demographics, such as age and sex, moderate treatment outcomes for anxiety disorders (e.g. Schneider *et al.*, 2015). These findings are encouraging as they suggest that group CBT provided in community hospital settings is similarly effective for people of different ages and biological sex and that these factors do not affect individuals' ability to benefit from treatment.

Lastly, participants' severity of depression and IU were not found to predict trajectory of change in chronic worry. Although unexpected, these findings are promising for the treatment

of GAD in community hospital settings. GAD and depression commonly co-occur and these findings suggest that regardless of the severity of depression symptoms, individuals can benefit from group CBT for GAD. Furthermore, IU maintains worry and changes in IU account for a significant amount of change in chronic worry in CBT for GAD (Bomyea *et al.*, 2015). Thus, given the role of IU in maintaining worry, it is encouraging that individuals benefit equally from treatment regardless of the extent to which they cannot tolerate uncertainty at baseline. These findings suggest that CBT for GAD probably does not need to be modified for individuals with GAD based on their level of depressive symptoms or IU.

Although this study has a number of strengths, including the large sample of community treatment-seekers with a diagnosis of GAD, the findings need to be considered in the context of the study limitations. Importantly, the sample consisted mostly of individuals who identified as white (93.9%) and female (77.6%). Thus, the demographics of the sample limit our ability to understand the effectiveness of group CBT in an out-patient hospital clinic for diverse groups. In addition, we were only able to investigate biological sex and not gender as a predictor of outcome due to lack of variability in gender in our sample. Consequently, future studies should evaluate the effectiveness of group CBT for GAD in more ethnically diverse samples and use targeted recruitment methods to recruit participants of varying genders due to important differences between sex and gender (i.e. biological versus societal influences). Additional demographics could also be investigated as predictors of treatment, including educational level and relationship status. Furthermore, although the DART has been shown to have excellent construct, convergent and discriminant validity with validated self-report measures of clinical symptoms (Schneider *et al.*, 2022), it has not been validated against a gold-standard diagnostic interview leaving some questions about diagnostic accuracy. Furthermore, given this is a naturalistic treatment setting, not every individual had a principal diagnosis of GAD at the initial assessment (22% of participants had another primary diagnosis) and consequently may have completed a different treatment group prior to CBT for GAD. However, this is also a strength, as we aimed to understand how this treatment performed in a real-world clinical practice setting, where individuals may receive other treatments prior to group CBT for GAD. Lastly, there were missing data as a result of the study taking place in a naturalistic setting rather than a highly controlled clinical trial; nevertheless, the sample size was adequate for all analyses.

This study supported that group CBT for GAD leads to significant improvements in GAD symptom severity, chronic worry, depressive symptoms, IU and level of functional impairment in an out-patient hospital clinic. Furthermore, the findings support that treatment response is fairly robust and is not affected by participants' biological sex, age, depressive symptoms, or IU. Importantly, these findings support that treatment adaptations are unnecessary for individuals whose primary concern is GAD, even if they have more severe symptoms, depressive symptoms, and co-morbidity. However, these findings may not extend to other clinical settings and samples with different patient profiles. Future research should replicate these findings in more diverse samples and across different community treatment sites. Furthermore, it will be important to continue to investigate other predictors of treatment to enhance our understanding of factors that impact treatment response for GAD such as gender identity, current stressors, and family symptom accommodation.

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(supporting); **Duncan Cameron**: Formal analysis (lead), Methodology (supporting), Writing – review & editing (equal); **Karen Rowa**: Conceptualization (equal), Investigation (equal), Methodology (equal), Supervision (lead), Writing – review & editing (equal); **Randi McCabe**: Resources (lead), Supervision (equal), Writing – review & editing (equal).

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Ethical standards. The authors assert that all procedures contributing to this work comply with the ethical standards of the Helsinki Declaration of 1975, and its most recent revision. The procedures and measures used in this study were approved by the local institutional review board (ref. no. 07-2955) and incorporated standard practices in the clinic. As part of the consent procedure, participants were informed that their data may be used for presentations, reports, or articles but that their identifying information would never be included.

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